AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 109–741

S. 3128: THE NATIONAL UNIFORMITY FOR FOOD ACT

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

ON

EXAMINING S. 3128, TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO PROVIDE FOR UNIFORM FOOD SAFETY WARNING NOTIFICATION REQUIREMENTS

JULY 27, 2006

Printed for the use of the Committee on Health, Education, Labor, and Pensions

Available via the World Wide Web: http://www.gpoaccess.gov/congress/senate

U.S. GOVERNMENT PRINTING OFFICE

29–373 PDF WASHINGTON : 2007

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

MICHAEL B. ENZI, Wyoming, *Chairman*

JUDD GREGG, New Hampshire
BILL FRIST, Tennessee
LAMAR ALEXANDER, Tennessee
RICHARD BURR, North Carolina
JOHNNY ISAKSON, Georgia
MIKE DEWINE, Ohio
JOHN ENSIGN, Nevada
ORRIN G. HATCH, Utah
JEFF SESSIONS, Alabama
PAT ROBERTS, Kansas

EDWARD M. KENNEDY, Massachusetts
CHRISTOPHER J. DODD, Connecticut
TOM HARKIN, Iowa
BARBARA A. MIKULSKI, Maryland
JAMES M. JEFFORDS (I), Vermont
JEFF BINGAMAN, New Mexico
PATTY MURRAY, Washington
JACK REED, Rhode Island
HILLARY RODHAM CLINTON, New York

KATHERINE BRUNETT MCGUIRE, *Staff Director*
J. MICHAEL MYERS, *Minority Staff Director and Chief Counsel*

C O N T E N T S

STATEMENTS

THURSDAY, JULY 27, 2006

	Page
Enzi, Hon. Michael B., Chairman, Committee on Health, Education, Labor, and Pensions, opening statement	1
Burr, Hon. Richard, a U.S. Senator from the State of North Carolina, opening statement	2
Prepared statement	4
Feinstein, Hon. Dianne, a U.S. Senator from the State of California, opening statement	6
Prepared statement	7
Boxer, Hon. Barbara, a U.S. Senator from the State of California, opening statement	9
Prepared statement	10
Chambliss, Hon. Saxby, a U.S. Senator from the State of Georgia, opening statement	13
Prepared statement	14
Roberts, Hon. Pat, a U.S. Senator from the State of Kansas, opening statement	15
Stadtlander, William, Owner, Homestat Foods, Dublin, Ohio	19
Prepared statement	21
Hutt, Peter Barton, Senior Counsel, Covington and Burling, Washington, DC.	23
Prepared statement	24
Murano, Elsa A., Dean, College of Agriculture and Life Sciences, Texas A&M University, College Station, TX	30
Prepared statement	32
Hubbard, William K., Former Associate Commissioner for Policy, Food and Drug Administration, Chapel Hill, NC	36
Prepared statement	38

ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.:	
Senator Kennedy	52
Senator Hatch	53
Senator Jeffords	54
Senator Nelson	54
Leslie G. Sarasin	55
Thomas R. Frieden	56
Benjamin Cohen	59
Response to Questions of Senator Jeffords by Panel II	86
Response to Questions of Senators Enzi, Kennedy, and Reed by William Stadtlander	87
Response to Questions of Senators Enzi, Kennedy, Harkin, Reed, and Clinton by:	
Peter Barton Hutt	90
Elsa A. Murano	109
Response to Questions of Senators Enzi, Kennedy, Harkin, and Reed by William K. Hubbard	111
Letters of Support	116
Letters of Opposition	123

S. 3128: THE NATIONAL UNIFORMITY FOR FOOD ACT

THURSDAY, JULY 27, 2006

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:00 a.m. in Room SD-430, Dirksen Senate Office Building, Washington, DC., Hon. Michael B. Enzi, chairman of the committee, presiding.

Present: Senators Enzi, Burr, Isakson, Feinstein, Boxer, Chambliss, and Roberts.

OPENING STATEMENT OF SENATOR ENZI

The CHAIRMAN. Good morning and welcome to this hearing on food safety standards and warning requirements. Today's hearing will help the committee understand how the National Uniformity for Food Act might affect food safety across our Nation. In looking at foods, we see that nutrition labeling is nationally uniform, health claims are nationally uniform, and allergen labeling is nationally uniform. As a result, consumers have consistent science-based information about these products. Yet warning labels and other notifications vary from State to State. How do I as a consumer use these different warnings to make good decisions in food choices? What do I do if benefit information is always the same but the risk information is different, depending on where I live? Can a loaf of bread be more dangerous in California than the same loaf in Wyoming or Massachusetts? The bill before us today, the National Uniformity for Food Act, would create a uniform, national system of food safety standards and warning requirements. The bill would create this system by preempting State laws regarding food warning labels and tolerances. The bill provides that where FDA has acted by setting a safety standard for a food ingredient, the States would adopt and enforce the same standard. If FDA has not set a safety standard for a particular substance in food, the States would remain free to set and enforce their own standards. The bill would also provide for national uniformity in product warnings. States would not be permitted to require a warning in labeling, advertising, or any other form of public communication if that warning differs from that imposed under Federal law. States would remain free to issue their own public warnings under State laws. Under the bill, a State with the requirement that differs from a related Federal requirement could petition the FDA either to adopt the requirement as a national requirement or exempt it from the

requirement of uniformity. FDA's decisions on State petitions would occur only after public input. The bill before us seeks consistency in substantive standards between State and Federal requirements. It does not address how requirements are enforced. The State requirements and authorities for handling potentially hazardous foods, sanitation, date marking and related issues would not be effected by the legislation. The bill also would preserve the authority of the States to act if a food presents an imminent hazard. Today the States inspect most food manufacturing establishments. This bill would not change the partnership between FDA and State authorities in food safety. In fact, just last week, FDA announced a program to create uniform standards for the multilevel inspection program. FDA worked with State food regulators to create the draft uniform standards. This is exactly the sort of thing that should be happening. When it comes to drugs, we've been talking a lot lately about how important it is to weigh risks and benefits together. Senator Kennedy and I agree on this, yet while half of all Americans take at least one prescription drug daily, every one of us eats daily. So we're all affected by the actions that our Federal and State Governments take in regulating food safety standards. The bill before us raises important questions and here are just a few: Why should we weigh risks and benefits together when it comes to drugs but separately by State when it comes to food? Why should we charge the FDA with regulating the positive information about foods but leave decisions about warnings and tolerances to the States? And do consumers really benefit from the 50-state hodge-podge of different warnings and labelings on these products? I hope this hearing will help us answer these questions as we consider the National Uniformity for Food Act and I appreciate our colleagues who are here to testify today. I have to apologize, I have to go to a mark-up of the Small Business Committee. We've got a couple of small business issues in Wyoming since that is all we have in Wyoming—small businesses.

So I'll turn the gavel over to Chairman Burr.

OPENING STATEMENT OF SENATOR BURR

Senator BURR [presiding]. Thank you, Mr. Chairman. I want to thank you before you leave for holding this hearing on uniformity and I want to welcome our colleagues. This is the way it is supposed to work. I sponsored this legislation in the 105th Congress. I never dreamed that I would be in this institution, the U.S. Senate, but I also never dreamed that it would take this long to bring what I thought was common sense legislation to this country.

I believe consumers should be able to make informed decisions about foods they purchase. As a Nation, we have uniform nutrition labeling and with S. 3128, we would have uniform warning labels as well. This legislation provides for a national, uniform and scientific approach to food safety regulation and it provides for consideration of State Food Safety requirements as national requirements.

This food uniformity legislation has been carefully crafted over many years to help ensure our system of food regulation remains the gold standard of the world. Currently, the Food and Drug Administration is widely recognized as the preeminent food regulatory

agency. This bill we discuss today will build on that strength and help make our food regulatory system even stronger.

The intention behind this uniformity legislation is quite simple. It is to provide strong and consistent national regulations to ensure the quality of our country's food supply. Right now, our system of food regulation involves actions not just by the FDA but States and localities as well. Each of those entities has an important role to play in ensuring the quality and the safety of our food supply.

Historically, the FDA has established standards to determine when food is safe and has established national requirements for food labeling. The FDA conducts some inspections of food facilities and participates in standard setting that occurs at a multinational level. State and local governments have historically inspected food facilities, in fact, often under a contract with the FDA and they play an important role in shellfish and dairy product safety, in retail, local restaurants and food service safety.

This uniformity legislation preserves and protects these important roles. Let me be clear. S. 3128 does not change any of these roles and functions, but I believe inconsistent, often conflicting and often nonscience-based requirements and warnings imposed at the State or local level—those also not supported by the FDA—create confusion for consumers and unnecessarily increase production costs for thousands of food manufacturers across the country.

In order to simplify the process, the bill provides for a single national standard on food adulteration and a system of determining whether food labels should bear particular warning labels. Clearly, we should rely on the FDA to make the final determination as to when food is adulterated and when food should bear a warning statement.

When a warning about food is supported by science and it is necessary to help consumers make informed decisions about the foods they purchase and consume—that warning should be applied to the food items sold in all 50 States. This bill achieves that result. I would respectfully suggest that if food is safe to be sold in one State or 20 States or 30 States, it should be safe in all 50 States. Likewise, if a warning is needed, surely that warning should be shared with consumers in all 50 States.

The concept of a national system for food adulteration, including warnings, is not new. In fact, the absence of uniformity between Federal and State food systems is an exception. For example, current law provides for uniformity in the regulation of meat and poultry products, pesticide residues, nutrition labeling, health claims and standards of identity. The uniformity bill before us is built on many years of uniform food regulation experience.

As I've said before, States play an important role in enforcing food safety requirements. States do this through inspection of food facilities and embargoing contaminated products. Under this legislation, States will continue to be in charge of inspections to enhance basic sanitation requirements in places such as restaurants, retail food stores, shellfish processors, and dairy farms. Recognizing this important role, unlike other uniformity bills considered by Congress, S. 3128 enables States to petition the FDA to consider potential Federal requirements of any food adulteration requirements under the State law that, on the date of enactment, does not

have a Federal counterpart and in this proposed process the State requirement remains in effect. Let me repeat that. Remains in effect until the FDA takes action on the State petition. Not only does the legislation provide for uniformity but it also includes a predictable process by which all existing State Food Adulteration requirements can be considered for adoption at the Federal level by the FDA.

I believe S. 3128 will ensure that food sold in this country is subject to a single contemporary standard that will benefit consumers. Again, I thank our colleagues for their willingness to come and at this time, the Chair recognizes the Senator from Kansas, for any statement you might like to make.

[The prepared statement of Senator Burr follows:]

PREPARED STATEMENT OF SENATOR BURR

Thank you, Chairman Enzi and Senator Kennedy, for holding a hearing on S. 3128, the National Uniformity for Food Act. I am proud to be the lead sponsor of S. 3128. I have sponsored legislation on this issue since the 105th Congress. I can assure you that back then I did not know I would be a member of the Senate HELP Committee participating in a hearing on this bill in the 109th Congress!

I believe consumers should be able to make informed decisions about the foods they purchase. As a Nation, we have uniform nutrition labeling, and with S. 3128 we would have uniform warning labeling as well. This legislation provides for a national, uniform, and scientific approach to food safety regulation and it provides for consideration of State food safety requirements as national requirements as well.

This food uniformity legislation has been carefully crafted over many years to help ensure our system of food regulation remains the gold standard of the world. Currently, the Food and Drug Administration is widely recognized as the pre-eminent food regulatory agency. The bill we are discussing today will build on that strength and help make our food regulatory system even stronger.

The intention behind this uniformity legislation is simple. It is to provide for strong and consistent national regulations to ensure the quality of our country's food supply. Right now our system of food regulation involves actions not just by the FDA, but States and localities as well. Each of those entities has an important role to play in ensuring the quality and safety of our food supply.

Historically, the FDA has established standards to determine when food is safe and has established national requirements for food labeling. The FDA conducts some inspections of food facilities and participates in standard setting that occurs at a multinational level. State and local governments have historically inspected food facilities (in fact, often under contract with the FDA), and play an important role in shellfish and dairy product safety, and retail, local restaurant and food service safety.

This uniformity legislation certainly preserves and protects these important roles. Let me be very clear—S. 3128 does not change any of these roles and functions. But I believe inconsistent, often conflicting, and nonscience-based requirements and warnings imposed at the State or local level—those also not supported by the FDA—

create confusion for consumers and unnecessarily increase production costs for thousands of food manufacturers across our country.

In order to simplify the process, the bill provides for a single national standard on food adulteration and a system of determining whether food labels should bear particular warning statements. Clearly, we should rely on the FDA to make the final determination as to when food is adulterated and when food should bear a warning statement.

When a warning about food is supported by science and is necessary to help consumers make informed decisions about the foods they purchase and consume, that warning should be applied to that food item sold in all 50 States. This bill achieves that result. I would respectfully suggest that if food is safe to be sold in one State, or 20 States, or 30 States, it should be safe in all 50 States. Likewise, if a warning is needed, surely that warning should be shared with consumers in all 50 States.

The concept of a national system for food adulteration, including warnings, is not new. In fact, the absence of uniformity between the Federal and State food systems is an exception. For example, current law provides for uniformity in the regulation of meat and poultry products, pesticide residues, nutrition labeling, health claims, and standards of identity. The uniformity bill before us is built on many years of uniform food regulation experience.

As I have said before, States play an important role in enforcing food safety requirements. States do this through inspections of food facilities and embargoing contaminated products. Under this legislation, States will continue to be in charge of inspections to enforce basic sanitation requirements in places such as restaurants, retail food stores, shellfish processors, and dairy farms. Recognizing this important role, unlike other uniformity bills considered by Congress, S. 3128 enables States to petition the FDA to consider potential Federal requirements of any food adulteration-related requirement under State law that, on the date of enactment, does not have a Federal counterpart. And, in this proposed process, the State requirement remains in effect until FDA takes action on the State petition. Not only does the legislation provide for uniformity, but it also includes a predictable process by which all existing State food adulteration requirements can be considered for adoption at the Federal level by the FDA.

I believe S. 3128 will ensure that food sold in this country is subject to a single contemporary standard that will benefit consumers. Again, I thank the Chairman for having this hearing today. Thank you and I look forward to the witnesses' testimony.

Senator ROBERTS. Mr. Chairman, I know that there are Senators on the panel who have time schedules as I do and I'm going to reserve my statement. I want to thank you for yours and I want to thank you for your leadership in this regard but I hope I can be recognized after the panelists make their statements. I know they are eager to go on to their other duties so I will yield at this time.

Senator BURR. Does the Senator from Georgia have——

Senator ISAKSON. I would like to publicly acknowledge the hard work over four Congresses, by the Senator from North Carolina on this issue. I appreciate his dedication to it and appreciate the members of the Senate being here to testify today.

Senator BURR. I'd like to welcome our three distinguished colleagues to the committee today, Senator Saxby Chambliss of Georgia, Senator Barbara Boxer from California, and Senator Diane Feinstein from California. I appreciate all of your longstanding interest in food uniformity, your willingness to appear before the committee and as would be a southern custom, we would start with our Senator from California, Senator Feinstein.

OPENING STATEMENT OF SENATOR FEINSTEIN

Senator FEINSTEIN. Thank you very much, Mr. Chairman. I appreciate the committee holding this hearing. I appreciate my colleague from California being here. Mr. Chairman, I must say that both of us are strongly opposed to this bill as is our Governor, Governor Schwarzenegger and others. I believe this bill would have a very deleterious effect on the people that we represent and that's 37.2 million Californians. I think it has to be looked at, that California is as big in population as 21 States and the District of Columbia put together. It is a huge consumer market and 17 years ago, the State passed an initiative known as Proposition 65. It passed with 63 percent of the vote and the product of 65 was to impose separate and distinct warning requirements for known carcinogens in consumer products. I must say that since that time, having been in public life, I have never had a single complaint from anybody about Proposition 65 and I very much doubt that my colleagues has either. There is strong bipartisan opposition to these proposed measures. Not only our Governor but the Governors of seven other States, the attorneys general of 39 States, the Association of Food and Drug Officials, the State Departments of Agriculture, Consumers Union and Rumors National Consumer and Environmental groups oppose pre-empting State and local Food Safety requirements. This legislation would pre-empt over 200 of these Food Safety State laws and regulations nationwide and they would impede States and localities from enacting and implementing food safety regulations stronger than those required by the Federal Government, even if that authority is needed to respond quickly to an incident, such as an act of bioterrorism. This bill is a major assault on California's initiative and it would cancel out major benefits under the law that protects California consumers from cancer-causing chemicals to lead and arsenic poisoning.

Let me give you a few examples. This year, the State used Proposition 65 to stop Pepsi from selling soda bottles with leaded labels, which can cause birth defects and cancer. With respect to lead in ceramic tableware, California required clear warnings for lead that leeches from ceramic tableware into food and beverages. The marketplace has responded. Now these ceramics have disappeared from shelves. Lead and calcium supplements—makers of calcium supplements such as Tums and Rolaids, agreed to reduce levels of lead contamination in their products. This result was reached without posting warnings that might have discouraged women from taking calcium. Leaded crystal, fully leaded crystal, especially when used for storage of beverages, leeches substantial amounts of lead. California requires point of sale signs while FDA has provided a consumer advisory. Mercury in fish—California requires that information be posted in stores where fresh fish is sold, warning pregnant

women about the high levels of mercury in seafood and it would no longer be able to do so. As you can see, this bill, in just these ways that I've elucidated, undermines California's Proposition 65 and this is not the first assault on California law. Earlier, similar efforts to overturn Proposition 65 and pre-empt State and local food safety laws, have been opposed by people on both sides of the isle. For example, the Reagan administration conducted an economic analysis of the impact of Proposition 65 in 1988, which the first President Bush concurred with and that found that industry's claims that Proposition 65's financial burden "vast overstate the potential impact on producers." Mr. Chairman, I think what I want to say is that on behalf of my colleague, Senator Boxer and I, if this bill were to come to the floor, we would use every parliamentary device available to us to stop it. We both strongly oppose this bill. Thank you very much.

[The prepared statement of Senator Feinstein follows:]

PREPARED STATEMENT OF SENATOR FEINSTEIN

Mr. Chairman, thank you very much for holding this hearing today.

I hope that this hearing—the first to be held on this issue—will clarify the major negative impact of establishing uniform requirements for food safety warning labels nationwide.

This legislation effectively cancels strong food safety laws approved by State and local governments, such as California's Proposition 65 ("Safe Drinking Water and Toxic Enforcement Act") enacted into law 17 years ago by 63 percent of Californians.

This Senate bill (S. 3128), like the house-passed bill, undermines hundreds of important food safety laws across the country. And it sets a dangerous precedent undermining States' rights.

There is strong bipartisan opposition to these proposed measures. Governors of eight States, including Governor Schwarzenegger, Attorneys General of 39 States, the Association of Food and Drug Officials, State Departments of Agriculture, Consumers Union and numerous national consumer and environmental groups oppose preempting State and local food safety requirements.

This Senate bill would:

- Preempt over 200 food safety State laws and regulations nationwide.
- Impede States and localities from enacting and implementing food safety regulations stronger than those required by the Federal Government, even if that authority is needed to respond quickly to an incident such as an act of bioterrorism.
- Threaten laws passed by California and at least eight other States limiting the sale of sodas and junk food in public schools aimed to promote healthy eating habits for children.

In September 2005, Governor Schwarzenegger signed two bills (one bill which takes effect in July 2007) restricting certain foods and beverages from being sold in California's public schools so that children are not exposed, for example, to such high levels of sugar in their food and beverages that contribute to the major issue of child obesity.

• Prohibit States, like California, to issue their own mercury warnings to pregnant women about the significant risks from high levels of mercury in seafood such as swordfish and shark. California requires that signs be posted in grocery stores where fresh fish is sold warning pregnant women about the high levels of mercury in seafood and would not be able to continue to post these warning signs that protect consumers.

• Force States to petition the FDA to maintain important food safety laws, imposing major financial burdens on the financially-strapped FDA and States. The Center for Science in the Public Interest estimates it will cost FDA at least $120 million to process the expected 300 waiver requests just for Proposition 65 (i.e. waivers for lead in calcium supplements and arsenic in bottle water).

This bill is a major assault on California's Proposition 65 and would cancel out major benefits under the law that protect California consumers from cancer causing chemicals to lead and arsenic poisoning.

Here are just a few examples:

• This year, the State used Proposition 65 to stop Pepsi from selling soda bottles with leaded labels which can cause birth defects and cancer.

• Lead in ceramic tableware: California required clear warnings for lead that leaches from ceramic tableware into food and beverages.

The marketplace responded. Now these ceramics have disappeared from shelves.

• Lead in Calcium Supplements: Makers of calcium supplements, such as Tums and Rolaids, agreed to reduce levels of lead contamination in their products. This result was reached without posting warnings that might have discouraged women from taking calcium.

• Leaded crystal: Fully leaded crystal, especially when used for storage of beverages, leaches substantial amounts of lead. California requires point-of-sale signs, while FDA has provided a consumer advisory.

• Mercury in fish: California requires that information be posted in stores where fresh fish is sold warning pregnant women about the high levels of mercury in seafood and it would no longer be able to do so.

As you can see, this bill significantly undermines California's Proposition 65. This is not the first assault on the California law.

Earlier similar efforts to overturn Proposition 65 and preempt State and local food safety laws have been opposed by people on both sides of the aisle.

For example, the Reagan administration conducted an economic analysis of the impact of Prop 65 in 1988—which the first President Bush administration later concurred with—that found industries claims of Prop 65's financial burden to "vastly overstate the potential impact on producers."

State and local governments should have the right to protect their citizens. Consumers deserve to know if the product they are purchasing may cause them harm.

The bottom line is this: Congress should NOT approve legislation that threatens hundreds of critical food safety laws across the country and puts at risk the health and safety of all Americans.

Thank you Mr. Chairman.

Senator BURR. Thank you for your willingness to speak.

Senator FEINSTEIN. I might be excused and I thank my colleague for allowing me to go earlier. I have a judiciary mark-up.

Senator BURR. We understand.

Senator Boxer.

OPENING STATEMENT OF SENATOR BOXER

Senator BOXER. Thanks so much, Mr. Chairman and I have a hearing in Foreign Relations with Ambassador Bolton and so I will also have to bolt after my statement. Thank you so much for allowing us to speak here. I know it is not a happy time for you to hear two colleagues lead off in opposition to a bill you really care about so in advance, let me say that I respect your view but we are in strong disagreement because, as Senator Feinstein has said, we view this legislation as a direct threat to California's Food Safety and Consumer Rights and their protections. Our people were heard at the ballot box. This isn't our opinion, this is the opinion—Republicans, Democrats, Independent voters, our Republican Governor—we're all united against this bill and that is why we are so, just letting you know right now, today, that I know you've fought long and hard for this but the fight is not over because we think this bill will roll back essential food safety laws and in essence, prevent State and local authorities from enacting food safety regulations. Our State is a national leader in ensuring food safety. We have more people than any other State by far, as was pointed out. We've got more kids, we've got more sick people, we've got more vulnerable populations and therefore, we have stepped out in our State, again Californians passing Prop 65 with 63 percent of the vote, one of the most popular initiatives we've ever had on our ballot in terms of pulling people together. It is interesting because really, the act of—it doesn't force anything. It just says to the manufacturer, let us know what is in your product and then people will decide and if you have high levels of arsenic in your bottled water, then people have a right to know and guess what? They're not going to buy that product and that's why this has been so successful, because we believe in the people's right to know and if the people know, they'll buy the safest products and it has worked really, really well. We don't want to go back to the days when our consumers were in the dark about dangerous contaminants in their food. Now, I know your response is, "Well the Federal Government will do just as good a job." That hasn't been proven to be the case and I want to talk about lead in candy. Senator Chambliss leaned over and said, "Wow! That looks awful good." And it does look awful good. This is candy with lead in it, dangerous lead and I want to show you a picture.

It just shows you how much I love you! Here we go. This is a photograph of lead-tainted candy being given to little children and they are having such a wonderful time eating this dangerous candy and in our State, we outlawed this. The Federal Government has no such law. It could have had. It doesn't have it and I want to

tell you about what this does to children. Lead is a dangerous toxin. It attacks the nervous system causing behavior problems, learning disabilities, seizures and even death. Children are at the greatest risk. The State of California, as I said, has a law to reduce lead in candy along with the State of Illinois and we know New York City has it. We believe if this bill becomes law, these important protections will be threatened and we could have kids eating bowls of this candy and unfortunately ingesting lead. Parents won't know any better. They trust their government would act but the fact is, we haven't acted here in the Federal Government, to ban this. We also in California have addressed other issues of arsenic, mercury in fish, lead in places Senator Feinstein mentioned, in gold and glassware and PCBs in salmon. We've also passed innovative State protections to combat childhood obesity by ensuring that public schools provide our children with healthy food: juice, milk and water rather than soda and it was a big fight in California but we did this and all of you know now that childhood obesity is likely to lead to an epidemic of diabetes later in life. So we are out there moving forward and we think this legislation will set us way back. Now, what I want to show you then, is another chart that gives you a sense of this bill and you know this better than I do, but if a State wants to be able to get around this bill, they have quite a maze to go through in order to get around this bill. We're going to use this to show our colleagues on the floor, it is just a bureaucratic nightmare. It is a petition process that just is not going to work for our State.

Mr. Chairman, I'd ask that the rest of my statement be placed in the record and since this is my sum-up time.

[The prepared statement of Senator Boxer follows:]

PREPARED STATEMENT OF SENATOR BOXER

Thank you, Mr. Chairman for allowing me to speak today on an issue of great importance to people in my State of California, and to people in every State across the Nation.

I am here today to voice my strong opposition to S. 3128, the National Uniformity for Food Act.

This legislation poses a direct threat to California's food safety and consumer right-to-know protections, including Proposition 65.

The bill would roll back essential food safety laws and prevent State and local authorities from enacting food safety regulations that act as a safety net and fill in critical gaps in Federal law.

And for a State like California, which is a national leader in ensuring food safety, this legislation is particularly harmful, threatening laws that protect the most vulnerable among us, including pregnant women and children.

Californians passed Proposition 65 in 1986 with 63 percent of the vote because they wanted to know if dangerous contaminants were in their food and drinking water, and they knew such a law would encourage food manufacturers to provide a safer product—because who wants to buy bottled water with an arsenic warning label?

For more than 20 years, this simple combination of consumer education and market forces has reduced exposure to dangerous substances in food throughout California.

But now, California's State food safety laws are under attack from special interests, who would keep consumers in the dark about dangerous contaminants in their food and water.

Why? Because of claims that food safety regulations may cut into profits.

Rather than looking at a picture like this (Chart—photo of children eating lead candy), and being disgusted at the sight of innocent children eating candy contaminated with lead, these special interests see dollars signs.

Lead is a dangerous toxin that attacks the nervous system, causing behavioral problems, learning disabilities, seizures and death, with children at greatest risk.

If this legislation becomes law, the Food and Drug Administration could do away with State laws prohibiting lead-infested candy from being sold in our supermarkets, and uninformed consumers will be the worse for it.

The State of California already has a law to reduce lead in candy, along with the State of Illinois and New York City. If this bill becomes law, these important State and local protections will be threatened.

Once again in convenience stores and at family picnics, children could see bowls like this full of enticing treats, and reach for them as a child would reach for a snickers bar or Hershey's kiss.

And unfortunately most parents won't know any better, because they trust that their government would not allow children to eat candy with high levels of lead. Unfortunately, the Federal Government does not have a requirement in place that would ensure children are protected from dangerous levels of lead in candy. This simple fact alone answers the question of why we need a State safety net.

In addition to addressing the issue of lead in candy, Californians have acted to reduce arsenic in bottled water, mercury in fish, lead in plates, bowls, and glassware, and polychlorinated biphenyls ("PCBs") in salmon.

Californians have also passed innovative State protections to combat childhood obesity by ensuring that public schools provide our children with healthy foods, juice, milk and water rather than soda.

The dangerous and bureaucratic process in S. 3128 that would in theory allow the Federal Government to consider allowing State protections to continue not only wastes scarce resources, but provides little hope of success. [Chart on S. 3128's Petition Process]

There is widespread opposition to efforts to eliminate State food safety and consumer right-to-know protections. Numerous State, public health, scientific, labor, environmental and other public interest groups have objected to the H.R. 4167, the House version of S. 3128, as well as the bill at issue in this hearing. I would like to place these letters into the record to accompany my statement.

[Editor's Note: The letters of opposition may be found in Additional Material.]

Don't let the nice title, "National Uniformity for Foods Act", fool you. This legislation poses a threat to the health of Americans in every State in the Union.

Senator BOXER. I'm going to just read a few of the groups that oppose this legislation: the National Association of State Departments of Agriculture, the National Association of Food and Drug Officials, Consumer Federation of America, United Steel Workers, Consumers Union, Center for Science in the Public Interest, National Environmental Trust, Physicians for Social Responsibility, Attorneys General in 39 States and territories, including California, New York, Hawaii, Alaska, Arizona, Connecticut, Delaware, Idaho—it goes on and on and interestingly, the North Carolina Consumers Union opposes this as well. The bottom line is, Mr. Chairman, I know that your aims and that of my colleagues are good. I have no question that your aims are good and your intentions are good but it is the practical impact of this. Coming from a State that is way out in front on food safety, we don't want to go back and our people don't want us to go back. This is not partisan and that's why Senator Feinstein and I are here. We so appreciate the chance to speak with you very directly. You're direct, we're direct. We know we have disagreements and honorably, we will debate those differences. Thank you very much.

Senator BURR. Senator Boxer, thank you. Your full statement will be a part of the record.

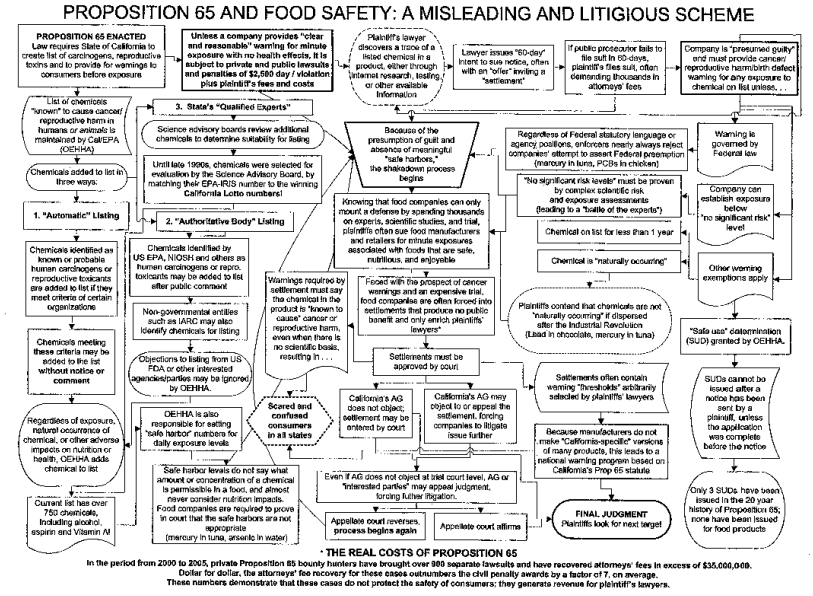
Senator BOXER. Thank you.

Senator BURR. I'll take this opportunity as I introduce my colleague from Georgia, to also put up a chart.

That chart is a chart of Prop 65.

Senator BOXER. Sure.

Senator BURR. If you will, it's over here.



Senator BOXER. Well, ours is prettier. Ours is in better color.

Senator BURR. We didn't have the money, you know, too——

[Laughter]

Senator BOXER. I know you spent the entire Federal surplus.

Senator BURR. Small thing here. We just had a copy machine. That's the only thing we had.

Senator from Georgia.

OPENING STATEMENT OF SENATOR CHAMBLISS

Senator CHAMBLISS. Well, as usual, I hate to follow my friend from Kansas. Thank you Mr. Chairman, Senator Isakson, Senator Roberts, I appreciate the opportunity to share my views with you on S. 3128, the National Uniformity for Food Act. As Chairman of the Senate Committee on Agriculture, Nutrition and Forestry, I engage in this debate from a unique perspective. The Senate Agriculture Committee oversees a significant portion of America's food safety system and the Federal food safety functions over which the committee has jurisdiction, have long employed uniform standards to protect public health.

The U.S. Department of Agriculture's Food, Safety and Inspection service is responsible for the safety of meat, poultry and egg products, both domestic and imported. It enforces uniform standards through the authority granted to the USDA by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

USDA isn't the only agency charged with enforcing national uniformity. There are many other areas where Congress has decided that national uniform standards are warranted. These areas include nutrition labeling, allergens, pharmaceuticals, and medical devices, just to name a few. For example, the Food Quality Protection Act, a State may not set tolerance levels for pesticide residues that differ from national levels unless the State petitions the Environmental Protection Agency for an exception.

I support the National Uniformity for Food Act because it will not only remove unnecessary and costly impediments to interstate commerce but even more importantly, it will provide consumers with clear and useful information.

The bill that you have drafted will ensure that consumers have access to the same accurate, science-based information regardless of where they live. It will eliminate consumer confusion and bolster confidence in the safety of our food supply by placing our Nation's food safety in the hands of the U.S. Food and Drug Administration, the world's leading food safety agency. In addition, this bill will streamline the regulatory process by creating a single process for establishing food safety standards and warning labels for packaged foods under the authority of the FDA.

States traditionally have played a strong role in the formulation of our Nation's food safety policy and that will not change under this bill. Under this legislation, States will continue to have authority for enforcements, sanitation inspections at local restaurants, licensing and the protection of public health in the event of a food emergency or a terrorist attack.

States will also be able to continue their constant communication and information sharing with the FDA when it comes to food safety. A unique provision in the bill allows any State to petition the

FDA to keep its existing State law or elevate that standard to the National level, following a thorough review of the entire body of scientific evidence. In fact, no State law would disappear upon the enactment of this bill. States would have 180 days to petition the FDA under the provision I just outlined. If the FDA fails to act on a State petition, then that State law would remain in effect.

With the world's safest food supply, every American benefits from uniform food safety standards. The National Uniformity for Food Act builds on that record of success by extending the same approach used by the USDA and other regulatory agencies to the FDA. This is not only a common sense approach but it assures every American that the food they enjoy is regulated by strict, national standards meant to ensure their health and well-being.

I would like to commend Chairman Enzi and you, Senator Burr and the other members of this committee, for holding this hearing today. It is important to debate this issue in a public forum so that American consumers understand our goal is to strengthen and harmonize food safety efforts in this country. It is rather ironic that at the international level, we actively pursue the goal of harmonizing food safety standards yet we still debate this issue at home. The National Uniformity for Food Act provides us with an opportunity to bring a long-needed, common sense approach to the regulation of packaged foods. I urge the members of this committee as well as the rest of our Senate colleagues, to support this bill and I thank you very much for letting me share these thoughts with you.

[The prepared statement of Senator Chambliss follows:]

PREPARED STATEMENT OF SENATOR CHAMBLISS

Thank you Mr. Chairman. I appreciate the opportunity to share my views on S. 3128, the National Uniformity for Food Act. As Chairman of the Senate Committee on Agriculture, Nutrition and Forestry, I engage in this debate from a unique perspective. The Senate Agriculture Committee oversees a significant portion of America's food safety system, and the Federal food safety functions over which the committee has jurisdiction have long employed uniform standards to protect public health.

The U.S. Department of Agriculture's Food Safety and Inspection Service is responsible for the safety of meat, poultry, and egg products, both domestic and imported. It enforces uniform standards through the authority granted to the USDA by the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act.

USDA isn't the only agency charged with enforcing national uniformity; there are many other areas where Congress has decided that nationally uniform standards are warranted. These areas include nutrition labeling, allergens, pharmaceuticals, and medical devices to name a few. For example, under the Food Quality Protection Act, a State may not set tolerance levels for pesticide residues that differ from national levels unless the State petitions the Environmental Protection Agency for an exception.

I support the National Uniformity for Food Act because it will not only remove unnecessary and costly impediments to interstate

commerce but even more importantly it will provide consumers with clear and useful information.

The bill will ensure that consumers have access to the same accurate, science-based information regardless of where they live. It will eliminate consumer confusion and bolster confidence in the safety of our food supply by placing our Nation's food safety in the hands of the U.S. Food and Drug Administration, the world's leading food safety agency. In addition, this bill will streamline the regulatory process by creating a single process for establishing food safety standards and warning labels for packaged foods under the authority of the FDA.

States traditionally have played a strong role in the formulation of our Nation's food safety policy, and that will not change under this bill. Under the legislation, States will continue to have authority for enforcement, sanitation inspections at local restaurants, licensing, and the protection of public health in the event of a food emergency or a terrorist incident.

States will also be able to continue their constant communication and information-sharing with the FDA when it comes to food safety. A unique provision in the bill allows any State to petition the FDA to keep its existing State law or elevate that standard to the national level following a thorough review of the entire body of scientific evidence. In fact, no State law would disappear upon the enactment of this bill. States would have 180 days to petition the FDA under the provision I just outlined. If the FDA fails to act on a State petition, then that State law would remain in effect.

With the world's safest food supply, every American benefits from uniform food safety standards. The National Uniformity for Food Act builds on that record of success by extending the same approach used by the USDA and other regulatory agencies to the FDA. This is not only a common sense approach, but assures every American that the food they enjoy is regulated by strict, national standards meant to ensure their health and well-being.

I would like to commend Chairman Enzi and the members of this committee for holding this hearing today. It is important to debate this issue in a public forum so that American consumers understand our goal is to strengthen and harmonize food safety efforts in this country. It is rather ironic that at the international level we actively pursue the goal of harmonizing food safety standards, yet we still debate this issue at home.

The National Uniformity for Food Act provides us with an opportunity to bring a long-needed, common sense approach to the regulation of packaged foods.

I urge the members of the committee, as well as the rest of my Senate colleagues to support this bill. Thank you very much.

Senator BURR. Mr. Roberts.

OPENING STATEMENT OF SENATOR ROBERTS

Senator ROBERTS. Well, I would never dismiss the Senator from Georgia. I'd let him ride off into the sunset if he wishes.

Mr. Chairman, thank you for holding this hearing today on the National Uniformity Food Act. This bill, as others have said, is an important piece of legislation. Quite frankly, we should have passed this a long time ago. I'm very pleased to have been a lead

sponsor of this bill in the past. I'm pleased to be joining Senator Burr and I am his shotgun rider or wing man, as of this time around and I think we ought to dispel some concerns and some news, as the Chairman has indicated, about this bill. We discussed this for a long time but recent events, Mr. Chairman, in the food industry and the courts show us that the time for debate has passed. It is time for us to do our jobs and bring uniformity to the food safety tolerances and the warning label systems for consumers nationwide. I just don't understand why you have—you don't have food safety concerns in 49 States but you do in one. I guess that means the consumers in the other States are undergoing a real problem or a real concern. I want to emphasize that facts can be stubborn things. The thing that occurred to me about—whoop! Put that candy back up there.

AUDIENCE MEMBER. OK.

Senator ROBERTS. Let me have that candy!

AUDIENCE MEMBER. Only if you promise not to eat it.

[Laughter]

Senator ROBERTS. All right. This has been tested in the lab and it contains high levels of lead. Can you tell what the tolerance is in regards to how much food a young child would have to eat in terms of candy before it would become a real problem? That's the thing, it seems to me, that is important because that would be important for every State and every consumer and every parent.

AUDIENCE MEMBER. One piece.

Senator ROBERTS. One piece of this particular candy?

AUDIENCE MEMBER. A child would exceed the daily limit based on——

Senator ROBERTS. On California standards?

AUDIENCE MEMBER. That's correct, but they are not——

Senator ROBERTS. Well, the thing that I remember so well is when we were talking about this—is this candy for sale in all 49 States? So it's unsafe in all 49 States? No, it's unsafe in California but it's not unsafe in all 49 States, is that right?

AUDIENCE MEMBER. I'm sorry. Essentially, the Federal Government, the FDA has a tolerance proposed but they don't have an enforceable standard and have not actually fulfilled a gap——

Senator ROBERTS. So it is an enforcement issue with the FDA, not the tolerance?

AUDIENCE MEMBER. They don't have enforceable requirements.

Senator ROBERTS. No enforceable requirements? Well, if this is being sold in 49 States, let me go back to my one example I at least know something about because on the floor of the House, when we were considering this 15 years ago and I was asking people why pancake flour in Pennsylvania was okay but pancake flour in California wasn't and even had a demonstration of flipping pancakes but that's another whole story.

We got the example of domenicide which was used to control pests in regards to the production of peanuts and the argument was that obviously domenicide was a carcinogen in certain amounts and if you raised it to certain levels, it is a real problem. So I ask about the tolerance level on how many peanuts a person would have to eat every day to reach the tolerance level set by the critics of the FDA and it turned out to be 600 pounds of peanuts a day.

That's a lot of peanuts. Now, I knew several members in the Congress at that time that I would have liked to have fed 600 pounds of peanuts a day but that was not an option. So I think we ought to at least use some common sense.

I am distressed to learn about the enforcement thing in terms of an enforcement mechanism but I think we have to look at this in this world of parts per trillion. There is a little bit of something in everything and you have to have a cost-benefit risk and you have to have a sound science risk and 49 States do, with the FDA. Not California.

The fact of the matter is, this legislation does not propose taking some unprecedented step in food and consumer safety; rather as many of our witnesses will testify today, the legislation simply intends to add national uniform standards for food safety tolerances and warning labels. Now what am I talking about? We've already got uniform requirements for meat and poultry products, nutrition labeling, allergen labeling, pesticide tolerances and medical devices.

Your bill, sir. Passed the Ag Committee in 2000. Now it's here where obviously you'd have jurisdiction and this debate should take place, don't misunderstand me. I just don't think it should be to one committee and then we go to the floor. Why shouldn't we also have them on the tolerance and warning label front, I just don't understand that. I think the FDA can do the job. This issue has always been focused largely on the tolerance and warning discrepancies between the rest of the United States and California. Not unusual and largely as a result of Proposition 65, as has been referred to by my friends and colleagues. But let me just state that there are a lot of people in California, if I can find my list, who are for this bill, Senator. The California Chamber of Commerce, the California Farm Bureau Federation, California Grocer's Association, California League of Food Processors, California Manufacturers and Technology Association, California/Nevada Soft Drink Association and the California Restaurant Association. I do not think these people are interested in the business of poisoning any family or any youngster or for that matter, anybody.

We found on the California Attorney General's Web site that if you take a look at Proposition 65 settlement dollars paid in private cases, including attorney fees, you'll see that the total amount for 2000 to 2005 was about $57 million. About $40 million of it, 70 percent, went to attorney fees. More significantly, the total civil penalties only averaged about $885,000 over a 6-year period.

So I think you can see that there are other factors in regards to opposition to this legislation. I don't think we need to look any further to understand the need for this legislation than the prepared testimony of Mr. Bill Stadtlander today. Bill, if I've mispronounced your last name, I apologize. Here is a man who has produced a product that the FDA has determined can be labeled, and I'm quoting, "heart healthy, bone healthy, may reduce the risk of certain types of cancer." May reduce the risk of certain types of cancer but the State of California says, in that regard that the product that Bill would like to sell, is that naturally occurring Acrylamide may—may cause cancer. He is now being subjected to a multi-million dollar lawsuit because his product does not contain a label saying that the State of California believes his product could—could,

may cause cancer. Forty-nine other States, Bill—why don't you bring your company to Kansas? Where are you?

[Laughter]

You know, Dodge City will give you a special deal. We'll make you Marshall. We'll give you the land—well, I'm maybe a little out of line there but at any rate, think about it. But at any rate, I think it is time to bring common sense to our food safety tolerance and warning label policies. Mr. Chairman, I thank you again for holding this hearing. Pardon my sort of wanderings here or being rather irascible in regards to this but 15 years we've tried to get uniform and we've done it on so many other different things, as I've said. Pesticides, allergens, nutritional labeling, pesticides in 1996, nutritional labeling in 1990, allergens 2004. As science has progressed in this parts per trillion, or even more than that in terms of technology. I think we can do the job. I think the FDA can do the job and I certainly would support funding in regards to enforcement practices. So I thank you again for holding the hearing. I urge my colleagues to help us move forward in ensuring this legislation is enacted as of this year if possible. I yield whatever time I have remaining, which is probably none.

Senator BURR. All right, I thank the Senator from Kansas for his work in the past and his work today. The Chairman also said that it is his understanding that the FDA is in the process of issuing, probably before the end of the year, a regulation as it relates to lead in candy. Were this to be the law today, California, in this particular case, because there was no Federal standard, would petition the FDA as it related to lead in candy. Until the FDA acted on that petition, this would be the letter of the law in California. We would not alter California's regulation of lead in candy and clearly, there is the opportunity that California may object with what the FDA came out with or in fact, California's experience might guide the FDA as to what that regulation should look like. But I think clearly, the point needs to be made that passing this bill would not in any way, shape or form, affect what California has done as it relates to lead in candy. The Chair would recognize Senator Reed if he has any opening remarks. He does not, then the Chair would call up the second panel. On our second panel is William Stadtlander, who has been president and CEO, owner of Homestat Farms, Limited since creating the company in 2001. The company is based in Dublin, Ohio and makes the hot cereals Maypo, Wheatena and Maltax as well as G. Washington Seasoning and Broth. Prior to creating Homestat Farms, Mr. Stadtlander worked at Abbott Laboratories for 21 years and served for 9 years as Vice President, Corporate Officer for the Ross Division of Abbott Labs. Mr. Stadtlander will discuss the impact of nonuniform food safety laws on his small business. In addition, Mr. Peter Barton Hutt is a Senior Counsel in the Washington, D.C. law firm of Covington and Burling, specializing in food and drug law. He began his law career practicing with the firm in 1960 and except for his 4 years in the Government, has continued at the firm ever since. From 1971 to 1975, he was the Chief Counsel for the Food and Drug Administration. Mr. Hutt will discuss the history of food regulation and why establishing uniformity in food adulteration regu-

lations and warning notifications is an important step forward. Welcome, Mr. Hutt.

Senator ROBERTS. Mr. Chairman, could I make a point?

Senator BURR. Yes.

Senator ROBERTS. I'm the candy man here again. You folks have to get a better example here, more up to date because this is pretty old stuff and it is hard to read the label but this candy is from Mexico and I think maybe this is a trade issue or certainly an inspection issue for products coming in from Mexico to California. And I would agree, I wouldn't eat this stuff. This looks like it is about 2 or 3 years old.

Senator BURR. I'm confident our second panel might be able to share some insight on that candy as well. In addition, Dr. Elsa Murano——

Senator ROBERTS. Jack, do you want some candy?

[Laughter]

Senator BURR. Dr. Elsa Murano is the former Undersecretary of the USDA. She is currently the Vice Chancellor and Dean of Agriculture and Life Science at Texas A&M University and Director of the Texas Agricultural Experiment Station. Prior to being appointed Undersecretary for Agriculture for Food Safety by President George Bush in 2001, Dr. Murano was a Professor in the Department of Animal Science at Texas A&M and holder of the Sadie Hatfield Professorship in Agriculture. Dr. Murano will discuss why food adulteration regulations need to be based on sound science. And before his recent retirement, Mr. William Hubbard advised the Commissioner of Food and Drugs on agency policy, coordinated the development of the agency rulemaking, directed the agency's congressional relations and legislative activities and oversaw the planning and evaluation functions of the Food and Drug Administration. He was also a principal representative of the agency with the Secretary of Health and Human Services, other members of the Cabinet, Governors and other senior officials of several States and with the White House. Mr. Hubbard will discuss the FDA's activities on food safety and the agency's interaction with States and I might also add—I understand you are now a resident of North Carolina. We're delighted to have you there.

Mr. Hubbard. Thank you, Mr. Chairman. I'm a native of the State and while those others down east are not as sophisticated or probably intelligent as those of you up in the Piedmont, we do appreciate your concerns, Mr. Burr.

Senator BURR. Thank you, Mr. Hubbard. We will start with Mr. Stadtlander.

STATEMENT OF WILLIAM STADTLANDER, OWNER, HOMESTAT FOODS, DUBLIN, OH

Mr. STADTLANDER. Thank you, Mr. Chairman.

Senator BURR. And I would ask all of you to make sure the mics are on and that you pull them close enough so everybody can hear.

Mr. STADTLANDER. Thank you, Mr. Chairman. My name is Bill Stadtlander. I own a small company, Homestat Farm, which makes Maypo, Wheatena and Maltex hot cereals. Homestat Farm was formed in October 2001, when I purchased these brands as well as G. Washington Seasoning and Broth, from ConAgra Grocery Prod-

ucts. My company is located in Dublin, Ohio and we have a manufacturing facility in Highspire, Pennsylvania, where our cereals are manufactured. We work with BCTGM Local 464. Homestat Farm is a small company. Our annual sales are $4.5 million. We employ about 20 people. Although I am a small company, I pay good wages to my employees. I pay 85 percent of their health insurance, have a pension plan for union employees related to their years of service. I spent more than 25 years working for food and consumer products companies, many of those years making nutritious foods. I created Homestat Farm because I wanted to continue to offer, as my slogan says, healthy nutrition for those you love.

The Wheatena story, which is the subject of a lawsuit right now in California, is what I am here for. The Wheatena story goes back a long way to 1879, when a small bakery owner on Mulberry Street in lower New York City, roasted whole wheat, ground it, sold it in packages branded Wheatena. That is pretty much what Wheatena remains today: a toasted wheat product with a unique taste and lots of healthy fiber, 25 percent more than the leading brand. Health experts now recognize that fiber is essential to a healthy diet. The FDA food pyramid and nutritionists across the world recommend eating high fiber diets and whole grains to maintain good health and to reduce both the risk of heart disease and some types of cancers. A healthy way for a person to start the day is to have a high-fiber breakfast. Wheatena provides that. People may disagree about what foods are healthy and which are not but I've never heard anyone dispute that Wheatena is a high-fiber, healthy food. Nevertheless, I have been sued by a trial lawyer in California who claims that because Wheatena—like hundreds of other cooked or heated foods—contains a naturally occurring by-product of the cooking process, I should have provided a Prop 65 cancer warning to Wheatena customers. What is this by-product? It is Acrylamide, a substance produced whenever foods that have starch are browned.

It's not just Wheatena that Acrylamide is found in, it's in whole grain breads and cereals such as Cheerios, Corn Flakes, Raisin Bran, Granola, Rice Krispies, and Shredded Wheat. It is found in crackers and cookies, toast and pastries. It is found in roasted nuts, prunes, grilled asparagus, to just name a few. Coffee also has Acrylamide. I'm told about 40 percent of the food people consume today have Acrylamide in it.

I am in compliance with all Federal laws, including NLEA labeling and health claims and I know now that the FDA actually says there should not be warnings on foods just because they contain Acrylamide but this lawyer claims that California law is otherwise. It is extremely difficult as a small businessman, to keep up with potentially 50 different State laws regarding ingredients and warnings.

Although I sell approximately $70,000 worth of Wheatena in California each year, California's Prop 65 allows this trial lawyer to sue me for millions of dollars. Food safety agencies around the world have been studying the Acrylamide issue intensively since the substance was first discovered in food 4 years ago and none of them found any significant health risks or recommended any Acryl-

amide warnings. But that does not stop the lawsuit against me, which I have to spend thousands of dollars to defend.

I understand that those who oppose the National Uniformity for Food Act claim it will gut the Nation's food safety laws. I do not believe that is true but I do know they will prevent a State from trying to dictate food policy to the rest of the country and giving bounty hunter lawyers a financial plug to make me think twice about selling Wheatena in that State. As a result of the California lawsuit, I have a real dilemma in that State. I am selling a product that reduces the risk of cancer but the lawyers claim I have to either remove the product from the market or put a cancer warning on it. A cancer warning on a product that nutritionists agree reduces cancer risk all because Acrylamide in Wheatena, even though the same Acrylamide is in lots of other foods with a lot fewer health attributes.

Wheatena is a healthy, all-natural, toasted wheat hot cereal that has been on the market since 1879. The Federal Government has very rigorous procedures for determining health claims a food product can make and Wheatena is in the minority of foods that are allowed three different health claims: heart healthy, bone healthy and may reduce the risk of certain types of cancer. Even though the FDA specifically determined that Wheatena may reduce the risk of cancer, California wants foods that contain Acrylamide, including whole grain breads and cereals, to have a warning that the product may cause cancer, even when no other regulatory party in the world believes warnings are required for Acrylamide at this time. Are you confused? I am and consumers are sure to be confused if Federal guidelines say a product may reduce the risk of certain cancers followed by a California warning that it may cause cancer.

The combination of the litigation costs and potentially pulling out of the State of California is enough to jeopardize my small business when I believe I am selling a very healthy cereal. Because of the real risk to my business, I am fully supportive of the National Uniformity for Food Act that provides for national uniform food safety standards and warning requirements. The basic rationale is for one, uniform, scientifically sound food safety standard rather than a patchwork of 50 different State laws. I want to thank the committee for allowing me to speak here today and I urge you to quickly pass this bill.

[The prepared statement of Mr. Stadtlander follows:]

PREPARED STATEMENT OF WILLIAM STADTLANDER

My name is Bill Stadtlander and I own a small company, Homestat Farm, which makes Maypo, Wheatena and Maltex—hot cereals which, as many mothers have said to their children, are good and good for you. Homestat Farm was formed in October 2001 when I purchased these brands, as well as G. Washington's Seasoning and Broth, from ConAgra Grocery Products. My company is located in Dublin, Ohio and we have a manufacturing facility in Highspire, PA. where our cereals are manufactured. We work with BCTGM Local 464.

Homestat Farm is a small company. Our annual sales are $4,500,000—all in the United States—with sales of $70,000 of Wheatena in California.

We have 3 full-time employees and 3 part-time consultants in our Dublin office which are new jobs that were created when I bought the business. In our manufacturing facility, we have 2 full-time employees in administration and 10 full-time union employees.

Although I am a small company, I pay good wages to my employees, I pay 85 percent of their health insurance, and I have a pension plan for the union employees related to their years of service.

I spent more than 25 years working for food and consumer product companies, many of those years making nutritious foods. I created Homestat Farm because I wanted to continue to offer (as my slogan says) "Healthy Nutrition for Those You Love."

I do not know how many on this committee had Wheatena growing up, but I did, and I did not want to see Wheatena disappear. The Wheatena story goes back a long way—to 1879, when a small bakery owner on Mulberry Street in lower New York City roasted whole wheat, ground it and sold it in packages branded Wheatena. That's pretty much what Wheatena remains today: a toasted wheat product, with unique taste, and lots of healthy fiber—25 percent more than the leading brand.

Health experts now recognize that fiber is essential to a healthy diet. The FDA food pyramid and nutritionists across the world recommend eating high fiber diets and whole grains to maintain good health and to reduce both the risk of heart disease and some types of cancers. A healthy way for a person to start the day is to have a high fiber breakfast—Wheatena provides it.

And Wheatena promotes health in other ways:

- It is Calcium fortified to help keep bones strong.
- It has, as I said, 25 percent more fiber than the leading brand of hot cereal.
- It is 100 percent natural, toasted whole wheat, rich in bran, protein and wheat germ.
- It is cholesterol free, low in fat, low in sugar, low in sodium and fortified Kosher by the Orthodox Union.

People may disagree about what foods are healthy and which are not. But I have never heard anyone dispute that Wheatena is a high fiber, healthy food. In fact, one of the most vocal consumer activist groups engaged in advocating for good nutrition, the Center for Science in the Public Interest (CSPI), lists Wheatena as a good source of whole grains in "Nine Weeks to a Perfect Diet" on its Web site.

Nevertheless, I have been sued by a trial lawyer in California who claims that because Wheatena—like hundreds of other cooked or heated foods, contains a naturally occurring by-product of the cooking process, I should have provided a Proposition 65 cancer warning to Wheatena customers. What is this by-product? It is acrylamide—a substance produced whenever foods that have starch are browned. It is not just Wheatena. Acrylamide is found in whole grain breads and cereals such as Cheerio's, Corn Flakes, Raisin Bran, Granola, Rice Krispies, and Shredded Wheat; it is found in crackers and cookies, toast and pastries; and it is found in roasted nuts, prunes, and grilled asparagus to name just a few. I am told that about 40 percent of the food people consume has acrylamide in it.

Apparently, acrylamide is one of the chemicals California has listed as requiring a cancer warning under its law. I am told that this requirement was adopted when people thought acrylamide existed only in synthetic form and was used in large quantities in industrial settings. I make food products and I try my best to keep up with food regulations. But nobody thought of this Prop 65 listing as applying to food. So I wasn't even aware of Prop 65 until I received notice of the lawsuit. I am in compliance with all Federal laws including NLEA labeling and health claims. And I know now that FDA actually says there should not be warnings on foods just because they contain acrylamide. But this lawyer claims that California law is otherwise. It is extremely difficult as a small businessman to keep up with potentially 50 different State laws regarding ingredients and warnings.

Although I sell only approximately $70,000 worth of Wheatena in California each year, California's Proposition 65 allows this trial lawyer to sue me for millions of dollars. Food safety agencies around the world have been studying the acrylamide issue intensively since the substance was first discovered in food 4 years ago, and none of them have found any significant health risk or recommended any acrylamide warnings. But that does not stop the lawsuit against me, which I have to spend thousands of dollars defending.

In the meantime, I understand that the same CSPI that love Wheatena, is leading the charge against the National Uniformity for Food Act, claiming it will "gut" the Nation's food safety laws. I do not believe that is true, but I do know that it will prevent a State from trying to dictate food policy to the rest of the country, and giving "bounty hunter" lawyers a financial club to make me think twice about selling Wheatena in the State.

As a result of the California lawsuit, I have a real dilemma in that State. I am selling a product that reduces the risk of cancer. But to limit the lawyer's claims,

I have to either remove the product from the market or put a cancer warning on it—a cancer warning on a product that nutritionists agree reduces cancer risk—all because of acrylamide in Wheatena, even though that same acrylamide is in lots of other foods with a lot fewer health attributes.

Wheatena is a healthy all natural toasted wheat hot cereal that has been on the market since 1879. The Federal Government has very rigorous procedures for determining the health claims a food product can make and Wheatena is in the minority of foods that are allowed three different health claims: (1) Heart Healthy; (2) Bone Healthy; and (3) May reduce the risk of certain types of cancer.

Even though FDA specifically determined that Wheatena may reduce the risk of cancer, California wants foods that contain acrylamide—including whole grain breads and cereals—to have a warning that the product may cause cancer, even when no other regulatory body in the world believes warnings are required for acrylamide at this time. Are you confused? I am. And consumers are sure to be confused if Federal guidelines say a product may reduce the risk of certain cancers followed by a California warning that it may cause cancer.

The alternative of a different label for one State than for the remaining 49 States is virtually impossible to implement because food chains and wholesalers pull from the same warehouse for different States and diverters move products around the country. Another possibility is to have a separate label with a different UPC code and carry duplicate inventory to conform to individual State requirements which is expensive and potentially confusing.

The combination of the litigation costs and potentially pulling out of the State of California are enough to jeopardize my small business when I believe I am selling a very healthy cereal that has been on the market for more than a century and is widely recommended by nutritionists.

Because of the real risk to my business, I am fully supportive of The National Uniformity for Food Act that provides for national, uniform food safety standards and warning requirements. The basic rationale is for one uniform, scientifically sound food safety standard rather than a patchwork of 50 different State laws. I understand that uniformity already exists for nutrition labels and for meat, poultry and eggs, and I believe that system works very well.

I want to thank the committee for allowing me to speak here today, and I urge you to quickly pass this bill.

Senator BURR. Thank you, Mr. Stadtlander.

Mr. Hutt. Welcome.

STATEMENT OF PETER BARTON HUTT, SENIOR COUNSEL, COVINGTON AND BURLING, WASHINGTON, D.C.

Mr. HUTT. Mr. Chairman and members of the committee, I am Peter Barton Hutt, Senior Counsel at the Washington, D.C. law firm of Covington and Burling. I have practiced and taught food and drug law for my entire professional career. From 1971 to 1975, I served as Chief Counsel for the Food and Drug Administration. I am the co-author of the casebook used to teach food and drug law throughout the country and since 1994, I have taught a full course on this subject each year at Harvard Law School. Mr. Chairman, I'm not from North Carolina but my younger daughter does teach at Duke Law School and enjoys it greatly. S. 3128 balances the need for a strong national law to assure safe food for all our citizens, wherever they may live, with the right and duty of each State to protect its own citizens from harm. It recognizes the primary jurisdiction of FDA to provide uniform requirements for safe and properly labeled food throughout the country, enforced by both Federal and—and I emphasize—State officials as well. It would be impossible to maintain a national food market of each of the 50 States who are free to impose their own separate food safety and food warning requirements. But at the same time, the States must be given the right to collaborate with FDA in assuring that appropriate national requirements are imposed and the States should

take the predominant role in public protection where uniquely local matters are involved. This legislation accomplishes both of these objectives. Let me hit just the highlights of this legislation. There is no impact on State administrative procedures in this bill. There is no impact on State enforcement power and there is no impact on State inspections of food manufacturers. States can fully enforce any State food law that is the same as the Federal food law. Nothing in the bill, nothing at all, disrupts the longstanding Federal/State partnership in food safety. No existing food safety program is weakened. Traditional local food sanitation matters are not subject to national uniformity under the bill. Thus, regulation of milk production, shellfish and restaurants is not under the bill. Economic adulteration is also excluded, thus the illegal addition of water or other adulterates to milk, juice, honey, cider vinegar or maple syrup, in order to deceive the public, are not included within the legislation. Now, in contrast, there are inherently national matters for which uniformity is essential to an orderly and free national marketplace. Regulation of the safety of food ingredients, color additives and packaging components must be consistent in every jurisdiction in the country in order to permit our free market economy to thrive. But even then, as S. 3128 explicitly confirms the authority of the States to enforce their identical State laws regardless whether FDA does or does not take action itself. But provisions of S. 3128 that relate to food warnings are narrowly limited to actual warnings and not to a large number of their types of statements relating to food. Thus, the legislation does not apply to directions for use such as keep refrigerated or to descriptions of the origin of a food such as farm-raised fish. Now, the Center for Science in the Public Interest erroneously asserts that more than 200 State laws will be affected by S. 3128. In fact, all but a handful of the State laws cited by CSPI are not affected by the legislation in any manner whatsoever. The most notable State law that would be affected by S. 3128 is, of course, California's notorious Proposition 65 that Bill has just described. This law has resulted in a veritable torrid of warnings as well as major litigation about the applicability to various food products in spite of numerous FDA letters opposing the warnings that California has required. For those nonuniform State laws and regulations that have already been enacted and are currently in effect, the State may petition for an exemption from uniformity or for a national standard. These existing State laws stay in place, as everyone recognizes, as long as it takes the FDA to rule on the petitions. Finally, there will be no flood of State petitions. Only six State exemption petitions have ever been submitted to FDA under the National Uniformity provisions of the Nutrition Labeling and Education Act of 1990. Not one exemption petition has been submitted by a State in the last 13 years. I'll be happy to answer any questions, Mr. Chairman.

[The prepared statement of Mr. Hutt follows:]

PREPARED STATEMENT OF PETER BARTON HUTT

Mr. Chairman and members of the committee, I am Peter Barton Hutt, senior counsel at the Washington, D.C. law firm of Covington & Burling. I have practiced and taught food and drug law for my entire professional career. From 1971 to 1975, I served as chief counsel for the Food and Drug Administration. I am the coauthor of the casebook used to teach food and drug law throughout the country and since

1994 I have taught a full course on this subject each Winter Term at Harvard Law School. My curriculum vita is attached to this testimony.

I appear today in support of S. 3128, the National Uniformity for Food Act. This legislation balances the need for a strong national law to assure safe food for all our citizens, wherever they may live, with the right and duty of each State to protect its citizens from harm. It recognizes the primary jurisdiction of FDA to provide consistent and uniform requirements for safe and properly labeled food throughout the country, enforced by both Federal and State officials. It would be impossible to maintain the national food market that we have come to demand if each of the 50 States imposed its own separate food safety and warning requirements. At the same time, the States must be given the right to collaborate with FDA in assuring that appropriate food safety and warning requirements are imposed and, where uniquely local matters are involved, to assume the predominant role in public protection. This legislation accomplishes these dual objectives.

It is fitting that, on this the 100th anniversary of our first national food and drug law, the Congress is considering legislation that strengthens the authority and responsibility of FDA to regulate the safety and labeling of the entire food supply. Our country has moved well beyond the day when most food was locally produced and consumed. Now, food that has been grown, produced, and packed all over the world is sold in every State. Different standards and warnings imposed on food in one State but not in others impedes commerce, confuses consumers, and increases the cost of food without commensurate benefit.

Consumers are entitled to assurance that the food they purchase and consume, whether for themselves or for their families, is safe. Whether it be a container of milk, a box of cereal, or a bottle of juice, the decision whether that food is safe ought to be applied consistently from State to State. Disparate standards and warnings—the current circumstance which S. 3128 addresses—does not facilitate informed decisionmaking by consumers about the foods that they choose to consume.

Let me provide an example of this point. There has been considerable recent discussion and controversy about regulation regarding mercury in fish. No one seriously questions that pregnant and nursing women and young children should limit their consumption of fish known to be relatively high in mercury. At the same time, the health benefits of eating fish (low fat, high protein, and an abundant source of omega-three fatty acids) are also well known. The challenge for health and safety regulators is thus to provide advice to consumers that properly balances the risks and benefits of fish consumption.

In 2004, the Food and Drug Administration and the Environmental Protection Agency did just that. The two agencies issued a comprehensive advisory to consumers that is scientifically based and carefully drawn to encourage consumption of fish while also permitting consumers—especially those most at risk—to avoid fish with relatively high levels of mercury. Nevertheless, one State, California, has taken a contrary position that focuses on the risk of mercury while minimizing or ignoring the benefits of eating fish.

The position California has taken is contrary to the public health. Several months ago, the highly regarded Tufts Health and Nutrition Letter reported on a study done at the Harvard School of Public Health. That study concluded that government warnings about mercury in fish *did more harm than good* because they caused consumers to avoid fish and thus to deprive themselves of the health benefits of fish in return for a negligible reduction in risk due to avoidance of mercury. Several studies have compared the risk of exposure to mercury with the benefits of omega-three fatty acids in terms of the risk of stroke and coronary heart disease and relative to prenatal development. The conclusion of those studies is clear: the health benefits to the pubic of consuming fish outweigh the risks from mercury.

The mercury in fish matter demonstrates the need for regulators to speak with one voice and to apply sound science to reach a conclusion that gives consumers a basis to make informed and sound choices about the food they consume. We do consumers a disservice when we perpetuate a system that allows inconsistent, indeed contradictory, standards to be applied and warnings to be issued in some places in the country which are at odds with the science-based conclusions that regulators with national responsibility have reached after thorough and careful consideration of the available scientific data and information.

S. 3128 would properly and effectively ensure that the standards to be applied and the warnings to be issued are based on sound science and consistent throughout the country.

The Congress has repeatedly exercised its Constitutional authority to regulate interstate commerce in the food and drug arena by enacting legislation that provides for uniformity in food and drug regulation. The legislation before the committee today is not novel, unique, or unprecedented. National Uniformity exists for meat

and poultry products under the Federal Meat Inspection Act and the Poultry Products Inspection Act, both of which are administered by the U.S. Department of Agriculture. When the Congress enacted the Nutrition Labeling and Education Act in 1994, it provided for national uniformity for nutrition labeling, health claims, nutrient content claims, ingredient labeling, standards of identity and numerous other aspects of food labeling. Congress has also provided national uniformity for pesticide regulation, medical devices, and cosmetic and over-the-counter drug product labeling.

In 1990, Congress enacted the Nutrition Labeling and Education Act (NLEA) which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to modernize food labeling. As part of that legislation, Congress included Section 403B of the FD&C Act, 21 U.S.C. 343-1, to require national uniformity for most aspects of food labeling. Two areas of food regulation were not included under the 1990 national uniformity provisions: (1) the food safety provisions of the FD&C Act and (2) food warnings. The National Uniformity for Food Act is intended to address these two important areas, in order to assure that food is safe throughout the Nation and that, whenever some form of warning is appropriate, it will be provided in every part of the country.

It is a conspicuous anomaly that a statutory requirement for national uniformity does not currently exist for food safety and food warnings for products regulated by FDA. The absence of uniformity in these areas is an historic accident that cannot be explained by fundamental differences between food safety and all of the other areas in which the Congress has provided for consistent and uniform regulation. Under the food safety related provisions of the FD&C Act, FDA has extensive statutory authority to establish standards for the adulteration of foods, establish tolerances or other limits for environmental contaminants in food, determine whether food additives, color additives and other categories of food ingredients are safe, and establish standards for the safe processing and packaging of foods. One cannot explain the absence of national uniformity for food safety and food warnings by claiming that the authority of the States to regulate food is more extensive than the authority that the Congress has given to FDA.

SUMMARY OF MAIN FEATURES OF S. 3128

The legislation divides food safety into two categories: (1) traditional local matters that have long been the subject of city, county, and State regulation and (2) inherently national matters for which a consistent policy throughout the country is essential to a nationwide market.

The pending legislation does not include traditional local food safety matters within the requirement for national uniformity. For example, there are three areas of local food sanitation that have long been handled by cooperative Federal/State/industry/academia programs: milk production (a program begun in 1923), seafood (begun in 1925), and regulation of restaurants, vending machines, and retail food stores (begun in 1935). All three of these areas largely involve food sanitation and administrative procedures that are excluded from national uniformity. Similarly, the economic adulteration provisions of the law that have long been handled at the local level are also excluded from national uniformity. For example, the illegal addition of water or other adulterants to milk, juice, honey, or maple syrup in order to deceive the public are not included within this legislation. Because each uniquely takes place in a local jurisdiction and regulation has no impact upon a nationwide market, there is no need for national uniformity in order to preserve the ability of the food industry to serve the entire country. As a practical matter, moreover, the cooperative programs that have long been used in these areas assure widespread uniformity in food sanitation and economic adulteration requirements that has served the public so well for decades.

In contrast, there are inherently national matters for which national uniformity is essential to an orderly and free national marketplace. Regulation of the safety of natural and synthetic food ingredients, color additives, and packaging components must be consistent in every jurisdiction in the country in order to permit our free market economy to thrive. If differing standards and requirements were adopted in each State, and specific ingredients were regarded as safe in some States but not in others, there would be economic chaos. Thus, national uniformity is applied under this legislation to all of these inherently national aspects of food regulation, with three exceptions which are addressed later in this testimony.

I now turn to the provisions of S. 3128 and describe briefly how these provisions would operate if enacted. Because there has been so much misinformation circulated about S. 3128 (and H.R. 4167, the version of the legislation that passed the House

of Representatives), I also address the major criticisms of the legislation that I conclude are without merit.

S. 3128 contains four main features:

- Uniformity for food safety regulation
- Uniformity for food safety warnings
- Implementation of the legislation and the process for consideration of State requirements
- Specific exemptions

I will address each of these features in turn.

Uniformity for Food Safety Regulation

Section 2(a) of S. 3128 provides for uniformity in food safety regulation. The bill would do this by amending the existing uniformity provision in Section 403A of the FD&C Act (21 U.S.C. 343-1). The bill sets forth 10 sections of Federal food safety law under which the vast majority of Federal food safety regulation arises and provides that State requirements that are the counterpart to these 10 sections must be identical. The 10 sections of Federal law that are included in the bill relate to adulteration of food, food and color additive regulation, regulation of contaminants in food, emergency permits for low acid canned food, and animal drugs used in food producing animals.

The bill defines "identical" broadly to encompass many State requirements that are not literally identical. As defined in Section 2(a)(4)(c)(1), "identical" means that the language of the State law is "substantially the same" as the Federal provision and that any differences in language do not "result in the imposition of materially different requirements." This definition is unique. Ordinarily when the Congress enacts legislation to create uniformity it merely requires that State law be identical to Federal law. The language in S. 3128, however, accommodates differences in the wording of State and Federal requirements that do not affect the meaning of the respective provisions.

The premise of this provision of S. 3128 strikes me as straightforward: the basic provisions of law—whether Federal or State—under which the safety of the food supply is regulated, ought to be the same. If a State were to apply different standards to determining, for example, whether a food was adulterated, than other States or the Federal Government, interstate commerce in food would be chaotic.

The notion that underlying food and drug law at the Federal and State levels should be the same is not new. The food and drug laws of virtually every State are patterned after the Model State Food and Drug Bill which was developed to foster uniformity. The Model State Bill was, in turn, patterned after Federal law. For example, Section 402(a)(1) of the FD&C Act, 21 U.S.C. 342(a)(1), has contained the basic food safety standard for 100 years. It provides that a food is adulterated if it contains any added poisonous or deleterious substance which may render the food injurious to health. This very same provision is found in the laws of all 50 States.

In point of fact, there are very few differences between Federal and State food safety laws, which is why I am puzzled that this provision of S. 3128 has generated so much discussion. With some exceptions, including notably Proposition 65 in California, existing differences between Federal and State food safety law are few and generally of a minor nature.

Section 2 of S. 3128 also contains provisions to clarify the ability of the States to enforce their identical State laws even in circumstances in which FDA has not or does not take enforcement action. Thus, under Section 2(a)(4)(c)(2) and (3), a State may enforce its identical State food safety law as it deems appropriate if FDA has not by regulation or final guidance applied Federal law to the matter in question. If there is an FDA regulation or final guidance, however, the State may still enforce its identical law, but it must conform that enforcement to the FDA regulation or final guidance. Finally, if FDA has formally considered a regulation or guidance and affirmatively concluded not to adopt one (where, for example, there is insufficient scientific evidence to support the adoption of a tolerance by regulation), then the State must abide by that FDA decision.

In my experience, State and local officials routinely consult with the FDA when they encounter a food safety problem and they will continue to do so under S. 3128. S. 3128 carefully preserves the ability of State officials to use the various enforcement tools available to them under State law to remove potentially dangerous food from the marketplace. It imposes no additional requirement to consult with FDA or to obtain the concurrence of FDA to take action. S. 3128 will help to ensure that, regardless whether it is a State or a Federal official deciding whether a food is safe, the standard applied to that food will be the same.

Uniformity for Food Safety Warnings

The provisions of the national uniformity legislation that relate to food warnings are narrowly limited to warnings, and do not apply to a large number of other types of statements relating to food. For example, the legislation does not apply to directions for use such as "keep refrigerated," or to descriptions of the origin of a food such as "free-range-chicken" or "farm-raised fish." It does not cover specialized laws found in many States that require that the term "honey" can only be used for a food that consists solely of honey, or that the term "maple syrup" can only be used if the product is made solely from the sap of the maple tree, or that "cider vinegar" must be made solely from apple cider. None of these is in the nature of a warning. Finally, the legislation itself excludes non-warning statutes and regulations relating to freshness dating, open date labeling, grade labeling, a State inspection stamp, religious dietary labeling, organic or natural designation, returnable bottle labeling, unit pricing, a statement of geographical origin, and dietary supplement regulation. None of these involve safety warnings and thus are explicitly excluded from the statute. One type of safety warning—a consumer advisory under the FDA Food Code relating to the risk of eating raw or undercooked food—has also been explicitly excluded from the legislation because it is already recommended on a national basis by FDA.

Thus, there are dozens of State statutes and regulations that are excluded from the legislation because they are essentially local in nature and do not in any way relate to food safety.

The national uniformity legislation focuses exclusively on food safety warnings. It prohibits a State from imposing any such warning that is in addition to or different from a warning imposed by FDA, in order to assure that the same information on food safety is provided to citizens in every part of the country.

Section 2(b) of S. 3128 provides for uniformity in food warnings. Under that section, States would not be permitted to impose on the food industry a requirement to communicate a "notification requirement for a food that provides for a warning" unless there is a Federal warning and the State warning is identical. States would remain free, however, to issue their own warnings to citizens of their States, even if there is no Federal label warning or if the State-issued warning contradicts a Federal warning.

In order for the warning uniformity language to apply, the State requirement must be (1) a notification requirement (2) that contains a warning and (3) is imposed on the food industry.

I am familiar with a report issued by the Center for Science in the Public Interest that asserts that nearly 200 State laws will be affected by S. 3128 (or the House counterpart). I have examined this report and conclude, as have others who have studied it in detail, that the CSPI report is incorrect. The CSPI report is incorrect because, while it collects numerous examples of State food laws or regulations, it assumes erroneously that the uniformity legislation will affect them without examining the language of the legislation to determine if that is so. For example, there are numerous State laws listed in the CSPI report that contain notification requirements for such things as "keep refrigerated," or "farm-raised," or that restrict the use of certain terms on food products unless certain conditions are met (Massachusetts law on halibut and Connecticut law on honey). None of these State laws are affected by the uniformity legislation because they are notification requirements but not warnings. S. 3128 makes it perfectly clear that it reaches only notification requirements that contain food-related warnings.

The most notable State law that would be affected by S. 3128 is California's Proposition 65. Proposition 65 was adopted in California in 1986 under the State's initiative process. It was promoted as a law to ensure the safety of the State's drinking water. As we have come to know, Proposition 65 is considerably broader. Under Proposition 65, the State maintains a list of chemicals "known to the State of California to cause cancer or reproductive toxicity" and makes it illegal to "expose" anyone to a listed chemical without providing a warning. California has listed more than 750 chemicals under Proposition 65. The law has resulted in a veritable flood of warnings in restaurants, bars, grocery stores, hotel lobbies, and elsewhere, as well as major litigation about its applicability to various food products.

Proposition 65 provides for substantial monetary penalties for violations ($2,500 per violation per day). In addition to the Attorney General, Proposition 65 may be enforced by private persons, which has given rise to lawyers who bring private Proposition 65 suits because, if successful, they receive not just attorneys fees, but a portion of the penalty imposed.

These suits are expensive to defend and risky to litigate because of the financial exposure involved. Many companies, faced with a Proposition 65 lawsuit, have elect-

ed to reformulate their products to remove or reduce the substance in the food that creates the legal exposure, rather than engage in protracted litigation.

Some have characterized these reformulations as "success stories" and as demonstrating that, under Proposition 65, action has been taken at the State level to make food safer in situations where the FDA has not acted. This argument cannot be sustained.

Under Proposition 65, chemicals in food are determined to present a significant risk by using a vastly different approach to risk assessment than that used by FDA and EPA. When assessing the potential risk to human health from a chemical shown to cause cancer in animal studies, for example, FDA and EPA calculate an upper limit on the risk as one potential additional cancer per 1 million persons. California, however, used a standard of one additional cancer per 100,000 persons. Further, in estimating the potential exposure of a person to a chemical, California assumes exposure 24/7 for 70 years. FDA and EPA, estimate exposure conservatively, but not constantly throughout one's lifetime, as is done under Proposition 65.

The result of the approach to assessing risk under Proposition 65 is that significant risk is asserted where it does not exist. Thus, the claims that Proposition 65 has resulted in safer food are often not correct. If a food contains a chemical in a small quantity such that the risk from exposure to it is negligible, forcing the manufacturer either to lower the level of the chemical in the food or to face costly and uncertain litigation and adverse publicity does not make the food less risky. Proposition 65 creates the illusion of safer food while simultaneously creating a proliferation of warnings that can only cause consumers to believe that "everything is unsafe."

Implementation of the Legislation and Process For Consideration of State Requirements

For both food safety requirements and safety warning requirements, the national uniformity legislation divides State laws and regulations into two categories: (1) those already existing as of the date of enactment of the legislation and (2) those that are the subject of State action after the legislation goes into effect.

For those State laws and regulations that have already been enacted and are currently in effect, the legislation provides for a 2-year process for FDA consideration as to whether the requirements can be justified on the basis of sound science or whether they cannot withstand close scrutiny. If a State wishes to abandon a requirement, it need do nothing further. If the State desires to continue enforcing the requirement, it can petition FDA either for an exemption from national uniformity or to adopt the State requirement throughout the country. Following a 2-year public process, FDA will make a decision based on sound science. That decision may also be appealed to the courts. At every stage of this process, the States will be intimately involved. If FDA fails to take action as required by the legislation, provisions authorize the courts to force the agency to do so. State requirements that are the subject of State petitions to FDA remain in effect until FDA takes action on the petition, however long that may take.

For future State safety requirements and warnings, there are three mechanisms by which a State may adopt provisions that do not conform to national uniformity. First, a State may petition FDA for an exemption from national uniformity in order to address a local problem. Second, the State may petition for a national standard that would impose a requirement throughout the country, in order to address a nationwide problem. Third, the State may act immediately in order to address an imminent hazard to health, for example, an issue of bioterrorism.

For all three of these areas, the legislation explicitly provides that FDA must expedite consideration of any requirement relating to a cancer risk or to the safety of pregnant women and children. Again the courts are empowered to force FDA to take action if the agency fails to do so.

Some have suggested that FDA will be overwhelmed with petitions under the petition process set forth in the legislation for existing State requirements. I will be very surprised if this were the case. First, as noted earlier in this testimony, there are likely to be very few State requirements in effect on enactment that will be affected by the legislation. Of the 196 State requirements in the CSPI report, in reality only 11 would be affected. Second, to the extent that States submit petitions to FDA out of caution, FDA will be able to address this summarily and without substantial expenditure of resources. Finally, to the extent that FDA is not able to resolve petitions in the time periods set forth in the legislation, State requirements will remain in effect.

Food Bioterrorism

The national uniformity legislation fully recognizes valid concern about the potential for bioterrorism through intentional poisoning of the food supply. First, States retain all of the enforcement authorities that exist under State law. Second, as already noted, any State can act immediately under the imminent hazard provision of the legislation in the event of food bioterrorism. Third, the entire bill will not go into effect unless and until the Secretary of HHS certifies to Congress, after consultation with the Department of Homeland Security, that implementation will pose no additional risk to the public health or safety from terrorism attacks.

CONCLUSION

The national uniformity legislation explicitly reinforces the unique and important role of State officials in enforcing food safety requirements. The legislation provides, for example, that it does not affect State administrative procedures or enforcement powers. The legislation explicitly confirms that States can enforce, at any time, local laws and regulations that are the same as the requirements of the FD&C Act. And States can at any time issue their own food safety warnings to their citizens, even if the State warnings do not conform to FDA policy. Thus, States retain substantial authority to protect their citizens. In this way, national uniformity is reconciled with the fundamental right and duty of a State to protect the public from unsafe food.

The national uniformity legislation represents a balanced approach, incorporating both the need for a consistent and coordinated approach to food safety and food warnings throughout the country, while retaining the authority of States to take the lead on local issues, to collaborate with FDA to assure appropriate national regulatory requirements, and to cooperate in a comprehensive enforcement system that will protect the public in every jurisdiction throughout the country.

Senator BURR. Thank you, Mr. Hutt.

Dr. Murano.

STATEMENT OF ELSA A. MURANO, DEAN, COLLEGE OF AGRICULTURE AND LIFE SCIENCES, TEXAS A&M UNIVERSITY, COLLEGE STATION, TX

Dr. MURANO. Thank you. My name is Dr. Elsa Murano. I am the Dean of the College of Agriculture and Life Sciences at Texas A&M University, Director of the Texas Agricultural Experiment Station and Vice Chancellor of Agriculture for the Texas A&M University system. Mr. Chairman, I am a food microbiologist by training, holding a Master's and Ph.D. degrees from Virginia Tech in Anaerobic Microbiology and Food Science and Technology. In the 1990s, I was Professor of Food Microbiology at Iowa State University and then at Texas A&M University.

From 2001 to 2004, I served as Undersecretary for Food Safety at the U.S. Department of Agriculture, where I was responsible for developing the policies and programs implemented by the Food Safety and Inspection Service or FSIS. This public health agency is believed to be the premier public health agency in the world, with FDA as a close second. This public health agency is charged with ensuring that the Nation's commercial suppliers of meat, poultry and egg products is safe, wholesome and correctly labeled and packaged. While Undersecretary, I was also responsible for representing the U.S. Government on the Codex Alimentarius Commission, which is an international organization that develops food standards guidelines and codes of practice to protect the health of consumers, ensure fair trade practices and promote coordination of all food standards at the international level.

Mr. Chairman, S. 3128 would provide a national approach for establishing food safety tolerances and inserting warning information on the label and related materials for packaged foods. The bill

would assure a consistent approach to labeling information for all 50 States. The proposed law is not a new concept as we have heard already this morning. National uniformity already exists for most of the U.S. food supply and many other products. The laws under which I operated as Undersecretary for Food Safety at the USDA are a good example. Besides my representing a new concept, S. 3128 is designed to ensure that the public is protected and well informed without impacting the fundamental food safety laws at the Federal or State level or affecting any enforcement authority at the State or Federal level. It is through cooperation that exists between Federal and State agencies that these activities are carried out. A good example of this cooperation is the Food Code. The FDA, the Center for Disease Control and Prevention and FSIS all contribute to the Food Code to make sure it addresses control for risk factors that the Government has identified as causing outbreaks of food borne illness. The Code provides food control authority at all levels of government, a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry. In fact, according to the FDA, local, State, tribal and Federal regulators use the FDA Food Code as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy. As a trained researcher, as a scientist, I understand how science can be used to determine the true risk posed by food-borne hazards. As Undersecretary, I put this back on to use, applying the scientific principle of hazard analysis, epidemiology, risk assessment and statistical sampling in order to develop policies that would reduce the risk of illnesses such as those caused by E. coli or 157H7, Listeria monocytogenes, among others. As a result, the number of illnesses caused by these pathogens was reduced by 42 percent and 40 percent respectively, as reported last year by the CDC. At the USDA, our scientific experts work very hard to develop the underlying data used in risk assessments, incorporating research also from the entire scientific community, which resulted in these public health improvements. Establishing a uniform national system will put food safety in the hands of the Nation's top food scientists and food safety experts, such as those at the USDA and just like USDA, the FDA is best positioned to assure that these scientists and experts are brought together, whether they come from Federal Government, State government or academia. There are few issues that are important to point out when applying science. First, science sometimes can be misinterpreted by people without sufficient expertise. In the area of food safety, a range of different interpretations leading to different advice or warnings in different States would be obviously problematic. The benefit of a national uniformity approach is that it will bring the best scientists together to address issues of public health significance, thereby helping to determine how best to communicate to consumers in all 50 States. Second, sometimes obtaining results via the scientific process can take time and all the answers to our questions may not be available as quickly as we want them to be. In these cases, the Federal agencies, as well as the States, have the authority and the capability to step in and protect the American public. The proposed law includes an eminent hazard authority that would retain the authority of the State's health regulators to

take protective actions on a local basis. Third, sometimes a safety issue appears locally, not nationally but because we have a national food supply, an action taken locally may not help all consumers. If there is a true safety issue, State authorities should bring it to the attention of the Federal agencies so that it can be confirmed and together, they can take a national approach to protect all U.S. consumers. The proposed law provides a process to establish national standards in order to protect all consumers, not just some. Fourth, on occasion, the data will show that a safety issue could truly be local and advice or warnings should be provided to consumers in that area. The proposed law recognizes this and allows for an exemption from national uniformity when a safety issue is demonstrated to be unique to a specific State.

So Mr. Chairman, S. 3128 would provide a national approach for establishing food safety tolerances and warning label requirements that are consistent in all 50 States. Incidentally, this objective is also consistent with activities the U.S. Government has been engaged in for international food standards. As I mentioned in my opening statements, while at USDA, one of my responsibilities was to represent the United States as a member Nation of the Codex Alimentarius Commission. Allow me to quote very briefly from a Codex document on the harmonization of food standards internationally to emphasize the value of national uniformity here in the United States,

> "With respect to the ever-increasing global market, in particular, the advantages of having universally uniform food standards for the protection of consumers are self evident."

It is not surprising, therefore, that the agreement on the application of sanitary and pseudo sanitary measures and the agreement on technical barriers to trade both encourage the international harmonization of food standards. As I think Senator Roberts said, it would be ironic for us to be supporting harmonization internationally and then here at home, allow and even encourage individual States to impose their own labeling requirements. In closing, it is incumbent upon those who are charged with protecting public health to avail themselves with the best data, obtained with the best scientific methodology and analyze using sound scientific principles in order to provide consumers with the most accurate information that can effectively reduce, if not eliminate, risks. Federal agencies like the FDA are charged with such a mandate and are best equipped to implement it on a nationwide basis in order to protect the health of Americans and every one over 50 States. In a world in which confusion and misinformation can provide either a false sense of security or create unwarranted fears in consumers, uniform tolerances and labeling requirements as provided by the proposed bill simply makes sense. Thank you, Mr. Chairman.

[The prepared statement of Dr. Murano follows:]

PREPARED STATEMENT OF ELSA A. MURANO

My name is Dr. Elsa Murano, and I am the Dean of the College of Agriculture and Life Sciences at Texas A&M University, the Director of the Texas Agricultural Experiment Station, which is the agency in the State of Texas charged with conducting research in agriculture and the life sciences, and the Vice Chancellor of Agriculture for the Texas A&M University System. I am a food microbiologist by training, and hold a Masters and Ph.D. degree from Virginia Tech in Anaerobic Microbiology and Food Science & Technology. During the 1990s, I was professor of food

microbiology at Iowa State University and then at Texas A&M University, where I taught and conducted research in food safety. I am very familiar with the scientific process of arriving at solutions to problems in food safety, having published dozens of peer-reviewed scientific papers, book chapters, and monographs. At Texas A&M, I also served as Director of the Center for Food Safety, in charge of research in this important area.

From 2001 to 2004, I served as Undersecretary for Food Safety at the U.S. Department of Agriculture (USDA), where I was responsible for developing the policies and programs implemented by the Food Safety and Inspection Service, or FSIS. This public health Agency is charged with ensuring that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. This duty is not limited to domestically produced products, but it also extends to ensuring the same for products that are imported from other countries. As Undersecretary for Food Safety, I was also responsible for representing the U.S. Government at the Codex Alimentarius Commission, an international organization created in 1963 by FAO and WHO which develops food standards, guidelines and codes of practice to protect the health of consumers, ensure fair trade practices, and promote coordination of all food standards at the international level.

As I mentioned, my experience in government was principally with USDA-regulated products. However, having worked very closely with my counterpart, the Commissioner of the Food and Drug Administration (FDA), I can assure you that the same principles we applied at USDA to ensure that the products we regulated were safe, wholesome, and appropriately labeled, are also employed by FDA for the foods they regulate.

S. 3128 would provide a national approach for establishing food safety tolerances and inserting warning information on the labels and related materials for packaged foods. The bill would thus assure a consistent approach to labeling information for all 50 States. As others have pointed out, the proposed law is not a new concept—national uniformity already exists for most of the U.S. food supply and many other products. In fact, Congress has repeatedly established uniform requirements for nutrition labeling, allergen labeling, standards and labeling of meat and poultry products, prescription drugs, medical devices and pesticide tolerances. The laws under which I operated as Undersecretary for Food Safety at USDA are a good example. The Federal Meat Inspection Act states that:

> "Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection." [21 U.S.C.§ 678]

Similarly, in the Poultry Products Inspection Act the Congress established uniformity in labeling:

> "Marking, labeling, packaging, or ingredient requirements (or storage or handling requirements found by the Secretary to unduly interfere with the free flow of poultry products in commerce) in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any official establishment in accordance with the requirements under this chapter . . ."[21 U.S.C.§ 467e]

As I mentioned before, Congress has on these and many previous occasions established nationally uniform requirements for labeling, and with good reason. Uniformity in labeling would provide a consistent national approach to addressing food safety issues and communicating effectively with American consumers important information to safeguard their health.

As mentioned previously, S. 3128 focuses on food safety tolerances and warning statements for packaged foods. The bill is designed to ensure that the public is protected and well-informed, without impacting the fundamental food safety laws at the Federal or State level, or affecting any enforcement authority at the State or Federal level. In fact, it is impressive to note just how much actual or *de facto* uniformity already exists between the FDA and the USDA and the State authorities responsible for food safety. The proposed bill does not impact such uniformity at all. For example, the FDA and the State Public Health Officials cooperate through the National Conference on Interstate Milk Shipments to establish milk sanitation standards and procedures for testing and evaluation, thus assuring the safety of the Nation's milk supply. FDA and the States cooperate similarly on seafood safety. Similarly, FSIS cooperates with States that like to conduct their own inspections so that the food safety systems they use are equivalent to those used by the Federal agency.

Another area of cooperation between Federal agencies and their cooperation with State and local food safety authorities is the *Food Code*. The FDA, the Centers for

Disease Control and Prevention (CDC) and the USDA's Food Safety and Inspection Service (FSIS) have all contributed to the *Food Code* to make sure it addresses controls for risk factors that the Government has identified as contributors to outbreaks of food-borne illnesses, and includes actions designed to strengthen the inspection process and improve food safety as product moves from the plant to the consumer. The *Food Code* is updated regularly taking into account current science, emerging food safety issues, and imminent health hazards related to food safety.

The Code provides food control authorities at all levels of government, a

> ". . . scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes). Local, State, tribal, and Federal regulators use the *FDA Food Code* as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy." [http://www.cfsan.fda.gov/dms/foodcode.html#get05, accessed July 24, 2006.]

The Association of Food and Drug Officials (AFDO) has reported that 48 of the 56 States and territories—or 86 percent representing 79 percent of the U.S. population—have adopted their own food codes modeled on the *Food Code*.

In fact, the *Food Code* was, and continues to be, very useful to USDA and its efforts with State food safety authorities to assure a safe food supply, as it no doubt is for FDA. In my opinion there is nothing in proposed S. 3128 that would limit, restrict or compromise the *Food Code* or the State or territorial codes modeled on it. Nor can I see anything that would impact FDA's or USDA's other cooperative food safety programs with the States.

As a trained researcher, I understand how science can be used to determine the true risk posed by food-borne hazards. As Undersecretary, I put this to use, applying the scientific principles of hazard analysis, epidemiology, risk assessment, and statistical sampling in order to develop policies that would reduce the risk of illnesses such as those caused by *E. coli* O157:H7, *Listeria monocytogenes*, among others. As a result, the number of illnesses caused by these pathogens was reduced by 42 percent and 40 percent, respectively, as reported last year by the CDC.

In 2003, application of the scientific principle of risk assessment provided me with the information I needed to develop science-based regulations that would virtually eliminate the risk of exposure to the mad cow disease agent. This assessment, conducted by Harvard University, showed that banning brain and spinal cord from animals older than 30 months from the food supply would present the greatest protection to human health. We quickly developed regulations that banned such materials. A follow-up analysis conducted to determine the effect of our policies showed that indeed, actions we took in 2003 virtually eliminated the risk of exposure to this agent.

At USDA, our scientific experts worked very hard to develop both the underlying data used in risk assessments, incorporating research from the entire scientific community, and the scientific models on which they are based. At the same time, they continue to pursue measures designed to reduce acute and chronic risks to public health. Establishing a uniform national system will put food safety in the hands of the Nation's top food scientists and food safety experts. Just like USDA, the FDA is best positioned to assure that these scientists and experts are brought together, whether they come from Federal Government, State Government, or academia.

As you have no doubt seen, science is not always absolutely certain or complete, and as a result it can be interpreted differently by different people. In the area of food safety a range of different interpretations, leading to different advice or warnings in different States, is obviously problematic. The benefit of a national uniformity approach is that it will bring the best scientists together to address issues of public health significance, thereby helping to determine how best to communicate to consumers in all 50 States.

It is important to point out that simple warning statements may not always be appropriate. Sometimes the science is complex and different population groups may be affected differently than others, and sometimes an ineptly worded warning statement could cause people to avoid certain foods and miss real benefits. This is another reason why it is better to have safety issues thoroughly evaluated on a national basis before warning statements are considered.

Sometimes, obtaining results via the scientific process can take time and all the answers to our questions may not be available as quickly as we want them to be. In these cases, the Federal agencies as well as the States have the authority and the capability to step in and protect the American public. The proposed law includes an Imminent Hazard Authority that would retain the authority of the States' health regulators to take the same protective actions on a local basis.

In other instances, there may be preliminary results that may seem to contradict existing data. In these cases, Federal agencies like FDA and USDA are best positioned to protect all consumers, given their significant resources, experience, and expertise that can be brought to bear in reviewing the entire body of scientific evidence in order to issue food safety regulations that will actually protect public health.

Sometimes a safety issue appears locally, not nationally. But because we have a national food supply, an action taken locally may not help all consumers. If there is a true safety issue, State authorities should bring it to the attention of the Federal agencies so that it can be confirmed and together they can take a national approach to protect all U.S. consumers. The proposed law provides a process to establish national standards in order to protect all consumers, not just some.

Similarly, on occasion, the data will show that a safety issue could truly be local, and advice or a warning should be provided to consumers in that area. The proposed law recognizes this and allows for an exemption from national uniformity when a safety issue is demonstrated to be unique to a specific State.

Again, S. 3128 would provide a national approach for establishing food safety tolerances and warning label requirements that are consistent in all 50 States. This objective is also consistent with activities the U.S. Government has been engaged in for international food standards. As I mentioned in my opening statements, while at USDA one of my responsibilities was to represent the United States as a member Nation of the Codex Alimentarius Commission. In establishing this international organization, the Food and Agriculture Organization, the World Health Organization, and the member countries felt that

> ". . . if all countries harmonized their food laws and adopted internationally agreed standards, such issues would be dealt with naturally. Through harmonization, they envisaged fewer barriers to trade and fewer barriers to trade and freer movement of food products among countries, which would be to the benefit of farmers and their families and would also help to reduce hunger and poverty. [*Understanding the Codex Alimentarius*, Rome, 2005 edition, p. 29]

The Codex, through the agreement of the participating countries, sets standards with the dual purpose to assure consumer safety and to facilitate international trade in food. These standards cover, among other topics, specific foods, food ingredients and additives, food hygiene procedures, and food labeling.

Allow me to quote from a Codex document on the harmonization of food standards internationally to emphasize the value of national uniformity here in the United States:

> With respect to the ever-increasing global market, in particular, the advantages of having universally uniform food standards for the protection of consumers are self-evident. It is not surprising, therefore, that the agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement) both encourage the international harmonization of food Standards. [*Understanding the Codex Alimentarius*, Rome, 2005 edition, Preface]

Codex has also commented on the potentially significant problems that may occur if countries went their separate ways in setting standards and tolerances:

> A principal concern of national governments is that food imported from other countries should be safe and not jeopardize the health of consumers or pose a threat to the health and safety of their animal and plant populations. Consequently, governments of importing countries have introduced mandatory laws and regulations to eliminate or minimize such threats. In the area of food, animal and plant control, these measures could be conducive to the creation of barriers to intercountry food trade. [*Understanding the Codex Alimentarius*, Rome, 2005 edition, p. 29]

It would be ironic for us to be supporting harmonization internationally and then here at home allowing, or even encouraging, individual States to impose their own labeling requirements.

In closing, it is incumbent upon those who are charged with protecting public health to avail themselves of the best data, obtained with the best scientific methodology, and analyzed using sound scientific principles, in order to provide consumers with the most accurate information that can effectively reduce, if not eliminate, risks. Federal agencies like FDA are charged with such a mandate, and are best equipped to implement it on a nationwide basis, in order to protect the health of Americans in every one of our 50 States. In a world in which confusion and misinformation can provide either a false sense of security, or create unwarranted fears

in consumers, uniform tolerances and labeling requirements, as provided by the proposed bill, simply make sense.

Senator BURR. Thank you, Dr. Murano.

Mr. Hubbard.

STATEMENT OF WILLIAM K. HUBBARD, FORMER ASSOCIATE COMMISSIONER FOR POLICY, FOOD AND DRUG ADMINISTRATION, CHAPEL HILL, NC

Mr. HUBBARD. Thank you, Mr. Chairman.

Senator BURR. Push the button, Bill.

Mr. HUBBARD. Thank you, Mr. Chairman. I have submitted written testimony, which I will not, in the interest of time, read. I'll just make a few brief remarks, if I may. I cannot speak formally for the FDA, as you know I have been retired, but I think I can give you some of the viewpoints from the point of view of the FDA. If I slip up and say we in talking about the FDA, please forgive me as old habits die hard.

Uniformity is a word to go and I would like to say more about that. Let me divide my comments up into three points. The premise behind the bill, interpretation of the bill and the effects of the bill and various implementation by the FDA of the bill. First of all, the premise, as you know, is that uniformity does not exist and the conflicts are rampant. The States and the FDA are very good partners and they've worked closely together over the years to develop a relatively seamless food safety enforcement system that I believe works very well. There, in fact, is great consistency now and inconsistencies—they have arisen, I think, have been relatively minor and generally get resolved by scientists working out the issues. In fact, in my 20 years of working on this issue, I've never had a consumer tell me he was confused by State labels that differ from Federal or I've never gotten a letter. The industry has often said that and I think that there are specific examples of where particular companies have had a problem and we heard one today but there has been very little evidence of a negative impact, is my view. I served on the Regan panel that looked extensively at this. I think they, in fact, weren't assigned the kind of inconsistency the industry alleged and after a very lengthy study, concluded that there just wasn't the sort of impact that was being alleged. That was repeated again in the Bush administration, repeated again in the Clinton administration. There has just been no adverse impact at the level that I think people often say. And the conclusion of all of these public officials over the years is that there has not been an adverse effect, impact and the action should be taken only if a serious problem does emerge. So to some extent, Mr. Chairman, I feel that this is a bill with a solution in search of a problem.

Only—pushed the bill into effect so I will not at all go into the provisions of the bill. There is voluminous documentation that I hope you've not attempted to read about all of these points that have been made today, between the industry and the opposing groups. They are obviously opposed. I think the fact that you have a consensus among State Attorneys General, Food and Drug officials in the States, consumer interest groups, that this will have very negative impacts. I think it is something to listen to. But I am particularly concerned that there are vast differences of opinion

about what the language even does or what it means and that—intent of Congress before this bill proceeds. Please don't raise this ambiguity that clearly exists between the competing parties. Nail all of the FDA scientists or the courts. I would beg you to look very closely at the differences of opinion and try to get those resolved because they are diametrically opposed and someone is right or someone is wrong or there is truth in the middle and I don't know which is which.

Last, I don't believe the FDA can implement this bill, Mr. Chairman. The food program of the FDA has undergone tremendous budget cuts in recent years. They've gone from being able to do 35,000 inspections of food facilities in 1972 to perhaps 5,000 today. When Proposition 65 was enacted, there were perhaps 100,000 imports of food coming to the United States. There will soon be 10 million coming into the United States. You took the lead on a very important bioterrorism bill that included a registration provision. FDA now has 200,000 registrants domestically and perhaps another 100,000 foreign. That's 300,000 food firms that they should be looking at and they can look at 5,000 a year. So to put on that system an additional burden of taking on State responsibilities, I am very concerned about. The FDA headquarters' staff that want to do this work, if this bill passes, has been reduced by 10 percent in just the last 2 years and is going down further. Overall, the food program at FDA, which includes—has lost hundreds of people since 1903 alone, at a time in which the Congress is saying worry more about bioterrorism. Be more active. I am very concerned about that. The program is weaker than at any time since the 1960s and the President's budget commands FDA to further reduce the food safety effort and put it over into terrorism, a worthy goal. But Dr. Murano mentions that the meat program has preemption. I think if the FDA got nine times more staff, as USDA does, including stackers, I think they would be very willing to say to you, we can do it now. But I don't think that's in the cards. When you've got an agency that has such pervasive regulatory influence over a problem such as the meat program or when you take a food label in the FDA, preemption, I believe, is appropriate because you have an area where the States will not inflate and the Federal Government came in to no votes and took control and I think that is a good idea. In the case of food safety, the States were doing this long before the FDA was created.

Last, I'll point out this petition process. Mr. Hutt may be right but certainly the Congressional Budget Office says there will be many petitions. I must tell you that the call petition process of the FDA is broken. They have a backlog of over 200 petitions now. Last year, they were able to get nine done. The backlog actually grows every year. If S. 3128 passes, the FDA can't implement it, Mr. Chairman. They cannot do it. If the CEO is correct and they'll get 200 petitions, virtually the entire food headquarters staff will drop everything else and do nothing but review these petitions. If the food industry is right, that there will be 300 of these petitions, they will drop everything and do nothing but this and still fail and of course, this is not a subjective determination. I can tell you objectively, they will fail massively in implementing a bill like this or

they will be forced to simply tell you no, we can't do it and to stand there and do nothing.

Either way, that is a very bad outcome for the public health and for the agency. So, in sum, Mr. Chairman, while consistency is a worthy goal, I think the bill appears to be unjustified by the current circumstances. It is lacking clarity about its extent and effects as we see from these differing opinions and I truly believe, Mr. Chairman, that it is impossible to regionally implement by the FDA under current circumstances and current resource levels. Thank you for your attention.

[The prepared statement of Mr. Hubbard follows:]

PREPARED STATEMENT OF WILLIAM K. HUBBARD

Thank you, Mr. Chairman, for inviting me to present views today on S. 3128, The National Uniformity for Food Act of 2006. I am William K. Hubbard, and until recently was an official of the Food and Drug Administration. I retired in 2005 after 33 years of Federal service, the last 14 of which were as an Associate Commissioner at the FDA. The issue of national uniformity for food safety laws was one in which I was involved repeatedly over the years, as successive Presidential Administrations sought FDA advice when they examined this issue.

Let me begin by observing that protecting citizens from unsafe food is a quintessential governmental function. Even before the creation of the United States, individual States (then colonies) were establishing laws protecting the public from hazards that could be intentionally or mistakenly placed in food sold in the marketplace. That role grew as commerce in food expanded, until, a century ago, in 1906, Congress determined that a Federal food safety role should be established as well, in the forms we know today as the Food and Drug Administration and the Agriculture Department's meat inspection program. With this addition of a Federal food safety structure, State and Federal food safety officials have become closely allied partners in protecting our citizens from unsafe food—sharing scientific data about potential risks to foods, cooperating on inspecting food manufacturing facilities, responding to outbreaks of foodborne illness, removing hazardous food from the market, and devising similar regulatory structures for overseeing the safety of the food supply.

Together, State and Federal health officials have developed a modern, science-based infrastructure that, along with the hard work and dedication to high standards of food producers, has given Americans a food supply of unparalleled abundance, affordability, quality, nutritional variety, and safety. There is no doubt that this system has served the Nation well, and that State and Federal food safety programs have not only co-existed, but have evolved to protect our citizens using essentially the same scientific standards, regulatory mechanisms and statutory constructs. Indeed, most States, in an effort to harmonize with the judgment of Congress, have enacted food and drug laws identical or quite similar to the provisions of the Food, Drug and Cosmetic Act (the principal source of FDA's food safety authority). There have, over the years, been occasional instances in which FDA and State determination about product safety (and their concomitant public warnings) have differed. But those instances have been relatively rare, and generally have been worked out amicably among the scientists involved. There certainly has not been the sort of mass conflict and confusion that would warrant a fundamental undermining of the strong Federal/State partnership that currently exists. And the States have served the valuable function at times of being the first to identify a health risk and, through their actions to protect their own citizens, have alerted the FDA, so that it could extend such protections nationally.

The issue before the committee today, of course, is whether Congress should preempt the laws of the States, in deference to the regulatory role of the FDA. There are certainly examples where Congress has done so. For example, USDA has meat inspectors in every slaughterhouse while that facility is processing meat, and a separate State function would be redundant. When Congress required all foods to bear nutrition labeling in 1990, it judged that a single Federal standard was appropriate, as the States had no separate nutritional labeling requirements at that time and FDA was authorized to create a strong, enforceable national standard. Most recently, Congress established standards for labeling the 8 major food allergens, and gave those preemptive effect.

However, in the case of contaminants in the food supply, Congress has never done so, and the circumstances are much different. The States' role in protecting against adulterated foods long pre-dates the creation of the FDA, and the FDA's ability to adequately oversee such potential threats to the food supply is inadequate today and growing weaker each year. So it is ironic that at this time Congress would be considering legislation that would remove a valuable food safety tool, and perhaps provide incentives to further weaken FDA. Let me explain the basis for those conclusions.

In 1972, FDA's food program constituted approximately one-half of the FDA's efforts, in terms of the agency's resource allocation. Today, it is about one-quarter, even though FDA has little more staff than it had in the 1970s. Likewise, 34 years ago, FDA conducted 35,000 inspections of food manufacturing facilities. This year, they will do perhaps 5,000. The volume of food imports from overseas is approaching 10 million per year, and the number that FDA inspectors physically examine is in the single digit thousands—making it virtually certain that any given food shipment will enter the United States with no FDA inspection. I could provide many more similar statistics, all of which paint a picture of an FDA regulatory structure that is under-resourced, under-staffed, and essentially incapable of meeting the growing demands to oversee food production, food additives, cosmetics, dietary supplements, nutrition labeling, foods produced from biotechnology, foodborne disease outbreaks, dangerous new pathogens that infect food, pesticides, and the many other responsibilities of that program. And, most recently, the President has proposed diverting traditional food safety resources toward protecting the Nation against terrorism threats to the food supply—a worthy effort, but one that will force FDA to rely even more on State food safety efforts.

Yet S. 3128, in the name of "uniformity," would remove FDA's partner in protecting against food adulteration, and throw even more responsibilities at the agency—in effect, moving problem solving from a source that has proven to be an effective complement to Federal authorities to one that cannot accept more responsibility and will thus be ineffective. Further, because the States' ability to deter adulterated foods would be weakened, and with FDA the only alternative, producers of food about which safety concerns have been raised would have incentives to maintain a weak FDA.

FDA's resource shortfalls beg for a focus on the mechanism embodied in S. 3128 to permit the States to act against adulterated food. The bill would create a petition process whereby a State wishing to maintain an existing standard, or create a new one, would petition FDA either for an exemption from preemption or to create a uniform, national standard. This provision is simply impracticable. First, FDA has shown demonstrably that resource constraints prevent it from processing the flow of citizen petitions that it *currently* receives. In fact, the agency slips further behind each year in its handling of citizen petitions; there is now a backlog of over 200 citizen petitions in the queue for response in the food program alone, many dating back several years; and that program managed to respond to only 9 petitions in all of 2005. Adding yet another flood of petitions to this already-overwhelmed system would merely build in additional failure.

But I can describe an even more dismal prospect regarding FDA's ability to respond to the petitions envisioned by S. 3128. The Congressional Budget Office assumes that FDA will receive at least 200 State petitions during the first year after the bill's enactment, and that it will cost $400,000 to review each petition. So FDA would be required to spend $80 million to answer those petitions—for no discernible public health gain. Mr. Chairman, the *entire* budget for salaries and expenses of the scientists in FDA's headquarters food program is under $100 million, so this bill, if enacted, would essentially mean that the food program would need to cease all other functions except for the review of State petitions, if it were to make a sincere effort to comply with Congress's charge. If the industry's prediction, that FDA would receive over 300 petitions from California alone, is correct, the effort to address the petitions would require more resources than the agency's food program possesses, meaning that FDA could not accomplish the goal even if ALL food headquarters staff were assigned only to petition review. Or, if FDA chose not to engage in this decimation of the agency's food safety programs, it could be forced to basically ignore the statute, thus setting the stage for great confusion, potentially endless lawsuits, and a vacuum in both State and Federal protection against food adulterants.

I would add that it is very unclear what the bill preempts. The dispute between the food industry and others—whether the State Attorneys General, State food safety officials, or the Center for Science in the Public Interest—about the number of laws preempted is a good indicator of that ambiguity. There is a very real question whether most State enforcement actions will be met with a rejoinder that the action is preempted by this bill. Resolving such disputes through the courts will add sig-

nificantly to State enforcement costs and inevitably reduce the volume of enforcement the States can undertake. Obviously, FDA will not have resources to take up any slack.

The bill does not give preemptive effect only to requirements imposed by FDA by regulation. Instead, it appears to completely eliminate State safety notifications, whether the FDA has acted or not. In terms of enforcing State safety standards themselves, the bill starts at the top, broadly preempting State safety requirements unless they are identical to Federal requirements. It then allows States to enforce only those State requirements that are identical to existing FDA requirements, or even guidances, which are non-binding FDA advisories to industry. Localities, such as New York City, are apparently preempted from enforcing their own requirements. While preemption focused on circumstances when FDA has made a well-reasoned determination can make sense, it is difficult to see a problem that supports such a broad preemption. Further, the bill would not require that FDA step in (even if it had the resources) and replace State and local laws that might be necessary, further exacerbating the vacuum in safety oversight that the bill would create.

In conclusion, Mr. Chairman, when a well resourced FDA has been able to examine a potential health risk in food, bringing to bear the best scientific data and analytical ability, and resulting in the establishment of a reasoned determination—whether to bless a substance's safety, to require safety warnings to consumers, or to ban the substance—it would be reasonable to consider whether that determination should be dispositive for the entire Nation, and whether States should second guess such a carefully reasoned disposition. However, until and unless FDA is given the resources and ability to deal with any and all questions about the safety of food constituents, I believe that the existing Federal/State cooperative relationship has passed the test of time in its effectiveness and ability to work together to protect our citizenry. Not only does the current system work well, but there is little evidence of a problem now that would justify the broad preemption envisioned by the bill, and no reason to believe that there will be a problem in the future. The vast majority of State attorneys general agree with that conclusion, as do the States' food and drug officials, and virtually all consumer interest groups. That practical consensus of opposition to S. 3128 should be seen as a significant cautionary message about this bill. Adding in FDA's absolute inability to implement this bill in any reasonable fashion should raise those caution flags even higher.

Thank you for giving me the opportunity to comment on this important matter.

Senator BURR. Bill, thank you. It is the intent of the Chair to recognize the Senator from Georgia first for questions but let me say, from 1995 to 1997, the FDA, as we worked on FDA modernization, said we can't absorb that type of change. Well, we did it and we went from, I believe, eight applications approved in 1997 to 81 in 1998. What we found was that sometimes when you find a system that is broken, our responsibility is to fix it. I don't think that is a suggestion that we didn't take on FDA modernization or that the FDA shouldn't exercise what is their mission and their responsibility as it relates to food safety. I think that if there is one individual and certainly we have one today, it's probably fairly easy for Mr. Stadtlander to say, "You know, it's not worth selling cereal in California. I'm just going to pull the damn thing off the shelf." But it's not just losing $70,000–$80,000 worth of revenue. In his case, it is a multi-million dollar lawsuit that he has to defend, so to suggest that there is not an impact, I think, is to ignore what's going on. We've got ample time with the few members that are here to explore a number of different areas and I'll take the opportunity to do that with all of you. But I do want to recognize the Senator from Georgia first, for a line of questions.

Senator ISAKSON. Well, thank you, Senator Burr and I apologize to the panelists for missing your live testimony but I had to go cast a vote in the Small Business committee. My experience in the private sector is not with the processing of food. I was in the construction and housing industry. By California standards, caused problematic issues even in that because California would have a stand-

ard, for example, in terms of suspended particles in the air and you'd get a lawsuit going and somebody would go find the California standard and you'd get sued in Georgia for not meeting a California standard even though it didn't apply because it was by that State. So it cost me and I got involved in one of those one time, it caused me to think of a few things and Mr. Hutt, again I apologize. I didn't hear your testimony but you're an attorney and I'm assuming that when you have a variety of different standards or an inconsistency of standards nationwide, that the practical effect of those inconsistencies for the mass producer of almost any product ends up being a lot of litigation. Is that correct or am I wrong?

Mr. HUTT. You have only two options. Either you meet the toughest standard in the entire Nation or yes, you are subject to numerous lawsuits.

Senator ISAKSON. Mr. Stadtlander, I read part of your testimony with regard to the product, Wheatena?

Mr. STADTLANDER. Yes, right.

Senator ISAKSON. OK. And you produce your product uniformly, I guess, at a production facility, is that correct?

Mr. STADTLANDER. Yes, sir.

Senator ISAKSON. So, in the case of this product, because of the Acrylamide or whatever that element was, you then, because of the California standard, just not sell in California? Or do you have to go into a separate processing facility or labeling facility? Tell me how you deal with that.

Mr. STADTLANDER. Wheatena, as well as 40 percent of the food that people in this room consume, would have Acrylamide as a byproduct, so it is impossible to sell these products without having Acrylamide because it is a byproduct of toasting. Otherwise, you'd be eating raw wheat or oats. As soon as you cook them—and it can be cooked at home, it doesn't need to be done by a manufacturer—you end up with Acrylamide. So the first answer to your question, it is impossible for the vast majority, 40 percent of what you're eating, to remove Acrylamide. That's the first thing. So the options are warning people on 40 percent of the food supply, that it may cause cancer, negating or confusing consumers when the Federal Government is saying I may reduce the risk of cancer because of high fiber content. So this package, to conform to California law, would say, may reduce the risk of cancer, Federal law and may cause cancer, California law. That's what I would be selling on the marketplace. It doesn't work that way. The other thing is, in terms of California saying this works, the 40 percent of the food supply that so-called may cause cancer because of Acrylamide, which is strictly California—the rest of the world has reviewed this and no one is coming to that conclusion of warning people on food supply. You end up with suits. So the suit I'm involved in right now, is the law firm says, we're suing because you didn't warn consumers. If you give me $250,000, I'll go away. I'm saying I'm not doing it. I'm selling a healthy product so California is still to be resolved because the 40 percent of the food supply that has Acrylamide is not warning consumers today that it may cause cancer. That's why the court is backed up with suits because manufacturers are saying, I can't remove it and I'm not going to label it or I can't label it strictly for

the State of California and 49 other States are going to have a cancer warning on my product. Manufacturers are not going to do that.

Senator ISAKSON. So Acrylamide is a natural occurring element we cannot control?

Mr. STADTLANDER. Exactly right, including if you toasted something at home. So it's not just manufacturers. I'm saying what you'd be doing is not selling ovens any more because you create Acrylamide anytime you'd put a starch product in your cooking facility.

Mr. HUTT. And that's not the only instance of naturally occurring substances that the California Proposition 65 applies to. There are suits on mercury in fish, which is naturally occurring, the lead in calcium, which is naturally occurring, the cancer-causing substances every time you grill a steak, charcoal broiled steak, every one in the country produces carcinogens and there are lawsuits on that. There is no end to this type of litigation in California.

Senator ISAKSON. Well, that was the reason. And again, I'm sorry I missed both of your testimony but the reason I brought the question up was because in my private life, my experience is that when you have a lack of uniformity, all you do is open up people who are doing good things in honorable businesses to be in court all the time, spending their money trying to defend something. But in the case of this, you couldn't have had any control over it anyway. Dr. Murano, I'm sorry I missed your testimony but which side do you come down on as the distinguished Head of the College of Agriculture, I think that is correct.

Dr. MURANO. Yes, sir. Well, as a scientist I have to tell you that you've got to use science in order to make the best decisions possible when it comes to food safety, for sure and to simply say that because there is a certain substance or ingredient in a food that may cause adverse effects, that that warrants a label, is irresponsible because as I think the gentleman at the other table said, there are so many foods that contain naturally occurring substances that, given enough of a dose, perhaps will make an adverse effect but yet the doses that we're exposed to, science has not shown to cause any adverse effect. It makes absolutely no sense and frankly affects the credibility of whatever agency requires such a label to be put on there because consumers will soon realize that if there is a warning on everything, because everything basically has a component that potentially could be harmful if consumed in high enough levels, then it ceases to have an impact. The credibility of the agency is compromised and frankly, as I was mentioning in my testimony, on the international arena, we have to abide by good, sound science because if we don't, we're surely prone to be accused by other countries of setting up false trade barriers because we're not basing them on science.

Senator ISAKSON. Thank you and I know my time is up but I did want to ask one question, Mr. Hubbard. Mr. Hubbard, do you think the FDA does a good job with the drug industry?

Mr. HUBBARD. Actually I do. I think it is a very good job. Congress has given the FDA pervasive regulatory authority over drugs to oversee their testing, their approval and the manufacturing and marketing. In fact, when California has attempted to step into the

drug area, the FDA has been assertive in saying, "Do not put a warning label on these products because we know these products better than you do." And we have tangled with them and we have prevailed. The problem here is that on the third side, you have a much less pervasive authority, much weaker program, much less information and the FDA has relied traditionally upon the States to be a strong partner in protecting the public against unsafe foods.

Senator ISAKSON. But I would assume that if the FDA had the authority over food like it has over drugs, they could do a good job.

Mr. HUBBARD. Whenever we have made a sound determination based on good science, about the safety of a product, whether to leave it on the market, take it off the market or label it, we have stood by that and we have told States, do not come up with a different answer. We have brought the science to bear and made the decisions and I said, we've tangle with California on this and I think we've prevailed. Generally we work it out in a scientist to scientist fashion. A few times we literally had to threaten them but those are occasions when FDA had the scientific leadership on the issue. That was not necessarily the case here. If I could comment on the Acrylamide, if I may. Acrylamide is really an example of both points of view. Acrylamide came as a surprise to the whole world for its safety risk in 2002. People have been screaming to understand what it means and the fact that the consensus said high levels of Acrylamide might cause cancer. However, it is in many, many of our foods and FDA has been trying to say to the industry, let's get it out but give them time. Let's don't scare people that there is an immediate risk. California has done a similar thing. They have stayed their rulemaking to give folks the time to understand that. Mr. Stadtlander is a victim of thing called a bounty hunter, which is a human provision they have in California which a trial lawyer can go to court on its own. I certainly hope personally that a judge will say, to the various food safety authorities who are looking at this, Mr. Stadtlander should not be punished because it is in many, many foods and you should not be singled out because his product has Acrylamide when so many others do. I will say, however, California put Acrylamide on their cancer warning list in the late 1980s so they kind of got there first and he, I think, started marketing his product many years later. But again, I don't want to defend the bounty hunter provision. There are some potential issues there that I think would be fair for you to look at.

Senator ISAKSON. You ought to send that testimony to your lawyer. I think it will help. Thank you, Mr. Chairman.

Senator BURR. I'm not so sure anything will help short of the amount of money you're going to have to pay your lawyer to hopefully get to a reasonable judge on the bench that makes a determination this shouldn't go forward. Unfortunately at the end of the day, it's going to cost you a lot of money. Without objection, I would ask that the entire testimonies of all of our witnesses be put into the record. It is my intent to share whatever time with my colleague from Georgia and if we're joined by any other member, to also include them. And I'm going to attempt to work my way down the line, if I can, and try to help enlighten us on not only what the current law is, what the language in this bill says, and how it affects current law, be it Proposition 65 or anything else. Let me ask

you, Mr. Stadtlander, has any other State raised an issue, other than California, on Wheatena?

Mr. STADTLANDER. No.

Senator BURR. Would it be possible to make a Wheatena box with a warning label just for California sales or does that, over and above the fact that you'd be saying contradictory things—lessen the chance of cancer and contributes to cancer—what does that challenge you to do in your distribution process?

Mr. STADTLANDER. From a commercial standpoint, it is virtually impossible if you're selling—basically, I'm selling in 50 different States. For me to have a separate label specifically for California, the chains that I sell through, people like Kroger, et cetera, have warehouses where they pull from for different States. They have diverters that buy product and move it across the country, so to have a label specifically for California would be, I don't want to say impossible, but extremely difficult, in the same way that chains, like the Krogers of the world, who normally would take a product in and distribute to all Krogers, so that would be one challenge. If you had a separate product for the State of California, and they ordered that separately, you would then still have confusion because what you would need is, the chains that specifically say this store is getting this product and that store is not going to get this product. So from a practical standpoint, it is impractical to virtually impossible to control that.

Senator BURR. You actually described a process though, where a stock person in a chain grocery store could, in fact, have two boxes, one marked for California and one marked for the other 49. A minimum wage worker may make a mistake and put on the shelves in California through a distribution truck, a box not labeled for California and you as a company would then be liable not by a bounty hunter but by the State, once the State promulgated those rules, even if you were well-intentioned to do that, that could happen to you?

Mr. STADTLANDER. Yes.

Senator BURR. Mr. Hutt, is Mr. Stadtlander alone?

Mr. HUTT. He is not alone.

Senator BURR. The only one in the country that has got this problem?

Mr. HUTT. The entire food industry is endangered here because as he pointed out, you can't eliminate, based on current science, Acrylamide from food and unfortunately, if Bill Hubbard were running California, we would have no problem but he's not. And the people who he deals—or used to deal with in the California government agency, are not the people who are running this show. It's the attorney general who has political ambitions to go higher and it's the bounty hunters who have an enormous economic stake here. They've been earning millions of dollars based on this litigation. If you take a look at all the food products involved, let's talk about mercury in fish, which as I already pointed out, is naturally occurring.

Senator BURR. Could you also, as you talk about mercury in fish, take us through the most current court case that manufacturers challenged and won?

Mr. HUTT. I'd be happy to do that. The court in California turned back the case that was brought again by the State—not by a bounty hunter but by the State of California. It was masterminded by the office of the Attorney General and the court said on three separate grounds, that the State of California's mercury level for fish was wrong. First they said it was not backed up by sound science. Second, they said—and in fact, what they said was that the State scientific witnesses had no scientific credibility. It was a remarkable opinion in that respect. Second, they said that deference should be given, under the Doctrine of Primary Jurisdiction, to the views of the FDA because the FDA thoroughly opposed the way that California was trying to bring that case. And finally, they said that the mercury was naturally occurring. It wasn't put in there by humans. Mercury is prevalent throughout the environment and thus, for those three reasons, the court threw out the California case. Now, the same might happen with Acrylamide. But Bill is going to have to pay millions of dollars if he wants to litigate that case in California. The same, presumably I hope would happen, with regard to benzthanrozine and other carcinogens in steak, in chicken and in any other cooked meat, we don't need a warning on every piece of meat in California. That is not—I'm sure Dr. Murano, you would agree with that, from your experience at USDA. So we're talking about the entire food industry being at risk here. If Bill Hubbard could negotiate with the State officials on a science basis, none of this would have occurred.

Senator BURR. Do you think the lawsuits that truly do come out of Prop 65 have peaked or are we going to see a continuation of a climb in lawsuits?

Mr. HUTT. Well, I'm afraid that my profession, other members of my profession—I'm not a trial lawyer—have found a gold mine in California and I don't think they will stop.

Senator BURR. Senator Feinstein, in her comments, talked about bioterrorism. Would S. 3128 impair the ability of a State to take action in the case of food bioterrorism, in your estimation, or any other food safety emergency?

Mr. HUTT. There are two provisions in the law that make it clear that it would not, in any way, impede the State. The first provision says that the bill cannot go into effect at all unless the Department of Homeland Security certifies to the Department of Health and Human Services, that there would be no impairment of bioterrorism protection. That's the first provision. The second one authorizes any State to act in the event of an emergency, an imminent hazard to health so that bioterrorism is covered fully in this legislation.

Senator BURR. One additional question, if I could. The Center for Science in the Public Interest released a study that concluded that nearly 200 State laws would be affected by the National Uniformity legislation. Do you agree with their conclusions?

Mr. HUTT. Well, their conclusions, as I testified earlier, are just dead wrong. They do not read the legislation. For example, the sanitation—I'll just give one example—the sanitation provisions of the Federal Food, Drug and Cosmetic Act under which restaurants and shellfish and milk—those three are regulated. Those are not covered by national uniformity but CSPI keeps saying, knowing

that it is untrue, that they are covered. Even if you take a look, for example, at the history of these three types of regulatory programs, the Milk Program that was begun 1923 by the Public Health Service, the National Shellfish Program that started in 1925 and the third one, the restaurants, in 1935. They are authorized under the Public Health Service Act. They are not even conducted under the Federal Food, Drug and Cosmetic Act and they are not subject in any way, shape or manner, to any form of national uniformity, under this legislation. The legislative history is clear and indeed, the statute or the bill, is clear. I agree with Bill Hubbard. The legislation should be clear. I don't know how it could be made any clearer.

Senator BURR. Thank you. Thank you for that and I think we all agree that we should require more people to actually read the legislation before they comment on the contents and the effects of the legislation. Dr. Murano, has uniform regulation of products under the USDA been a good thing?

Dr. MURANO. It has been a great thing. It's been great when we were faced with outbreaks of food-borne illness, the E. coli in undercooked hamburger meat, for example, because we were able to very, very quickly, as we developed policies that could be enacted nationwide without any obstacles to really getting that implemented as quickly as one could. When we, for example, implemented some new policies regarding ways to avoid exposure to the Mad Cow Disease agent and we put policy that removed certain high-risk materials from the food supply, again having that authority to do it nationwide by virtue of one piece of regulation, gave us a tremendous advantage because we were able to not only protect the public's health, which is uppermost in our consideration but also had the credibility worldwide that what we were doing was going to be implemented nationwide and was going to be backed up and it was backed up by scientific studies, risk assessments that were conducted by Harvard University that had been shown, now most recently by a further study of the impact of our regulation to have been the most significant thing we could have done to prevent exposure to the Mad Cow Disease agent and protect the public's health.

Senator BURR. Do you feel that there is enough evidence-based science behind the food-related activities in California's Proposition 65?

Dr. MURANO. If we take, for example, the Acrylamide question, since that is the one that affects the discussion here this morning as a good example, there is evidence certainly that Acrylamide may cause cancer. It has been shown to do so in laboratory animals. But the levels at which Acrylamide is naturally found in all the many foods that have been mentioned already, including good coffee by the way, so if you had coffee this morning, you consumed a little bit of Acrylamide but what is a little bit? A little bit, we're talking about microgram amounts and even less than that and the scientific evidence is just not there to support any claim of that being a hazard to human health at all whatsoever. So the question here is, if you have a substance in a food, naturally occurring or otherwise—what science does for us is it permits us to figure out what is the dose, the exposure level that will cause a detrimental effect

and if that exposure level is not met because the amounts are so well below that tolerance level, then it is not a hazard to human health and it is misinformation to put a warning on a product simply because there is the presence of a certain amount. If it is below a tolerance level, if it is below a level that has been shown to cause deleterious effects, then it is not a hazard, by definition, by scientific definition.

Mr. Chairman, I just wanted to add something somewhat unrelated to your question—and I feel compelled to do so because my colleague is formally from FDA as I am formally with the USDA—I wanted to point out when I was Undersecretary, I worked very closely with the Commissioner of FDA to make sure that if the FDA needed help or assistance—for example, in conducting inspections or any other function that our inspection force could help them with—they could deputize our inspectors to do so. There are Federal agencies that work for the good of public health and we work together and we have a Memorandum of Understanding and other agreements in order to be able to maximize the resources that we are both given. So I feel certain that if this legislation becomes law that the resources of the Federal Government would be put to use and in fact, if FDA needed assistance from other agencies, those agencies would certainly assist them.

Mr. HUBBARD. Mr. Chairman, if it is not tomorrow, in fact, Mr. Burr's bioterrorism bill of a couple years ago did in fact do that. It gave FDA the authority to deputize and that is working very well and I think everyone is appreciative of your leadership on that.

Senator BURR. Thank you for that. I'm curious and I should know the answer to this but all of the products that might resemble yours, from the standpoint of makeup and crackers and other things, do they all have to have that warning or is there a threshold that you hit from the standpoint of what California set as a tolerance, that they haven't?

Mr. STADTLANDER. There is no threshold in California at this point in time. So any amount.

Senator BURR. So technically—and I trust you—you are a microbiologist. You've got Acrylamide in coffee. Does coffee have to have a label in California that says may cause cancer?

Mr. HUTT. Yes.

Senator BURR. All coffee does?

Mr. HUTT. Yes.

Senator BURR. Does wine have any in it?

[Laughter]

Mr. HUTT. No, but I will—I'm glad you brought up that issue because of the concern expressed by the two Senators from California about lead in candy and various other—pottery, etcetera. What they failed to point out is that California is the only State that has a law that explicitly allows lead foil for closures of wine.

Senator BURR. Interesting. At this time, I ask unanimous consent. I'm going to enter into the record a chart that shows for 2005, the Prop 65 settlement dollars paid in private cases, a total of $56 million and the breakout of the attorney fees from that, which is $38 million. I think it is only appropriate to have that in the record, matched with civil penalties, $5,300,000.

[The previously referred to information follows:]

Proposition 65 Benefits Private Attorneys, Not the Public

Year	Prop. 65 settlement dollars paid in private cases (incl. attorneys' fees)	Attorneys' fees	Percent of settlement going to attorneys' fees* [In percent]	Civil penalties
2000	$9,030,974	$5,675,457	63%	$590,712
2001	7,584,034	4,704,800	62	559,875
2002	6,443,808	3,676,455	57	325,015
2003	8,090,248	5,290,940	65	566,300
2004	15,385,638	12,656,669	82	1,857,508
2005	9,892,989	6,145,768	62	1,414,800
6-year Total	$56,427,691	$38,150,089		$5,314,210
6-year Average	$9,404,615	$6,358,348	65%	$885,702

*In addition to attorneys' fees, ''Prop. 65 settlement dollars paid'' includes additional payments that go directly to the plaintiffs or are steered to organizations that work in conjunction with plaintiffs.

SOURCE: Office of The California Attorney General, data available at http://ag.ca.gov/prop65/index.htm.

Senator BURR. Bill, I sort of feel like you're holding up the whole end of the table.

Mr. HUBBARD. Thank you.

Senator BURR. I should say thank you for your long service and I think over the last decade, there has been a partnership between Congress and the FDA to move forward and to make advances. You and I probably still have a long way to go and just under the mission of the FDA, the challenge is huge. I'm not sure that we all fully understand and appreciate what this global economy is going to produce to us and we had it first on drugs as we talked about harmonization with the EU and when we looked at the EU, which walked out and said, "We'll just accept everybody's standard." When we went to harmonize with the EU and we saw that they accepted the Italian standard. We looked at it and said there is no way that we can operate within that system—we found that there is a great need for us to uphold that solid foot-in-the-ground gold standard that we had. I understand your concerns about staffing and I understand your concerns about budgets. Were the FDA to be charged with this and we addressed those staffing and budgetary issues, any question in your mind as to whether the FDA could do this job?

Mr. HUBBARD. Well, as I said, Mr. Chairman, I believe this is a reasonable approach and that had the FDA had the scientific wherewithal to make a judgment on food or drug or anything else and could bring the best science to bear, they would make a reasonable decision. I believe it is appropriate for the FDA to then say to the States, don't do anything different. You can require the same label that FDA or warning or whatever the FDA has decided and then you get the compliment of the States acting and I think that's your goal. I think the problem is that in some areas of regulation, FDA had that but, in this area, it does not and it is unlikely to get it anytime soon and the States have been able to fill the back in many ways and do some important things. Certainly the California experience has been challenging, shall I say, for industry and the FDA. But, I surely would hope that you wouldn't necessarily take

a nationwide approach to one particular problem that perhaps has some particular eccentricities about it in California.

Senator BURR. I think you stated it very clearly in the beginning of your written statement when you said, and I quote, "Most States have enacted food and drug laws identical or quite similar to the provisions of the Food, Drug, and Cosmetic Act." Later you said that the bill is unclear in what it creates. Now, I'm sort of with you, Mr. Hutt and its not because I'm the author. It's because I've had an opportunity to read it and read it and read it. And when I do, I see that in the bill, if State food laws are identical in language or meaning to Federal food laws, the State food law remains in effect. I don't see how it could be any clearer than that. You acknowledged in your written testimony, you know, States are out doing this. Then, there is patchwork, there is a lack of consistency, some do, some don't. The real basis that this bill came from was not to penalize States that have actually been out there doing this but if the Federal standard was the same in language or in meaning, the State could feel confident that their language, in fact, stayed in effect.

Mr. HUBBARD. May I comment?

Senator BURR. Sure.

Mr. HUBBARD. I would never question Mr. Hutt's legal opinions. It is rumored at the FDA that he was there to change the diapers of the first FDA Commissioner and so I would not question what he is telling you at all, but the fact that the majority of attorneys general, the Food and Drug officials in the States and so many consumer groups have also looked at this with their legal expertise, their statutory and legislative expertise, and disagreed. I guess I'm simply saying to you that there needs to be some effort to understand whether they are right or wrong and then perhaps amend your bill accordingly because someone is right or wrong here and I will not pretend to tell you who that someone is.

Senator BURR. I can only share with you that as the author, it is my intent that it be applied exactly like I read it. I have no reason to dislike lawyers but they go through extensive training to look at a sentence and figure out if it really means something different and then lie. I think Mr. Hutt has had a long experience dealing with FDA, you're exactly right. He will outlive both of us from a standpoint of his tenure.

Mr. HUTT. Could I, Mr. Chairman, give two examples of the misinterpretation and of this legislation?

Senator BURR. Sure.

Mr. HUTT. Recently CSPI has added two more types of State laws that they saw would be drastically changed and indeed, in effect, repealed. The first deals with State laws that require messages to put at bars, warning pregnant women not to consume alcoholic beverages. In 1976, the U.S. District Court held that FDA has no authority whatsoever with regard to the labeling and advertising of alcoholic beverages. So FDA—that all occurs under the Federal Alcohol Act. It does not occur under the Federal Food, Drug and Cosmetic Act and thus, this legislation has absolutely no impact at all. The FDA has no jurisdiction in this area. The second set of laws that they say would be affected deal with State and local laws that govern when food can be sold, particularly snacks

and soft drinks, can be sold in schools. Those laws are, as Dr. Murano knows, solely the jurisdiction of USDA and they are not in any way affected by the Federal Food, Drug and Cosmetic Act. So all of this misinformation is being put out there. People are becoming States—are therefore doing what Bill Hubbard said, "they're expressing concern for absolutely false reasons."

Senator BURR. Trust me when I tell you, some of us have been the subject of media accounts that would—the basis for being against the bill was because of what we did to Meat and Poultry. Again, as you referenced earlier, Meat and Poultry is not included in this and I would say this for all of you. What we've found is that as we've been contacted by AGs, as we've been contacted by State Ag Commissioners who expressed concerns, we said go back and read the bill and then call us back and tell us if you've got a problem and in many cases, not all—but in many cases, individuals have changed their opinion of the legislation because in fact, the consumer groups basically put out a notice that said, "this is a bad bill." Those that were being kind just said it was a bad bill. They didn't use the host of things that were inaccurate and I think as reasonable people have gone back and read it, they found that to be the case. I'm going to ask you one more question, Mr. Hubbard. You mentioned that State enforcement actions may be pre-empted in this bill. I wanted to point out page 5, lines 15–23 of the bill, affirm that the State enforcement actions are not impacted by the bill, including notification, disclosure, inspection, mandatory recall, embargo, and detention orders. This is for my own good. Tell me where I am unclear.

Mr. HUBBARD. Well, I think I was reflecting the predominant opinion by the Attorneys General so if I'm wrong, let's go back and look at what their concerns are.

Senator BURR. I appreciate your candor on that because I think, at the root of this, I really do, I think many of the concerns come from individuals who have not read the legislation, who have been handed, in some cases, not by their staffs, a Talking Point sheet that contains many things that are inaccurate but it has forced me to go back through the legislation and read it with staff to make sure that the clarity that existed when I read it the first few times, was in fact, there and that it was a misinterpretation. I would turn to my colleague from Georgia to see if he has any additional questions.

Senator ISAKSON. One question. Mr. Hutt's comment about the wine closures in California and the exemption to the lead standards probably is a pretty good example of the economic interests of the State having an effect on the regulatory power of the State, which begs a question to Dr. Murano because I think in your answer to me, Doctor, you referred to exports of agricultural products. I remember the Japanese used key MOs basically as scare tactics to try and limit importing of American food products. It would seem like to me the uniformity of labeling would be of benefit to us from the standpoint of our international exports, is that correct?

Dr. MURANO. That is correct, sir and frankly, it is the TTO that is the world body, where you are supposed to settle disputes when there are disagreements of a nature and it is the standards that are agreed to by countries in food safety, through the Codex

Alimentarius Commission that are used as the evidence and actually were the reason why the European Union could no longer not allow GMO products to be sold there from the United States and it is because it has to be based on science. It cannot be just an arbitrary regulation or warning label without basis for science because then if everyone does that, we'll have a chaotic situation and trade certainly can come to a screeching halt.

Senator ISAKSON. Thank you and that's all the questions I have, Mr. Chairman.

Senator BURR. Last thing, Mr. Stadtlander. Senator Feinstein testified to something that I have no reason to question the accuracy. She said that she had never heard a complaint from her constituents about Prop 65. If you are forced to pull Wheatena from the marketplace, do you think there is at least one person out there that likes that product well enough that they may complain about this?

Mr. STADTLANDER. I can make sure they complain.

[Laughter]

Senator BURR. I thank you for that and I will warn her exactly how I set her up. I would like to thank all of you for your willingness to be here, to share your experience, your knowledge and your concerns as it relates to your livelihood but more importantly, the safety of food and labeling for the American people. I think the hearing has been a great contribution to the debate and I think one would have to say that the top bullet that people should leave here with is, go read the bill again. Even if you think you know everything that is in it, go read it one more time. I am told we have no further questions. I ask unanimous consent that all members' statements be included in the record of the hearing and I also ask unanimous consent that the Letters of Support for S. 3128 be included. Without objection, so ordered. Members of this committee may submit questions in writing for any of the witnesses and I would ask you to make yourself available, as we would appreciate a timely response to any questions. The record will remain open for 10 days for these questions and for further statements from my colleagues. Again, thank you for your time commitment to us and for instilling in us the knowledge on this issue.

The hearing is adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR KENNEDY

Thank you, Mr. Chairman, for calling this hearing on the National Uniformity for Food Act, which would prohibit States from applying food safety laws unless they are identical to provisions of the Federal Food, Drug, and Cosmetic Act.

This extreme bill is a giveaway to the food industry, and all Americans will pay for it with their health. Everyone agrees that the bill would preempt Proposition 65, the California law that requires warning labels on products that contain ingredients known to the State to cause cancer, birth defects, or reproductive problems. But there is little agreement after that.

The food industry claims that only about a dozen State laws would be preempted, but the Center for Science in the Public Interest, with the support of many State officials, has identified about 200 such laws.

For example, according to the Center, the bill would preempt statutes regulating the quality of milk and food served in restaurants in all 50 States. It would preempt laws on unsafe food and color additives and laws on shellfish in more than a dozen States. It would preempt warnings required by at least 18 States about the effect of alcohol consumption by pregnant women on their unborn children.

In Massachusetts, the sale of dead lobster is banned, because it decomposes so rapidly. We can now set more stringent bacterial standards for milk than under FDA guidelines, and ban or require warnings about food or color additives that are considered safe under Federal law. These and potentially other food safety laws in Massachusetts would be preempted by S. 3128.

In fact, the bill is so vaguely written that we don't know how broad the preemption of State and local health laws would be. There will certainly be costly litigation on the issue. Otherwise, States will have to assume their laws are preempted and resort to the costly process in the bill to petition the FDA for exemptions. The Congressional Budget Office estimated costs of $100 million to FDA and $64 million to the States for these petitions over 5 years. But the estimate assumes that California will file one petition for Proposition 65, instead of one for each compound for which that law now requires a warning. Because determinations for each compound are obviously highly fact-specific, there will need to be individualized petitions for each one, and the CBO estimate is obviously too low.

State officials across the Nation argue that their laws would be unfairly preempted and their efforts to improve the safety of food would be crippled. The legislation obviously is intended to benefit the food industry, regardless of its impact on the right of States to protect the health of their citizens.

Even identical State laws would be limited under this bill. Every State enforcement action would potentially be subject to a Federal preemption defense, on the ground that the State is imposing a "materially different" requirement than under Federal law. The cases could even be removed to Federal court, and this is especially

true when neither the FDA nor the State has issued a regulation setting a tolerance for a harmful substance in food.

The bill would, however, allow a State to enforce when FDA has issued a regulation setting a tolerance level for a harmful substance or, if the FDA hasn't issued a regulation, when the State has a policy on the harmful substance, either through regulation or administrative decision.

But the bill blocks the State from enforcing a policy rejected by the FDA. This prohibition is true even when the FDA rejected the policy 20 years ago and there is new science validating the policy.

The bill also implies that a State may not enforce its laws when there is neither an FDA nor a State regulation or policy. In such cases, the State should be permitted to allege that a food contains a substance, that the substance is poisonous, and that it may be injurious to health. The bill implies that local food safety laws—such as those in New York City—may never be enforced, even when they are identical to Federal laws.

The uncertainty surrounding enforcement and the hugely increased cost to the States of each enforcement action would drastically reduce the number of those actions, and could deter the States from even bringing them at all. We can't expect an underfunded FDA—which conducts only about 20 percent of domestic inspections and is able to inspect, at most, 2–3 percent of imported food—to fill this gap.

Congress shouldn't even be considering such a step, especially when we've all focused on strengthening the Nation's ability to respond to bioterrorism. Do we really want to prevent a State from doing more to protect its citizens from bioterrorism than the Federal Government does? Why disarm our State food safety officials—who will be our first responders if terrorists put anthrax in our food supply? The certification by the Secretary of Health and Human Services is hollow reassurance that this won't happen—all it indicates is that the authors of the bill know this is a real possibility.

If we ever mark this bill up, the first amendment should be to rename it the "Make Way for Terrorism with Foods Act."

Cal Dooley, the President of the Food Products Association, could not cite a single case in which manufacturers had to put two different labels on a food, let alone 50 labels. Label uniformity is obviously not the issue here. Yet the food industry wants us to cripple State efforts to enforce the safety of our food.

In fact, as we all know, the industry wants to be able to add ingredients to food that some States feel may cause serious health risks, or even cancer or birth defects. Which of the Proposition 65 ingredients, for example, does the food industry want to put in our food? I hope these hearings will help us get to the bottom of issues like this.

I thank the Chairman and I look forward to today's testimony.

PREPARED STATEMENT OF SENATOR HATCH

Mr. Chairman, I regret that a prior commitment precludes my attendance at this hearing today, because I am very interested in this legislation.

I commend Senator Burr for his work on this important issue.

Mr. Chairman, I am very sympathetic to the goals of this legislation. Indeed, I appreciate that differing food safety tolerances and warning labels among the various States can be disruptive to interstate commerce.

That being said, I look forward to examining this legislation and its impact in more detail as the committee process moves forward. For example, I would like to understand more fully how the bill defines food, if the bill is significantly flexible to allow State and local authorities the ability to respond to emerging public health problems associated with foods, and if the Food and Drug Administration will be able to meet the timeframes established for the petition process.

Thank you for holding this hearing today and for considering my concerns.

PREPARED STATEMENT OF SENATOR JEFFORDS

Mr. Chairman, thank you for this hearing and for giving those of us with strong reservations about S. 3128, the National Uniformity for Food Act of 2005, a chance to ask questions and receive testimony. To our witnesses, thank you for appearing today before this committee.

In May, I joined 20 of my Senate colleagues in writing to the Senate leadership asking for, at least, some committee consideration of this legislation. As a former chairman of this committee, I appreciate, Mr. Chairman, your willingness to hold this hearing and proceed under regular order.

I have heard from many Vermonters who are genuinely concerned with S. 3128 and its counterpart H.R. 4167. To these constituents, the enactment and enforcement of strong food safety laws are legitimate functions of State governments. As a former Attorney General, I agree.

This hearing will also bring to light the growing gap between the many responsibilities given to the Food and Drug Administration (FDA) and the funding levels that fall short of being adequate to carry out those responsibilities. If S. 3128 were to be enacted into law, it would exacerbate the FDA's lack of funding and possibly cause more problems than it is intended to fix.

Again, thank you, and I look forward to the testimony of our witnesses.

PREPARED STATEMENT OF SENATOR NELSON

Mr. Chairman, I would like to express my support for S. 3128 and national uniformity for our Nation's food products. I am proud to be an original cosponsor of this bill seeking to set a national standard for food safety, food safety labeling and put food safety in the hands of the Nation's top food scientists and food safety experts.

My commitment to a safe food supply is second to none, but I also understand the reality that our food supply is national, and indeed global, in scope. Effective regulation of this national food supply and assurance of safe, wholesome and affordable food requires uniformity in food safety regulation, especially warnings. Because our food supply is truly national in scope with products made in

one facility distributed and sold throughout the Nation, both consumers and food manufacturers should be able to rely on national, scientifically-based standards for food safety.

I think this legislation reflects a commonsense understanding that consumers should have the same confidence about the food they consume regardless of the State they live in or the State in which the food is sold. Food cannot be safe in one State and unsafe in another and food that is safe should be freely sold in all States and food that is not safe should not be sold anywhere.

I believe that States have an important role in making sure that the food supply is safe and sanitary. I think the States should actively cooperate with FDA to develop sensible, science-based requirements and to assist in the enforcement of these uniform, national requirements. I am convinced that S. 3128 will facilitate the development and enforcement of uniform food safety and food warning requirements, while preserving the ability of the States to use their enforcement authorities to prevent the sale of unsafe foods and to remove such foods from the marketplace. This bill will improve the safety of the food supply, remove unnecessary burdens on the food industry and help to ensure that our food supply is as safe, wholesome and affordable in the future as it has been in the past.

The National Uniformity for Food Act provides the mechanism for a national, uniform, and scientific approach to food safety regulation. The bill also provides a mechanism for considering State food safety requirements as national requirements. To the extent that there are State requirements that are stricter than Federal requirements, the bill ensures that all of those State requirements will be considered for adoption by Federal regulators. State authority to take action against adulterated food is preserved and they will still be in charge of inspections to enforce basic sanitation requirements in places such as restaurants, retail food stores, shellfish processors and dairy farms.

Uniformity in food regulation is not unprecedented and already exists for all meat and poultry products regulated by the U.S. Department of Agriculture; health claims, standards of identity, pesticide residue tolerance, medical devices, and drugs regulated by the U.S. Food and Drug Administration are all regulated at the Federal level.

I would like to reiterate that when a warning about food is supported by science and is necessary to help consumers make informed decisions about the foods they purchase, then the warning should be applied to food sold in all 50 States. Food cannot be safe in one State and unsafe in another, and that is why I am an original cosponsor of S. 3128 and I urge my colleagues to support this bill.

PREPARED STATEMENT OF LESLIE G. SARASIN

The American Frozen Food Institute (AFFI) supports S. 3128, the *National Uniformity for Food Act of 2006*. S. 3128 would set uniform national food safety standards that will provide all Americans with the same high level of confidence in and protection with the Nation's food supply.

On March 8, 2006, the House passed the bill (H.R. 4167) with a strong bipartisan vote of 283–139. Support from committee members during the Senate HELP Committee hearing is absolutely critical to this legislation becoming law this session.

AFFI is the national trade association that promotes and represents the interests of all segments of the frozen food industry. The approximately 500 members of the Institute are engaged in the processing of frozen foods, as well as other functions in the frozen food supply chain. These functions include ingredient supply, cold storage, transportation, packaging, marketing and scientific research. The Institute fosters industry development and growth, advocates on behalf of the industry before legislative and regulatory entities, and provides additional value-added services for its members and for the benefit of consumers.

AFFI has consistently endorsed policy initiatives that facilitate the needs of its members while maintaining core consumer interests. *The National Uniformity for Food Act of 2006* is not only vital to frozen food manufacturers who engage in interstate commerce, but ensures the promotion of accurate and consistent food safety information for consumers.

The legislation provides for science-based uniform food safety standards and warning requirements so that Americans in every State are protected equally. It is common-sense legislation that will help consumers make educated decisions for themselves and their families in an ever-changing and confusing food labeling environment. Consumers deserve a single standard when it comes to food safety, and this bill will allow States and the Food and Drug Administration to work collaboratively in establishing sound food safety policies that benefit, rather than confuse, consumers.

The National Uniformity for Food Act is a top priority for the frozen food industry. In advocating this policy, AFFI is mindful of concerns that States should have the opportunity to establish policies according to their discretion based on local or regional issues. However, it is important to note that the legislation contains provisions that give States the ability to petition the Federal Government to seek variances from the Federal standard should there be a belief that a different requirement is necessary or appropriate. Furthermore, issues of interstate commerce are appropriate topics for Federal policymaking.

AFFI is enthusiastic that the *National Uniformity for Food Act* is advancing and appreciates the committee's consideration of this legislation, which clearly constitutes good public policy. AFFI urges its enactment.

PREPARED STATEMENT OF THOMAS R. FRIEDEN, M.D., M.P.H.

The legislation being considered by this Senate Committee, S. 3128, represents dangerous public policy and would, if enacted, seriously jeopardize public safety by compromising the ability of State and local officials to protect their citizens from unsafe foods.

Similar legislation was passed by the House of Representatives in March 2006 without public hearings, despite the strenuous opposition of 39 State attorneys general, the National Association of State Departments of Agriculture, the National Conference of State Legislatures, the Association of Food and Drug Officials, and many other State and local elected and appointed officials representing diverse geographic and political views. I commend the Senate HELP Committee for holding hearings and I strongly urge that you not pass this legislation, noting the strong objections of national, State and local food safety experts who work on the front lines to ensure food safety. These are the individuals and institutions responsible for assuring the public that the food in their own neighborhoods—their markets, restaurants, school cafeterias and corner delis—is safe and unadulterated.

As the chief health officer of the Nation's largest city, I urge the committee to prevent this significant nationwide diminution of food safety protection. Not only would it compromise traditional and fundamental State and local responsibilities regarding food safety, it would also likely prevent cities and States from taking timely action to protect the public in the event of a terrorist attack involving contaminated food. This is especially important in light of the increased risk of terrorism, especially in large urban areas such as New York City.

S. 3128 is often described as a food-labeling bill, but it goes far beyond legislating uniformity of food labels. It preempts State and local laws and regulations that are not identical to Federal laws or regulations regarding adulterated food or food that "bears or contains any poisonous or deleterious substance which may render it injurious to health." Thus, the act prevents State and local governments from enacting or enforcing their own laws and regulations bearing upon contaminated, adulterated or poisoned food—even when particular regional or local circumstances warrant, justify or require State and local laws, regulations and enforcement, or when State or local action is needed to cover areas and circumstances not addressed by Federal law.

Furthermore, S. 3128 would prevent enforcement of *local laws* even when they are identical to Federal law. For New York City, whose population is greater and whose health department is correspondingly larger than that of many States, and for other large cities with marketplaces that serve large diverse and increasingly international populations, this would create extremely dangerous enforcement gaps. Any expectation that State or Federal Government, or any other entity, would or could fill these gaps is completely unrealistic. According to S. 3128, the States, *but not local governments*, could petition the Federal Government for an exemption, or for establishment of a national standard. These are not acceptable options when lives and health are threatened by adulterated or contaminated food in the marketplace and when preventing deaths or illness may depend on enforcement action within hours—rather than the weeks or months required for a bureaucratic petitioning process.

For more than a century, assuring food safety has been a fundamental State and local responsibility. The highest Federal court in New York recognized that "States have traditionally acted to protect consumers by regulating foods produced and/or marketed within their borders." [*Grocery Manufacturers of America* v. *Gerace*, 755 F.2d 993, 1003 (1985)]. State and local agencies conduct more than 80 percent of the food safety and enforcement activities in the country's marketplaces and food service establishments.

This proposal is an unwarranted intrusion on traditional State and local governments' inherent police powers and responsibilities to act to protect the public health. If enacted, it will create endless confusion and costly litigation around what constitute "identical laws," causing delays in removing contaminated food from circulation. It will prevent cities such as New York from acting when the Federal Government has not addressed, or has not adequately regulated, a dangerous food contaminant. Furthermore, it can be interpreted as preempting State action even when the Federal Government has not established a standard. This would be a particular problem for cities such as New York, where each day potentially dangerous food products from all over the world find their way into the local food supply.

The bill's language and its sponsors suggest that there exists a comprehensive body of Federal laws and standards that should be applied uniformly across States, such that State and local responsibilities are unneeded or duplicative. New York City's experience informs us that the reality is far different, and in fact often quite the opposite of what is being suggested. *Time and time again, we have sought clear Federal standards to address adulterated food products that have been directly linked to illnesses, but have found either no standards, or unenforceable guidelines.* A recent example is the discovery of lead in certain imported candy in New York City. The lack of adequate or enforceable Federal standards led to enactment of a local law banning the sale of lead-containing candy in New York City. *This law could be preempted and unenforceable if S. 3128 were enacted.*

The bill is dangerously ambiguous. Although the bill's proponents have stated that under the proposed law, States would be free to regulate "in the void"—that is, to regulate when the Federal Government has no existing standards—they have also stated the following:

> "Where States have existing requirements without a Federal counterpart and those State requirements 'protect an important public interest that would otherwise be unprotected,' the State's petition will be found by FDA to be well taken. Where States have requirements without Federal counterpart and those State requirements cannot be justified as contributing to the safety of the food supply, the State requirements will ultimately not be sustained."

These statements seem completely inconsistent with authorizing States to regulate in the void. Further, it appears that what would be contemplated is for the State to submit a petition in order for the necessary determinations to be made.

The longstanding authority of States and localities to regulate the safety of the food provided to their own citizens, particularly in areas such as food preparation in food service establishments, must be preserved. For example, *this law would preempt various State statutes such as those that require food establishments that sell alcoholic beverages to post a sign warning pregnant women about the risk of birth defects.* This is just one example of the very type of activities that must continue to remain within the purview of State and local government regulation.

In the event of a terrorist attack involving deliberate poisoning or contamination of food, the proposed law could cause serious delays while public health officials consult, deliberate and debate to determine whether a relevant "identical" State and Federal law and standard exists. If no relevant Federal standard were found to exist, would a State be expected to petition the Federal Government for a determination of imminent hazard authority *before* action could be taken? This peti-

tioning process is not only cumbersome and time-consuming, but, as discussed previously, only a State, and *not a locality*, is an eligible petitioner. These are not acceptable scenarios, particularly in view of the heightened threat of terrorism in New York City.

Enactment of S. 3128 would have serious consequences for the enforcement of New York City's Health Code, which has historically regulated food safety in more than 20,000 local restaurants and food service establishments and which provides the authority to seize and embargo any unsafe food. With Federal support and encouragement, the city has developed a state-of-the-art disease surveillance system capable of detecting food-borne and other illnesses early on. Yet S. 3128 could prevent the city from using its authority under its Health Code to act on critical information gathered from this system, because it would eliminate local authority to remove adulterated food from stores or restaurants. Accompanying this testimony is an attachment entitled *New York City's position on S. 3128, The National Uniformity for Food Act of 2005*, which contains additional examples of important enforcement actions the New York City Department of Health and Mental Hygiene has taken over past decades that would have been preempted, had S. 3128 been in effect.

The effect of S. 3128 would be to prevent States and localities from legislating on health-related matters affecting their citizens, a result that more than 100 years ago the U.S. Supreme Court recognized was not intended in the conferring upon Congress the regulation of commerce. [See *Sherlock* v. *Alling*, 93 U.S., 99, 103 (1876).]

I believe that if members of this committee consider carefully the opinions of the many national, State and local organizations who collectively represent substantial expertise in food and safety and the law and who have raised fundamental concerns about the serious consequences of this legislation, you will reach the conclusion that this bill should not be enacted into law.

I appreciate the opportunity to provide these comments and thank the committee members for your attention to these concerns. I would be happy to discuss my comments in person or provide any additional information you might request.

ATTACHMENT

New York City's Department of Health and Mental Hygiene (NYC DOHMH) is responsible for supervising and regulating the food supply in New York City. [New York City Charter § 556(x)(9)] Food service establishments in New York City are licensed and regulated by the Department in accordance with Article 81 of the New York City Health Code. The Department is also authorized by existing local law to seize, embargo or condemn food that is adulterated or otherwise constitutes a danger to public health. [New York City Health Code §§ 3.03(a) and 71.22] These authorities are essential public health tools that the city has used for many decades to protect its citizens. City health officers must be able to continue this critical public health activity, especially in light of New York City's disproportionate risk for future acts of terrorism, including the threat of deliberate contamination of food. Following are examples of actions the city has taken and that could be preempted by S. 3128 or be subject to legal challenges, creating dangerous delays and costly litigation. The law in such critical areas of public health should not be left unsettled and unclear. The authority to act needs to be unequivocal.

- NYC DOHMH issued a warning to city residents to avoid eating certain candies and food products made in Mexico that had been found to contain lead. Based on its authority under the Health Code and in cooperation with New York State authorities, NYC DOHMH inspected and tested these products. These actions, along with actions by other States and localities, resulted in a voluntary recall by a candy manufacturer. However, under this bill, if the manufacturer had not voluntarily taken this action, the city would have been preempted from taking enforcement action to remove candy from the market because there were no enforceable FDA safety standards regarding lead in candy.
- Because any increase in lead exposure to New York City's children is a serious public health concern, the New York City Council subsequently adopted a law banning sale of candy products containing lead. This action was prompted by concerns about the inadequacy of Federal regulatory efforts to set allowable safety limits for lead in food products and stop contaminated products from entering the country.
- NYC DOHMH linked certain imported cheeses to infection by *Mycobacterium bovis*, a form of tuberculosis found in cattle; 35 cases, including the death of an infant, were attributed to *M bovis* tuberculosis. The city monitored certain markets to assure that no contaminated cheese was sold, and would have relied upon its

local Health Code authority to seize or embargo such products had they been discovered

• NYC DOHMH used its powers under the city's Health Code to embargo certain herbal products after several cases of adult lead poisoning were confirmed among residents who used these products. Although there were National Academy of Science recommendations about tolerance levels, there were—and continue to be—no specific Federal standards. In previous years, NYC DOHMH had also ordered the cessation of sale of an herbal tea that contained high concentrations of lead and arsenic. While an amendment in the House-passed version of S. 3128 exempts regulation of dietary supplements, it is unclear whether food products containing dietary supplements would be similarly exempted.

• Following a sewage back-up in a manufacturing establishment in which specialty desserts and candies were made, NYC DOHMH used its powers under the city's Health Code to order the owner to cease production and thoroughly clean the processing area. NYC DOHMH embargoed and ultimately destroyed the contaminated products.

• NYC DOHMH, under the authority in the City Charter and the Health Code, ordered the surrender of shellfish that had been identified as the source of several cases of cholera.

• Recent New York City Health and Nutrition Examination Survey (HANES) data revealed that mercury levels are elevated in the Asian population. NYC DOHMH is currently examining reasons behind these elevated levels. The investigation may reveal certain food staple products or traditional remedies commonly used by Asians to be the source. However, if the act becomes law, NYC DOHMH will be unable to remove these products from the market.

PREPARED STATEMENT OF BENJAMIN COHEN

"In all that we do, *our purpose will be to strengthen the family by . . . promoting decisionmaking at the level closest to the people*—our communities, counties, schools districts and, most importantly, our homes." (emphasis added) (Mission Statement of Senator Michael B. Enzi for Senate Committee on Health, Education, Labor, and Pensions (on wall of Room 835 Hart Senate Office Building))

On behalf of its 800,000 members in the United States, the Center for Science in the Public Interest [1] is pleased to submit this testimony in strong opposition to the National Uniformity for Food Act, S. 3128, which was introduced by Senator Richard Burr on May 25, 2006.

The fallout from this thermonuclear attack on California's Proposition 65 could be the destruction of hundreds of other State and local food safety and labeling laws in every State (including six from North Carolina) (see attached table).[2] This destruction would occur even though Cal Dooley, President of the Food Products Association, admitted in March 2006 (according to a *USA Today* editorial opposing the bill) that he could not "cite a single instance in which manufacturers have to put *two* different labels on a [food] product, let alone 50." [3] (emphasis in original)

INTRODUCTION

S. 3128 does not mention Proposition 65. Instead, it preempts any State or local food safety or labeling law—with the exception of returnable bottle labeling and 10 other specific categories [4]—that is not "identical" to a requirement of the Food and Drug Administration ("FDA"). S. 3128 (but not its companion bill, H.R. 4167) would allow any State "policy such as a State regulation or an administrative decision, that is based on a State law that contains a requirement that is identical to" the adulteration requirement in section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act [5] ("FFDCA") if the FDA has not issued "a regulation or adopted final guidance" on this matter. S. 3128 does not, however, identify which State laws, if any, are protected by this vague provision.[6] Moreover, it certainly does not shield local government laws and may only protect State regulations—rather than State statutes.

A State can ask the FDA to waive this preemption by filing a petition. For State or local laws passed after the legislation is enacted, the State or local law—with the exception of one dealing with an "imminent hazard"—cannot take effect until the FDA grants the waiver; for State or local laws in effect on the day the legislation is enacted, the law remains in effect until the FDA denies the request for a waiver (which must be submitted within 180 days after enactment). The FDA may grant the waiver if the FDA determines that the State or local law "protects an important public interest that would otherwise be unprotected" and "would not unduly burden interstate commerce." [7]

In its February 2006 analysis of the companion House bill, H.R. 4167, the Congressional Budget Office ("CBO") estimated that roughly 200 petitions for existing laws and an additional 40 petitions for future laws could be filed with the FDA and that—at a cost of about $400,000 per petition—it would cost the FDA about $100 million (over 5 years) to process these petitions.[8] This new burden on the FDA comes at a time when the number of FDA employees devoted to food issues has fallen steadily by 10 percent over the last 4 years (from 3,167 in fiscal year 2003 to 2,843 in fiscal year 2006).[9]

There has been a rising tide of bipartisan opposition to this legislation. Attorneys General of 37 States, Governors of 8 States (California, Delaware, Illinois, Iowa, Michigan, New Jersey, New Mexico, and Oklahoma), food safety officials in 7 States (Colorado, Florida, Georgia, Michigan, New York, Washington, and Wisconsin), and food safety officials in New York City and Baltimore have told Congress they oppose H.R. 4167.[10] The Association of Food and Drug Officials, the National Association of State Departments of Agriculture, numerous consumers groups and environmental organizations, the Humane Society of the United States, and labor unions also oppose the legislation.[11] As the Attorneys General put it, "under this bill, States would be forbidden from adopting their own policies, even if the Federal Government had not acted in a particular area or adopted a particular warning . . . this bill would strip State governments of the ability to protect their residents through State laws and regulations relating to the safety of food and food packaging." [12]

I. The Ambiguity of the National Uniformity for Food Act Would Lead to Much Litigation About Its Scopes As Even the Food Industry is Uncertain As to Which State Laws It Threatens

The CBO said "the scope of the State and local regulations that would be affected by the legislation is ambiguous." [13]

On April 24, 2006 Cal Dooley, the President and CEO of the Food Products Association, and C. Manly Molpus, the President and CEO of the Grocery Manufacturers of America, held a press conference; they were joined by Stuart M. Pape, an attorney with the Washington law firm of Patton Boggs, and John W. Bode, an attorney with the Washington law firm of Olsson, Frank and Weeda. In their summary statement they claim that H.R. 4167 affects only 11 State laws,[14] but in their accompanying (unsigned) detailed table they concede that at least 26 laws are preempted.[15] Five of these are food labeling laws: California's Proposition 65, laws in Connecticut and Michigan requiring warning of a possible allergic reaction to bulk foods containing sulfites, a Maine law requiring a warning on the risks of eating smoked alewives, and a Nevada law requiring a warning in restaurants and other food establishments that sell alcoholic beverages of the risks, to pregnant women of drinking alcoholic beverages. The others are food safety laws: food additive laws in 16 States; milk safety laws in Massachusetts, Michigan, and Nebraska; and laws in Michigan and Virginia banning the use of sulfites in restaurants and other food service establishments.

We, however, have identified at least 220 State and local laws that are threatened by S. 3128 (see attached table). We have also identified at least 240 State and local laws that are threatened by H.R. 4167 (see attached table). Our estimates are conservative, as—with a few exceptions—they ignore both State regulations (as distinct from State statutes) and food safety and labeling requirements of the more than 87,000 local governments.

This uncertainty about the scope of the legislation will, of course, lead to litigation in both State and Federal courts.

II. The Food Industry Concedes That California Would Have to File About 300 Petitions With the FDA to Preserve the Requirements of Proposition 65 if Congress Were to Pass the National Uniformity for Food Act, Thereby Forcing the FDA to Spend About $120 million Just on These Petitions

The food industry concedes that California's Proposition 65 would be preempted by this legislation.[16] Proposition 65—passed by referendum in 1986—requires a warning when a product contains a chemical that may cause cancer or birth defects if the amount of the chemical is above a certain threshold. California has established "safe harbor" ceilings for about 270 carcinogens and about 25 chemicals causing reproductive toxicity.[17] Some—such as lead—have long been known to be present in some foods. Others—such as acrylamide and benzene—have only recently been discovered to be in foods.

The food industry admitted at its April press conference that in order to preserve these "safe harbors" California would have to file a separate petition for each chemical that may be in a food—as the science for each chemical and the impact of the

required warning on interstate commerce would differ for each chemical. Thus, California would likely have to file about 300 waiver petitions in order to preserve its ability to enforce these Proposition 65 safe harbors. Using CBO's estimate of $400,000 per petition, the FDA would have to spend $120 million to handle these Proposition 65 petitions.

III. The Food Industry Concedes that at Least 17 States Would Have to File Petitions With the FDA to Preserve Their Law That Allows the State to Establish a Ceiling for a Food Additive That is More Protective of Public Health Than One Established by the FDA

At least 17 States—Alabama, California, Colorado, Florida, Hawaii, Illinois, Indiana, Kansas, Maryland, Massachusetts,[18] Montana, New Hampshire, North Dakota, Oregon, South Carolina, Texas, and Utah—have a law that authorizes the State to adopt standards for unsafe food and color additives that are more protective of human health than those the FDA has set.

The food industry concedes that these laws would be preempted by this legislation, but asserts this preemption would be of no "practical effect" because the State has never used this authority.[19] Even if this assertion were true, there may come a time when the State may want to use its authority because the FDA has not acted, and so each State would have to ask the FDA for a waiver in order to preserve the option of using these laws in the future.

IV. The Food Industry Has Not Refuted the Argument of State Food Safety Officials That at Least 100 State Laws Governing the Safety of Milk, Restaurant Food, and Shellfish or Fish Are Threatened by S. 3128

S. 3128 (at page 2, lines 7–21) amends the FFDCA to preempt any State or local requirement that is not "identical" to 10 sections of the FFDCA. Of particular relevance here, the State or local law must be identical to subsection 402(a)(1) and section 406 of the FFDCA. Subsection 402(a)(1) provides, in pertinent part, that a food is adulterated if it "contains any poisonous or deleterious substance which may render it injurious to health," and in order "to protect the public health" section 406 directs the FDA to set a ceiling for the amount of any poisonous or deleterious substance that can be added to a food if such substance is required to produce the food.

The Wisconsin Secretary of Agriculture, Trade and Consumer Protection told Congress that his lawyers had examined H.R. 4167 and concluded that it "would severely hinder Wisconsin's ability to protect citizens from contaminated foods."[20] He went on to point out that "there are no *Federal laws* governing the inspection and regulation of grade A milk production for interstate commerce, shellfish harvester and processors, or regulation of retail food establishments like grocery stores and restaurants." (emphasis in original)[21] The Florida Commissioner of Agriculture and Consumer Services told Congress, after having H.R. 4167 examined by his lawyers, that H.R. 4167 would "place at risk our . . . programs for milk, dairy and shellfish."[22] New York's Commissioner of Agriculture and Markets told Congress that "food inspection enforcement laws relating to grade A milk, grocery stores and shellfish would be preempted" by H.R. 4167.[23]

In order to fill the gaps in the FDA's regulations,[24] every State has a law to ensure the safety of milk and a law to ensure the safety of food served in restaurants, cafeterias, nursing homes, and other food service establishments. At least 16 States have a law to ensure the safety of shellfish, and Arizona has a law to ensure the safety of farm-raised fish. About 88 percent (100 of these 116 laws) are clearly threatened by S. 3128 (see attached table).[25]

The food industry claims that these laws—with the exception of milk safety laws in Massachusetts, Michigan, and Nebraska—are not affected by this legislation because they deal with food "sanitation" rather than with food adulteration.[26]

The Association of Food and Drug Officials rejects this argument. It told Congress "Proponents of this bill emphasize that H.R. 4167 does not impact State sanitation laws, and thus, will not impact State programs. *Nothing could be further from the truth.* States perform sanitation inspections in an effort to assist food businesses in preventing contamination or adulteration of products, but one of the States' critical complementary functions is to take action when these preventive measures fail . . . If enacted, H.R. 4167 would significantly impede resolution of the unsafe conditions and removal of contaminated foods from the human food supply. Sanitation and adulteration are not identical, but rather complementary. . . . *While proponents [of H.R. 4167] argue that programs such as the cooperative milk and shellfish programs are not at risk our attorney, along with 11 other State attorneys, read the bill quite differently.*"[27] (emphases added)

V. S. 3128 Threatens at Least Ten Other Food Safety Laws (Including Bans on Lead in Candy) of at Least Nine States and New York City That Fill Gaps in the FDA's Regulations

There are at least 10 State and local government food safety laws (in addition to the milk, restaurant, and shellfish laws discussed above) that fill gaps in the FDA's current requirements and are not part of a State's general food safety law. California has a law limiting the amount of lead in candy and a law dealing with the adulteration of wine. Illinois has a law limiting the amount of lead in food. Maine, Mississippi, and Utah have laws governing the safety of honeybees.[28] New York has a law prohibiting the combined amount of lead, cadmium, mercury, and hexavalent chromium in any package from exceeding 100 parts per million. New York City has a law banning lead in candy. Texas has a regulation setting a minimum chlorine residual level in water that is being hauled. Virginia has a law banning sulfites in foods served in restaurants and other food service establishments.

Consider, for example, lead in candy. In 1995 the FDA told the candy industry—via an unenforceable guidance document[29] rather than through a regulation—that the FDA would consider enforcement action against candy with lead levels exceeding 0.5 parts per million ("ppm"). In May 2005 the New York City Council determined that "lead poisoning is linked to many adverse health effects among children . . . [and] that certain candy products have been discovered to contain dangerously high levels of lead."[30] So New York City banned the sale of candy products containing lead. In October 2005 Governor Schwarzenegger signed a California law limiting the amount of lead in candy to the amount that cannot be avoided by good agricultural, manufacturing, and procurement practices. Perhaps in reaction to these two bans, in December 2005 the FDA urged the candy industry to reduce the maximum amount of lead from 0.5 ppm to 0.1 ppm; the FDA explained that this new guidance "describes the Agency's current thinking on a topic and should be viewed only as recommendations."[31] In June 2006 Illinois's Governor signed a law banning the sale of food (and other items) containing lead in excess of 0.06 percent of the weight of the food. The National Uniformity for Food Act threatens these laws of New York City, California, and Illinois and, if enacted, would leave children and other consumers of candy protected only by the FDA's "recommendation" to the candy industry.

VI. The Food Industry Concedes that the Legislation Threatens the Laws of at Least 17 States Requiring That Establishments Selling Alcoholic Beverages Post A Sign Warning Pregnant Women About the Risks of Birth Defects from Drinking Such Beverages

The FDA shares jurisdiction over alcoholic beverages with the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury.[32]

The food industry concedes that the legislation would preempt Nevada's law requiring that establishments selling alcoholic beverages post a sign warning pregnant women of the risks of drinking such beverages.[33] At least 16 other States—Alaska, Arizona, Delaware, Georgia, Kentucky, Minnesota, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, South Dakota, Tennessee, Washington, and West Virginia—have similar laws. (These State laws complement the Congressional requirement that bottles of alcoholic beverages carry such a warning.)

VII. The National Uniformity for Food Act Threatens at Least 32 Other Food Labeling Laws in at Least 26 States and a County

The legislation provides that a State or local government may not require any "notification" for "a food that provides for a warning concerning the safety of the food" unless it is "identical" to a notification requirement of the FDA.[34] The legislation goes on to say that "the term 'warning' . . . means any statement, vignette, or other representation that indicates, *directly or by implication, the food presents or may present a hazard to health or safety.*" (emphasis added).[35]

There are at least 31 State food labeling laws in 26 States[36] that the food industry claims are not affected by the legislation.[37] However, it is clear that these laws are "warnings" within the broad meaning of H.R. 4167 and S. 3128 because "directly or by implication," as the bills state, they may be about health or safety—and so they are threatened by S. 3128 and H.R. 4167. For example,

- Alaska requires the labeling of genetically modified fish or fish products. Many consumers believe that such fish would be less safe than fish that has not been genetically modified.
- At least four States require disclosure on whether fish are farm raised: Alaska (salmon), Arkansas (catfish), Louisiana (catfish), and Mississippi (catfish). Certain farm-raised fish may contain elevated levels of PCBs or other contaminants.

• At least three States—New Hampshire, New York, and Vermont—have statutes that require that a food labeled as "maple syrup" consist only of maple syrup. By contrast, the FDA permits a product labeled as "maple syrup" also to contain salt, chemical preservatives, and defoaming agents.[38] Consumers may believe that such an additive-containing product is less healthy than pure maple syrup.

• At least 10 States—Connecticut, Georgia, Iowa, Minnesota, Montana, Nevada, New York, Ohio, Pennsylvania, and Washington—have laws requiring that a food labeled as "honey" be only honey. Such honey labels may be challenged as preempted by the legislation under the guise that these restrictions are an implied warning to consumers who believe that natural food is healthier than foods that contain artificial sweeteners and flavorings, or highly refined sugar.

• Los Angeles County requires restaurants to display letter grade reports on what the county's inspectors found about the safety of the food in the restaurant.

VIII. The Legislation Threatens Laws Passed by at Least Nine States That Restrict the Sale of Sodas and Certain Foods and Beverages in Schools in Order to Promote the Health of Children

In September 2005 Governor Schwarzenegger signed two bills restricting what foods can be sold in California's schools. SB 12 requires local school districts to prohibit, beginning July 2007, the sale of certain foods and beverages. SB 965 requires local school districts to prohibit the sale of certain beverages during various times, depending on whether it is an elementary school or a middle or junior high school. The California legislature determined in section 1 of SB 12 that the ingredients in certain foods, including added sugar in soft drinks, contribute to the "growing epidemic of overweight children," which is "putting growing numbers of California children at risk for type 2 diabetes, hypertension, heart disease, and cancer."

Laws in at least eight other States—Arizona, Arkansas, Connecticut, Indiana, Kentucky, Louisiana; North Carolina,[39] and West Virginia—also restrict the sale of sodas and other foods and beverages in public schools.[40]

The FDA has broad power to restrict the sale of any food that, in the words of section 402(a)(1) of the FFDCA, contains a "deleterious substance which may render it injurious to health." Section 406 of the FFDCA authorizes the FDA to issue regulations to limit the amount of a deleterious substance as the FDA "finds necessary for the protection of public health." Section 409(a) of the FFDCA directs the FDA to establish conditions under which a food additive may be safely used. As discussed above, S. 3128 amends the FFDCA and provides, in pertinent part, that "any requirement [of any State or political subdivision of a State] for a food described in section 402(a)(1), . . . 406, [and] 409" is preempted unless the State or local government's requirement is identical to a requirement of the FDA.[41]

As the FDA has not used its broad legal powers to issue any regulations restricting the sale of foods, including soft drinks containing added sugar or artificial sweeteners, to children, the laws of these nine States restricting sales in schools could be preempted by S. 3128 and H.R. 4167.[42]

CONCLUSION: CONGRESS SHOULD NOT TAMPER WITH THE FEDERAL-STATE FOOD SAFETY PARTNERSHIP THAT THE FOOD INDUSTRY ADMITS IS NOT NOW BROKEN

More than 70 years ago Supreme Court Justice Louis D. Brandeis said "It is one of the happy incidents of the Federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[43] For decades the food safety partnership among the FDA, the States, and local governments has worked well. As discussed above, Cal Dooley, President of the Food Products Association, admitted to *USA Today* in March 2006 that he could not "cite a single instance in which manufacturers have to put *two* different labels on a [food] product, let alone 50."[44] (emphasis in original) Congress should not tamper with this partnership merely because the food industry thinks there may be an unspecified problem in the future.

Attachment: Examples of State and local food safety and labeling laws and regulations threatened by either H.R. 4167 (as passed by the House of Representatives on March 8, 2006) or S. 3128, the National Uniformity for Food Act.

NOTES

1. The Center for Science in the Public Interest, a nonprofit organization based in Washington, DC., is supported by about 900,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the Nation's health through better nutrition and safer food since 1971.

2. This July 2006 table reflects criticisms by the food industry of a March 2006 table. My CSPI colleagues Hilary Kennedy and Samantha Williams were of great help in the preparation of these tables.

3. *USA Today* (March 27, 2006) at 12A.

4. The other exempt categories are "freshness dating, open date labeling, grade labeling, a State inspection stamp, religious dietary labeling, organic or natural designation, . . . unit pricing, a statement of geographic origin, dietary supplements, or a consumer advisory relating to food sanitation that is imposed on a food establishment, or that is recommended by the Secretary, under part 3-6 of the [Model] Food Code issued by the Food and Drug Administration," the Centers for Disease Control, and the U.S. Department of Agriculture. H.R. 4167, page 14, lines 9–25 and S. 3128, page 14, lines 12–23. The Model Food Code is published periodically and deals with more than consumer advisories; it can be used by State and local governments in establishing their own regulations to ensure the safety of food served in restaurants, schools, hospitals, nursing homes, and other food service establishments.

5. This exception also applies to nine other enumerated parts of the FFDCA that deal with any poisonous or added deleterious substance added to food (subsection 402(a)(2)), a food container that contains a poisonous or deleterious substance (subsection 402(a)(6)), irradiated food (subsection 402(a)(7)), the safety of color additives in foods (subsection 402(a)(c)), emergency permits (section 404), tolerances for poisonous ingredients in foods (section 406), the safety of food additives (section 409), the safety of new animal drugs (section 512), and the safety of color additives in foods, drugs, devices, or cosmetics (subsection 721(a)). See S. 3128 at page 3, lines 5–12.

6. For example, in North Carolina it might refer to regulations adopted pursuant to the North Carolina Food, Drug, and Cosmetic Act ("NCFDCA"). North Carolina General Statutes, Chapter 106, Article 12, sections 106-120–106-145. However, other important North Carolina food safety laws—such as those dealing with the safety of milk, food eaten in restaurants and other food service establishments, and shellfish, are not part of the NCFDCA and so are threatened by S. 3128.

7. H.R. 4176 at page 10, lines 1–13 and S. 3128 at page 10, lines 1–10. The courts will, of course, strike down any State or local food safety or labeling law that unduly burdens interstate commerce. For example, more than 60 years ago the U.S. Supreme Court held that a Madison, Wisconsin ordinance requiring that all pasteurized milk be bottled at an approved pasteurization plant located within a five mile radius of the center of Madison violated the Commerce Clause of the U.S. constitution. *Dean Milk Co.* v. *City of Madison*, 340 U.S. 349 (1951). See also *Granholm* v. *Heald*, 544 U.S. 460 (2005) (Michigan and New York laws banning out-of-state wineries from selling directly to consumers violate the Commerce Clause).

8. H.R. Rept. 109–379, 109th Cong. 2d Sess. (February 28, 2006) at 11.

9. FDA, Office of Management and Budget Formulation and Presentation, "Foods" www.fda.gov/oc/oms/ofin/budget/2007/pdf/3consolidatednarrative.pdf (visited May 1, 2006).

10. March 1, 2006 letter of National Association of Attorneys General; April 18, 2006 letter of Governor Arnold Schwarzenegger; March 2, 2006 letter of Governor Rod R. Blagojevich; March 7, 2006 letter of Governor Ruth Ann Minner, Governor Tom Vilsack, Governor Jennifer M. Granhohn, Governor Jon S. Corzine, Governor Bill Richardson, and Governor Brad Henry; January 30, 2006 letter of Colorado Commissioner of Agriculture; February 14, 2006 letter of Florida Commissioner of Agriculture and Consumer Services; March 24, 2006 letter of Georgia Commissioner of Agriculture; February 17, 2006 letter of Michigan Director of Agriculture; March 1, 2006 letter of New York Commissioner of Agriculture and Markets; February 27, 2006 letter of Washington Assistant Director of Agriculture; December 12, 2005 letter of Wisconsin Secretary of Agriculture, Trade and Consumer Protection; April 21, 2006 letter of Baltimore Commissioner of Health; July 10, 2006 letter of New York City Commissioner of Health and Mental Hygiene. Many of these letters are available at *http://www.house.gov/waxman/issues/health/food_safety_hr 4167.htm* and *http://www.house.gov/waxman/issues/health/food_safety_hr_4167_letters_oppostion.htm.*

11. See, e.g., January 16, 2006 letter of Association of Food and Drug Officials; June 1, 2006 letter of National Association of State Departments of Agriculture. These and other letters opposing H.R. 4167 are available at *http://www.house.gov/waxman/issues/health/food_safety_hr_4167.htm* and *http://www.house.gov/waxman/issues/health/food_safety_hr_4167_letters_opposition.htm.*

12. March 1, 2006 letter of National Association of Attorneys General at 1.

13. H.R. Rept. 109–379, 109th Cong. 2d Sess. (February 28, 2006) at 11.

14. National Uniformity for Food Coalition press release (April 24, 2006) www.uniformityforfood.com/coalitionrelease042406pressconf.pdf.

15. *Analysis of State Laws Cited in CSPI Report Shredding the Food Safety Net* (hereafter cited as Pape-Bode paper). www.uniformityforfood.org/statelawanalysis summarydetails.pdf. The Pape-Bode paper deletes the first six pages of our March 2006 report, thereby making it appear that we were presenting the maximum number of laws—rather than examples of laws—that are threatened by H.R. 4167. The full text of our report—*Shredding the Food Safety Net, A Partial Review of 200 State Food Safety and Labeling Laws Congress is Poised to Effectively Kill with H.R. 4167* (Center for Science in the Public Interest and Natural Resources Defense Council March 2006)—is available at www.cspinet.org/new/pdf/shredding.pdf.

16. Pape-Bode paper at 4.

17. www.oehha.ca.gov/prop65/pdf/Augt2005statusreport.pdf (visited May 1, 2006). California has identified about 770 chemicals that cause cancer or reproductive toxicity. www.oehha.ca.gov/prop65/prop65__list/files/060906p65single.pdf (visited July 19, 2006).

18. In 1988 the Massachusetts Supreme Court rejected a challenge by the food industry to the Massachusetts statute whereby the Massachusetts Department of Public Health had set a ceiling for daminozide residue in processed apple products that was lower than what the FDA had established. *Processed Apples Institute, Inc.* v. *Department of Public Health*, 402 Mass. 392 (1988).

19. See, e.g., Pape-Bode paper at 4.

20. December 12, 2005 letter of the Wisconsin Secretary of Agriculture, Trade and Consumer Protection at 1.

21. *Id.* at 2.

22. February 14, 2006 letter from Florida Commissioner of Agriculture and Consumer Services at 2.

23. March 1, 2006 letter of New York Commissioner of Agriculture and Markets at 2.

24. The FDA prohibits the interstate shipment of both contaminated shellfish and unpasteurized milk. 21 CFR 1240.60 and 1240.61. However, its regulations do not deal with ensuring the safety of milk or shellfish within a State. The FDA has no regulations governing the safety of food in restaurants and other food service establishments.

25. Sixteen milk safety, restaurant safety, and shellfish safety laws in Alaska, Kentucky, Massachusetts, Michigan, Missouri, Nebraska, Ohio, Wisconsin, and Wyoming may not be threatened by S. 3128 because in these States these laws are part of the State law that resembles the FFDCA.

26. See, e.g., Pape-Bode paper at 1.

27. January 16, 2006 letter from Association of Food and Drug Officials at 1, 2.

28. At a press conference on March 7, 2006 the Attorney General of Utah said he opposed the legislation, in part because, in his opinion, it threatened Utah's honeybee safety law.

29. James T.O. Reilly, *Food and Drug Administration*, 2nd ed. (2005) volume 1 at 4-71–4-72 ("Guidelines have the legal status of advisory opinions, which are merely an indication of policy directions . . . guidelines are legally unenforceable—rather a list of desires than of mandates . . .") (footnotes omitted). See 21 CFR 10.90(c).

30. New York City Law No. 49 (May 19, 2005).

31. *www.fda.gov/bbs/topics/NEWS/2005/NEW01284.html.* (visited March 1, 2006).

32. See, *www.fda.gov/ora/compliance__ref/cpg/cpgfod/cpg510-450.html.* (visited July 6, 2006)

33. Pape-Bode paper at 21.

34. H.R. 4167 at page 4, lines 11–22 and S. 3128 at page 4, lines 8–19.

35. H.R. 4167 at page 5, lines 9–13 and S. 3128 at page 5, lines 5–9.

36. Alaska requires both the labeling of farm-raised salmon products and the labeling of genetically modified fish or fish products. Arkansas requires a label that catfish be labeled as "farm-raised," "river or lake," "imported," or "ocean." California requires labels to disclose both if the food contains more than ½ percent alcohol and if a food is perishable when not refrigerated. Connecticut, Georgia, Iowa, Minnesota, Montana, Nevada, New York, Ohio, Pennsylvania, and Washington each have a law governing when "honey" can be on the label of a food. Delaware requires that carbonated beverages containing artificial sweeteners be labeled as dietetic. Iowa also has a law governing when a food can have on the label the word "sorghum." Louisiana has a law requiring that any catfish product be labeled as farm-raised or naturally produced. Maine has laws requiring disclosure of whether fresh produce has had a post-harvest treatment and whether apples have been exposed to controlled

atmosphere. Maryland has a law requiring disclosure of whether a "fresh" food has been previously frozen. Massachusetts has a law governing the labeling of halibut. Minnesota also has a law governing the labeling of various types of wild rice. Mississippi requires any catfish product to be labeled as "farm-raised," "river or lake," or "ocean." New Hampshire, New York, and Vermont have laws requiring that maple syrup be made solely from the sap of the maple tree. New York also requires a label to disclose whether a frozen food has previously been offered for sale in unfrozen form. North Carolina has a law governing the labeling of milk used in summer camps. Oregon has a law requiring that food that has been "salvaged" have a label stating that fact. Rhode Island has a law requiring disclosure of whether uncooked fish or shellfish have ever been frozen and a law governing the labeling of closed packages of apples. South Dakota requires a food label to disclose whether the food contains chloroform and various narcotics. Wisconsin has a labeling law governing the age of cheese made in Wisconsin.

37. See, e.g., Pape-Bode paper at 2. Depending on the particular State labeling law, the food industry gives one of three reasons why it is not affected by H.R. 4167: (1) the label is not a "warning" as defined in the bill, (2) the label deals with what the industry calls "economic adulteration" (a term that does not appear either in the National Uniformity for Food Act or the FFDCA), or (3) there is no comparable FDA requirement (even though for other State labeling requirements—such as Proposition 65—the industry says the law is preempted although there is no comparable FDA requirement).

38. 21 CFR 168.140(b).

39. The North Carolina law also bans the sale of foods containing trans fatty acids from partially hydrogenated vegetable oils.

40. For further discussion of State efforts to restrict the sale of certain foods and beverages in schools, see *School Foods Report Card* (CSPI June 20, 2006) available at http://cspinet.org/new/pdf/school__foods__report__card.pdf.

41. S. 3128 at page 2, lines 7–21.

42. These State laws are not part of the State law resembling the FFDCA.

43. *New State Ice Co.* v. *Liebmann*, 285 U.S. 262, 311 (1932) (dissenting opinion).

44. *USA Today* (March 27, 2006) at 12A.

EXAMPLES OF STATE AND LOCAL FOOD SAFETY AND LABELING LAWS AND REGULATIONS THREATENED BY EITHER H.R. 4167 (as passed by the House of Representatives on March 8, 2006) or S. 3128, THE NATIONAL UNIFORMITY FOR FOOD ACT

Revised July 24, 2006

Alabama	Statutory provision prohibiting terra alba, barytes, talc, chrome yellow, or burnt umber in confectioneries. 1 (Safe Food Act, Title 20, Chapter 1, § 20-1-23). Statutory provision authorizing tolerances for infested, moldy, or decayed pecans and other nuts. 1 (Safe Food Act, Title 20, Chapter 1, § 20-1-90). Statutory provision governing the safety of milk. (Code of Alabama, Title 2, Chapter 13, Article 3, §§ 2-13-80- 2-13-94). Statutory provision governing the safety of food in restaurants and other food service establishments. (Code of Alabama, Title 22, Title 1, Chapter 20, §22-20-5). Statutory provision governing shellfish safety (Code of Alabama, Title 22, Title 1, Chapter 2, §22-2-2 and Title 9, Chapter 12, Article 2, §9-12-126)
Alaska	Statutory provision requiring labeling of farm-raised salmon products. (Alaska Food, Drug and Cosmetic Act, Title 17, Chapters 17-20 §17.20.040 (12)). Statutory provision requiring labeling of genetically modified fish or fish products. (SB 25; signed by Governor May 19, 2005) Statutory provision barring "halibut" on a food label if the food is not either hippoglossus or hippoglossus stenolepsis (Alaska Food, Drug, and Cosmetic Act, Title 17, Chapters 17-20 §17.20.045). Statutory provision governing the safety of milk. 2 (Alaska Food, Drug, and Cosmetic Act, Title 17, Chapters 17-20 §17.20.005(4)). Statutory provision governing the safety of food in restaurants and other food service establishments. 2 (Alaska Food, Drug, and Cosmetic Act, Title 17, Chapters 17-20, § 17.20.005(1)).

1May not be preempted by S. 3128 because part of Alabama's Safe Food Act (Title 20, Chapter 1).
2 May not be preempted by S. 3128 because part of Alaska's Food, Drug, and Cosmetic Act (Title 17, Chapter 17.20).

	Statutory provision governing shellfish safety. 2 (Alaska Food, Drug and Cosmetic Act, Title 17, Chapters 17-20, §17.20.005(5)). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Alaska Statutes, Title 4, Chapters 4-21, §4.21.065).
Arizona	Statutory provision governing the safety of milk and other dairy products (including raw milk). (Arizona Revised Statutes, Title 3, Chapter 4, Article 1, §§ 3-601- 3-634). Statutory provision governing the safety of food in restaurants and other food service establishments. (Arizona Revised Statutes, Title 36, Chapter 1, Article 1, §36-104(b)(i)) Statutory provision governing fish safety (Arizona Revised Statutes, Title 3, Chapter 16, Article 1, §§3-2901- 3-2904). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Arizona Revised Statutes, Title 4, Chapter 2, Article 4, §4-261). Statutory provision prohibiting sale of certain foods and beverages in public schools. (Arizona Revised Statutes, Title 15, Chapter 2, Article 2, §15-242.E)..
Arkansas	Statutory provision authorizing regulations governing the safety of salvaged food. (Arkansas Code, Title 20, Subtitle 4, Chapter 57, Subchapter 1, §20-57-102). Statutory provision requiring any catfish product to be labeled as "farm-raised," "river or lake," "imported," or "ocean". (Arkansas Code, Title 20, Subtitle 4, Chapter 61, Subchapter 2, §20-61-206). Statutory provision governing the safety of milk. (Arkansas Code, Title 20, Subtitle 4, Chapter 59, Subchapters 1-2, §§20-59-101-20-59-248). Statutory provision governing the safety of food in restaurants and other food service establishments. (Arkansas Code, Title 20, Subtitle 4, Chapter 57, Subchapter 2, §§20-57-201-20-57-204). Statutory provision prohibiting the use of "honey" on a food label if the food is not pure honey. (Arkansas Code, Title 20, Subtitle 4, Chapter 57, subchapter 4, §20-57-402). Statutory provision prohibiting vending machines offering food and beverages in elementary schools. (Arkansas Code, Title 20, Subtitle 2, Chapter 7, Subchapter 1, §20-7-135 (c)).

2 May not be preempted by S. 3128 because part of Alaska's Food, Drug, and Cosmetic Act (Title 17, Chapter 17.20).

California	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Sherman Food, Drug, and Cosmetic Law, Cal. Health and Safety Code, Division 104, Part 5, Chapter 2, Article 1, §§110085 and 110090). Statutory provisions requiring that consumers be notified of contaminants that are known to the state to cause cancer or reproductive toxicity. (Proposition 65) (Cal. Health & Safety Code, Division 20, Chapter 6.6 §§25249.5 *et seq.*). Statutory provisions on shellfish safety. (Cal. Health & Safety Code Division 104, Part 6, Chapter 5, Article 2 §§112160 *et seq.*) Statutory provision limiting the amount of lead in candy. (AB 121; signed by Governor October 7, 2005.) Statutory provision requiring label to disclose if food contains more than ½ of one percent alcohol. (Sherman Food, Drug, and Cosmetic Law, Cal. Health and Safety Code, Division 104, Part 5, Chapter 5, Article 6 §110695). Statutory provision requiring label to disclose if food is perishable when not refrigerated. (Sherman Food, Drug, and Cosmetic Law, Cal. Health and Safety Code, Division 104, Part 5, Chapter 5, Article 6, §110700). Statutory provisions pertaining to the adulteration of wine. (Sherman Food, Drug, and Cosmetic Law, Cal. Health and Safety Code, Division 104, Part 5, Chapter 5, Article 5, §110597). Statutory provision governing the safety of milk (including raw milk). (Food and Agriculture Code, Division 15, Part 1, Chapter 5, §§32901- 32921 and Division 15, Part 2, Chapter 2, Articles 1-8, §§35751-35928). Statutory provision governing the safety of food in restaurants and other food service establishments. (Cal. Health & Safety Code, Division 104, Part 7, Chapter 4, §§113700-114475). Statutory provision prohibiting the sale of certain foods and beverages in public schools. (SB 12; signed by Governor September 15, 2005). Statutory provision prohibiting the sale of certain beverages during various times in public schools. (SB 965, signed by Governor September 15, 2005).

	Statutory provision governing the safety of milk. (Delaware Code, Title 16, Part 1, Chapter 1, Subchapter 2, §122 (3)f.). Statutory provision governing the safety of food in restaurants and other food service establishments. (Delaware Code, Title 16, Part1, Chapter 1, Subchapter 2, §122 (3)u). Statutory provision governing shellfish safety (Delaware Code, Title 7, Part 2, Chapter 19, §§1901- 1902) Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Delaware Code, Title 4, Chapter 9, §903).
Florida	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Florida Food Safety Act, Title XXXIII, Chapter 500, §500.13(2)). Statutory provisions on shellfish safety. (Florida Aquaculture Policy Act, Title XXXV, Chapter 597). Numerous statutory provisions concerning labeling of citrus fruit, canned citrus juices, and frozen citrus juices. (Florida Agriculture, Horticulture, and Animal Industry, Citrus Code, Title XXXV, Chapter 601, §§601.99 *et seq.*). Statutory provision governing the safety of milk. (Florida Statutes, Title XXXIII, Chapter 502, §§502.012- 502.232). Statutory provision governing the safety of food in restaurants and other food service establishments. (Florida Statutes, Title XXXIII, Chapter 509, Part 1, §§509.013-509.101).
Georgia	Statutory provision permitting ingredients of a carbonated beverage to be disclosed through an affidavit to the Commissioner rather than on the label. (Georgia Statutes, Title 26, Chapter 26-2, §26-2-28(9)(c)). Statutory provision regulating when a food can have the label "honey." (Georgia Statutes, Title 26, Chapter 26-2, §26-2-32(a)). Statutory provision governing the safety of milk. (Georgia Dairy Act of 1980, Title 26, Chapter 26-2, §§26-2-230- 26-2-250). Statutory provision governing the safety of food in restaurants and other food service establishments. (Georgia Statutes, Title 26, Chapter 26-2, §§26-2-371- 26-2-373.1). Statutory provision governing the safety of fish and seafood (Georgia Statutes, Title 26, Chapter 26-2, §§26-2-318).

Colorado	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Colorado Food and Drug Act, Title 25, Article 5, Part 4, §25-5-413(2)). Statutory provision governing the safety of milk. (Colorado Revised Statutes, Title 25, Article 5.5, Part 1, §§25-5.5-101- 25-5.5-117). Statutory provision governing the safety of food in restaurants and other food service establishments. (Colorado Revised Statutes, Title 25, Article 4, Part 16, §§25-4-1601-25-4-1612). Statutory provision governing shellfish safety (Colorado Revised Statutes, Title 25, Article 4, Part 18, §§25-4-1803- 25-4-1813).
Connecticut	Statutory provision prohibiting the use of "honey" on the label of a food that does not contain honey. (General Statutes of Connecticut, Volume 7, Title 21a, Chapter 417, §21a-24). Statutory provision prohibiting the sale of cider vinegar unless made wholly from apple juice. (General Statutes of Connecticut, Volume 7, Title 21a, Chapter 417, §21a-25). Statutory provision requiring a warning about a possible allergic reaction when any sulfiting agent is present in any bulk food. (General Statutes of Connecticut, Volume 7, Title 21a, Chapter 418, §21a-104a). Statutory provision governing the safety of milk (including raw milk). (General Statutes of Connecticut, Volume 8, Title 22, Chapter 430, §§22-127- 22-203h). Regulatory provision governing the safety of food in restaurants and other food service establishments. (Public Health Code, Volume 6, Title 19a, Chapter 368a, §§19a-36a- 19a-36b). Statutory provision governing shellfish safety (General Statutes of Connecticut, Volume 8, Title 26, Chapter 491, §§26-192a-26-192g). Statutory provision prohibiting the sale in schools of certain beverages during various times. (SB 373; signed by Governor May 19, 2006)
Delaware	Statutory provision requiring carbonated beverages containing artificial sweeteners to be labeled as "dietetic." (Delaware Code, Title 16, Part 4, Chapter 43, §4312).

	Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Georgia Statutes, Title 3, Chapter 3-1, §3-1-5).
Hawaii	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Hawaii Food, Drug, and Cosmetic Act, Volume 6, Chapter 328, §328-13(b)). Statutory provision governing the safety of milk. (Hawaii Revised Statutes, Volume 6, Chapter 321, §321- 11(14)). Regulatory provision governing the safety of food in restaurants and other food service establishments. (Hawaii Administrative Rules, Title 11, Chapter 12).
Idaho	Statutory provision governing the safety of milk. (Idaho Statutes, Title 37, Chapter 4, §§37-402- 37-413). Statutory provision governing the safety of food in restaurants and other food service establishments. (Idaho Statutes, Title 39, Chapter 16, §§39-1601-39-1608).
Illinois	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Illinois Food, Drug, and Cosmetic Act, Chapter 410, Subhead 620, §13(b)). Statutory provision deeming egg products adulterated if processed in a manner that increases the risk of microbial contamination. (Illinois Food, Drug, and Cosmetic Act, Chapter 410, Subhead 620, §10(f); Illinois Egg and Egg Products Act, Chapter 410, Subhead 615, §3.1(1)). Statutory provision limiting the amount of lead in food. (HB 4853; signed by Governor June 20, 2006). Statutory provision governing the safety of milk. (Grade A Pasteurized Milk and Milk Products Act, Chapter 410, Subhead 635, §§635-1-635-19). Statutory provision governing the safety of food in restaurants and other food service establishments. (Food Handling Regulation Enforcement Act, Chapter 410, Subhead 625, §§1-3.1) Statutory provision prohibiting the use of "honey" on a food label if the food is not pure honey. (Illinois Food, Drug, and Cosmetic Act, Chapter 410, Subhead 620, §11(p)). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Liquor Control Act, Chapter 235, Subhead 5, §6-24b).

Indiana	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Indiana Food, Drug, and Cosmetic Act, Title 16, Article 42, Chapter 2, §16-42-2-5(b)). Statutory provision governing the safety of milk. (Indiana Code, Title 15, Article 2.1, Chapter 23, §§15-2.1-23-1- 15-2.1-23-17). Statutory provision governing the safety of food in restaurants and other food service establishments. (Indiana Code, Title 16, Article 42, Chapter 5, §§16-42-5.05-16-42-5-28 and Chapter 5.2, §§16-42-5.2-1-16-42-5.2-15). Statutory provision banning vending machines that dispense food or beverages in elementary schools. (Indiana Code, Title 20, Article 26, Chapter 9, §20-26-9-19 (b)).
Iowa	Statutory provision regulating when a food can have the label "honey." (Iowa Code, Title V, Subtitle 4, Chapter 189, §189.14(2)). Statutory provision regulating when a food can have the label "sorghum." (Iowa Code, Title V, Subtitle 4, Chapter 189, §189.14(3)). Statutory provision governing the safety of milk. (Iowa Grade "A" Milk Inspection Law, Title V, Subtitle 4, Chapter 192, Section 192.101-192.127 and Chapter 194, Section 194.8). Statutory provision governing the safety of food in restaurants and other food service establishments: (Iowa Code, Title IV, Subtitle 2, Chapter 137F, §§ 137.F1- 137F.19).
Kansas	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Kansas Food, Drug, and Cosmetic Act, Chapter 65, Article 6, §65-667(b)). Statutory provision governing the safety of milk (including unpasteurized milk). (Kansas Statutes, Chapter 65, Article 7, §§65-771- 65-791). Statutory provision governing the safety of food in restaurants and other food service establishments. (Kansas Statutes, Chapter 36, Article 5, §§36-507-36-515c). Statutory provision prohibiting the use of "honey" on a food label if the food is not pure honey. (Kansas Food, Drug, and Cosmetic Act, Chapter 65, Article 6, §65-681).

Kentucky	Statutory provision governing the safety of milk (including unpasteurized goat milk). (Kentucky Revised Statutes, Title XXI, Chapter 260, §§260.775- 260.845 and Title XVIII, Chapter 217C.090). Statutory provision governing the safety of food in restaurants and other food service establishments.3 (Kentucky Revised Statutes, Title XVIII, Chapter 217, §§217.127). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Kentucky Revised Statutes, Title XX, Chapter 243, §243.895). Statutory provision banning sale of certain beverages in vending machines in elementary schools. (Kentucky Revised Statutes, Title XIII, Chapter 158, §158.854).
Los Angeles County (California)	Regulatory provision requiring restaurants to display letter grade card on food safety. (Title 8, Chapter 8.04, §8.04.225).
Louisiana	Statutory provision on shellfish safety. (Revised Statutes, Title 40, 40:5.3). Statutory provision requiring any catfish product to be labeled as farm-raised or naturally produced. (Revised Statutes, Title 56, 56:578.11). Statutory provision governing the safety of milk. (Revised Statutes, Title 40, §§40:921- 40:925). Statutory provision governing the safety of food in restaurants and other food service establishments. (Revised Statutes, Title 40, 40:5.5) Statutory provision banning the sale of certain beverages in elementary and secondary schools during certain times. (Revised Statutes, Title 17, 17:197.1.B).
Maine	Statutory provision requiring disclosure of whether fresh produce has had a post-harvest treatment. (Maine Revised Statutes, Title 22, Subtitle 2, Part 5, Chapter 551, Subchapter 1, §2157.14). Statutory provision requiring sign stating that eating smoked alewives poses a health risk. (Maine Revised Statutes, Title 22, Subtitle 2, Part 5, Chapter 551, Subchapter 1, §2173).

3 May not be preempted by S. 3128 because part of Kentucky's Food, Drug and Cosmetic Act (Title XVIII, Chapter 27, §§217.005- 217.215).

	Statutory provision regulating the sale of apples that have been exposed to "controlled atmosphere." (Maine Revised Statutes, Title 7, Part 2, Chapter 103, Subchapter 1, §539). Statutory provision governing the shellfish of safety (Maine Revised Statutes, Title 12, Part 9, Subpart 2, Chapter 625, §6856). Statutory provision governing the safety of milk. (Maine Revised Statutes, Title 7, Part 7, Chapter 601, §§2900- 2910-A). Statutory provision governing the safety of food in restaurants and other food service establishments. (Maine Revised Statutes, Title 22, Subtitle 2, Part 5, Chapter 562, §§2491-2501). Statutory provision governing the safety of honeybees (Maine Revised Statutes, Title 7, Part 6-A, Chapter 527, §2801).
Maryland	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Maryland Health Code, Food, Drug, and Cosmetics Act, Title 21, Subtitle 2, §21-239(c)). Statutory provision requiring label to disclose if "fresh" food was previously frozen and thus should not be refrozen. (Maryland Health Code, Food, Drug, and Cosmetics Act, Title 21, Subtitle 2, §21-210(b)(11)). Statutory provision prohibiting the sale of frozen food that has been previously thawed from a prior freezing. (Maryland Health Code, Food, Drug, and Cosmetics Act, Title 21, Subtitle 2, §21-207(b)(8)). Statutory provision governing the safety of milk. (Maryland Health Code, Food, Drugs and Cosmetics Act, Title 21, Subtitle 4, §§21-401- 21-430). Statutory provision governing the safety of food in restaurants and other food service establishments. (Maryland Health Code, Food, Drugs, and Cosmetics Act, Title 21, Subtitle 3, §§21-301-21-323.1). Statutory provision governing the safety of shellfish (Maryland Natural Resources Code, Title 4, Subtitle 7, §4-742 and Sections 4-743)
Massachusetts	Statutory provision barring "halibut" on a food label if the food is not either hippoglossus hippoglosus or hippoglossus stenolepsis. (General Laws of Massachusetts, Part 1, Title XV, Chapter 94, §194B).

	Statutory provision governing the safety of milk. 4 (General Laws of Massachusetts, Part 1, Title XV, Chapter 94, §§13-48D). Statutory provision governing the safety of food in restaurants and other food service establishments. 4 (General Laws of Massachusetts, Part 1, Title XV, Chapter 94, §§305A-305B). Statutory provision banning the sale of dead uncooked lobster and requiring frozen lobster to have a label indicating the date of processing. 4 (General Laws of Massachusetts, Part 1, Title XV, Chapter 94, §77G). Statutory provision allowing the state to adopt tolerances for food additives that are more protective of the public health than the applicable Federal tolerances. (General Laws of Massachusetts, Part 1, Title XV, Chapter 94, §192).
Michigan	Regulations on smoked fish. (Michigan Admin. Code, Regulation 569, r. 285.569). Statutory provision banning the use of sulfiting agents in restaurants and other food service establishments.5 (Michigan Compiled Laws, Chapter 289, Food Law of 2000, Chapter VI, §289.6139). Statutory provision requiring a warning about a possible allergic reaction when any sulfiting agent is present in any bulk food. (Michigan Compiled Laws, Chapter 289, Food Law of 2000, Chapter VIII, §289.8103). Statutory provision governing the safety of milk. (Michigan Compiled Laws, Chapter 288, Manufacturing Milk Law of 2001, Articles 1-13, §§288.471- 288.711). Statutory provision governing the safety of food in restaurants and other food service establishments.5 (Michigan Compiled Laws, Chapter 289, Food Law of 2000, Chapter 6101, §§289.1105-289.6135).
Minnesota	Statutory provision regulating when a food may be sold as "honey." (Minnesota Statutes, Chapter 31, §31.74). Statutory provision requiring labeling of various types of wild rice. (Minnesota Statutes, Chapter 30, §30.49). Statutory provision prohibiting the sale of a confection containing alcohol to a person under the age of 21 and requiring labels on such confections.6 (Minnesota Statutes, Chapter 31, §31.76).

4 May not be preempted by S. 3128 because part of Part 1, Title XV, Chapter 94 of General Laws of Massachusetts.
5 May not be preempted by S. 3128 because part of Michigan's Food Law (Chapter 289, §§289.1101- 289.8111)
6 May not be preempted by S. 3128 because part of Minnesota's Food Law (Chapter 31, §§31.001-31.96)

	Statutory provision governing the safety of milk. (Minnesota Statutes, Chapter 32, §§32.01-32.398). Statutory provision governing the safety of food in restaurants and other food service establishments. (Minnesota Statutes, Chapter 157, §§157.011-157.22). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Minnesota Statutes, Chapter 340A, Section 340.A.410, Subdivision 4b(3)).
Mississippi	Statutory provision requiring any catfish product to be labeled as farm-raised, river or lake, or ocean. (Mississippi Code, Title 69, Chapter 7, Article 13, §69-7-607). Statutory provision governing the safety of milk (including raw goat milk). (Mississippi Code, Title 75, Chapter 31, Article 1, §75-31-65). Statutory provision governing the safety of food in restaurants and other food service establishments. (Mississippi Code, Title 69, Chapter 1, §69-1-18). Statutory provision governing the safety of oysters. (Mississsippi Code, Title 49, Chapter 15, Article 1, §49-15-37). Statutory provision governing the safety of honeybees. (Mississippi Code, Title 69, Chapter 25, Article 3, §69-25-105).
Missouri	Statutory provision governing the safety of milk. 7 (Missouri Revised Statutes, Title XII, Chapter 196, §§196.520-196.610). Statutory provision governing the safety of food in restaurants and other food service establishments.7 (Missouri Revised Statutes, Title XII, Chapter 196, §§196.240-196.265). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Missouri Revised Statutes, Title XX, Chapter 311, §311.299).
Montana	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Montana Code Annotated, Montana Food, Drug, and Cosmetics Act, Title 50, Chapter 31, Part 1, §50-31-108). Statutory provision regulating when a food can have the label "honey." (Montana Code Annotated, Montana Food, Drug, and Cosmetics Act, Title 50, Chapter 31, Part 2, §50-31-204).

7 May not be preempted by S. 3128 because part of Missouri's Title XII, Chapter 196.

	Statutory provision governing the safety of milk. (Montana Code Annotated, Title 81, Chapter 22, Parts 1-4, §§81-22-101-81-22-419). Statutory provision governing the safety of food in restaurants and other food service establishments.8 (Montana Code Annotated, Montana Food, Drug, and Cosmetic Act, Title 50, Chapter 31, §§50-31-103- 50-31-106).
Nebraska	Statutory provision governing the safety of milk. (Nebraska Statutes, Nebraska Manufacturing Milk Act, Title 2, §§2-3913- 2-3946). Statutory provision governing the safety of food in restaurants and other food service establishments.9 (Nebraska Statutes, Title 81, §§81-2,244.01-81-2,276). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Nebraska Statutes, Title 53, §53-148.01).
Nevada	Statutory provision prohibiting the use of "honey" on a food label if the food does not consist solely of honey. (Nevada Revised Statutes, Title 51, Chapter 585, §585.355). Statutory provision governing the safety of milk (including unpasteurized milk). (Nevada Revised Statutes, Title 51, Chapter 584, §§584.180- 584.210). Statutory provision governing the safety of food in restaurants and other food service establishments. (Nevada Revised Statutes, Title 40, Chapter 446, §§446.017-446.945). Statutory provision requiring restaurants and bars to post a sign warning pregnant women of the risk of drinking alcoholic beverages. (Nevada Revised Statutes, Title 40, Chapter 446, Section 446.842).
New Hampshire	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (New Hampshire Revised Statutes, Title X, Chapter 146, §146:21-II). Statutory provision prohibiting the sale of cider vinegar unless made solely from apple cider (New Hampshire Revised Statutes, Title X, Chapter 146, §146:14). Statutory provision requiring that maple syrup be made solely from the sap of the maple tree. (New Hampshire Revised Statutes, Title X, Chapter 146, §146:13).

8 May not be preempted by S. 3128 because part of Montana's Food, Drug and Cosmetic Act (Title 50, Chapter 31).
9 May not be preempted by S. 3128 because part of Nebraska's Pure Food Act (Title 81, §§81-2,239- 81-2,292).

	Statutory provision governing the safety of milk (including raw milk). (New Hampshire Revised Statutes, Title XIV, Chapter 184, §§184:30-a- 184:30-h). Statutory provision governing the safety of food in restaurants and other food service establishments. (New Hampshire Revised Statutes, Title X, Chapter 143A, §§143.A:1-143. A:11). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (New Hampshire Revised Statutes, Title XIII, Chapter 175, §175:4.IV)
New Jersey	Statutory provision prohibiting the sale to a person under the legal age of a confection containing more than 1/2 percent alcohol.10 (New Jersey Statutes, Title 24, §24:5-9.1) Statutory provision governing the safety of milk. (New Jersey Statutes, Title 4, §§4:12A-19- 4:12A-21). Statutory provision governing the safety of food in restaurants and other food service establishments. (New Jersey Statutes, Title 26, §§26:1A-7- 26:1A-10). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (New Jersey Statutes, Title 33, §33:1- 12a).
New Mexico	Statutory provision governing the safety of milk (including raw milk). (New Mexico Statutes, Chapter 25, Article 7 and Article 8, §§25-7-1- 25-7-8 and §§25-8-1). Statutory provision governing the safety of food in restaurants and other food service establishments. (New Mexico Statutes, Chapter 25, Article 1, §§25-1-1- 25-1-13). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (New Mexico Statutes, Chapter 60, Article 6A, §60-6A-30).
New York	Statutory provision prohibiting the combined amount of lead, cadmium, mercury, and hexavalent chromium in any package from exceeding 100 parts per million. (Chapter 43-B of the Consolidated Laws, Environmental Conservation Law, Article 37, Title 2, §37-0205). Statutory provision requiring label to disclose whether frozen food has previously been offered for sale in unfrozen form. (Chapter 69 of the Consolidated Laws, New York Agriculture and Markets Law, Article 17, §214-g).

10 May not be preempted by S. 3128 because part of New Jersey's Title 24.

	Regulations regarding processing of smoked fish. (Rules and Regulations of New York, Title I, Part 262, §262.5). Statutory provision governing the safety of milk. (Chapter 69 of the Consolidated Laws, Agriculture and Markets Law, Article 21, §254- 258r). Statutory provision governing the safety of food in restaurants and other food service establishments. (Chapter 69 of the Consolidated Laws, Agriculture and Markets Law, Article 28, §500). Statutory provision governing the safety of shellfish (Chapter 43-B of the Consolidated Laws, Environmental Conservation Law, Article 13, Title 3, §13-0307). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Chapter 3-B of the Consolidated Laws, Alcoholic Beverage Control Article 8, §105-b). Statutory ban on the sale of imitation maple syrup. (Chapter 69 of the Consolidated Laws, Agriculture and Markets Law, Article 17, §203). Statutory requirement that any mixture of olive oil and other oils indicate the specific percentage of olive oil. (Chapter 69 of the Consolidated Laws, Agriculture and Markets Law, Article 17, §204-a). Statutory ban on the use of "honey" on the label of a food that is not pure honey. (Chapter 69 of the Consolidated Laws, Agriculture and Markets Law, Article 17, §206).
New York City (New York)	Regulatory provision prohibiting the sale of candy containing lead. (New York City Administrative Code, Title 17, Chapter 1, §17-189).
North Carolina	Statutory provision on shellfish safety. (North Carolina General Statutes, Chapter 130A-, Article 8, §130A-230). Regulation requiring that in summer camps only grade A pasteurized milk be used and that the milk be served in the individual, original container so that the consumer can see the name of the milk distributor. (North Carolina Admin Code, Title 15A, Subchapter 18A, Section.1021(a)). Statutory provision governing the safety of milk. (North Carolina General Statutes, Chapter 106, Article 29, §§106-267- 106-268.1). Statutory provision governing the safety of food in restaurants and other food service establishments. (North Carolina General Statutes, Chapter 130A, Article 8, §§130A-247- 130A-250).

	Statutory provision prohibiting sale of soft drinks in certain schools at certain times. (North Carolina General Statutes, Chapter 115C, Article 17, §§115C-264.2). Statutory provision banning the sale of foods in the school lunch program containing trans fatty acids from partially hydrogenated vegetable oils. (North Carolina General Statutes, Chapter 115C, Article 17, §115C-264(b)).
North Dakota	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (North Dakota Century Code, Title 19, Chapter 19- 01, §§19-02.1-12(2)). Statutory provision governing the safety of milk. (North Dakota Century Code, Title 4, Chapter 4-30, §§4-30-01- 4-30-56). Statutory provision governing the safety of food in restaurants and other food service establishments. (North Dakota Century Code, Title 23, Chapter 23-09.2, §§23-09.2-01- 23-09.2-04).
Ohio	Statutory provision prohibiting the use of "honey" on a food label if the food is not honey. (Ohio Revised Code, Title XXXVII, Chapter 3715, §3715.38). Statutory provision governing the safety of milk (including raw milk). (Ohio Revised Code, Title IX, Chapter 917, §§917.01- 917.99). Statutory provision governing the safety of food in restaurants and other food service establishments.11 (Ohio Revised Code, Title XXXVII, Chapter 3717, §§3717.01- 3717.33).
Oklahoma	Statutory provision governing the safety of milk (including raw milk). (Oklahoma Statutes, Title 2, Article 7, §§2-7-402- 2-7-421). Statutory provision governing the safety of food in restaurants and other food service establishments.12 (Oklahoma Statutes, Title 63, Article 11, §11-1118).
Oregon	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Oregon Revised Statutes, Volume 13, Title 49, Chapter 616, §616.366). Statutory provision requiring food that has been "salvaged" to have a label stating that fact. (Oregon Revised Statutes, Volume 13, Title 49, Chapter 616, §616.250(16)).

11 May not be preempted by S. 3128 because part of Ohio Pure Food and Drug Law (Title XXXVII, Chapter 3715).
12 May not be preempted by S. 3128 because part of Oklahoma's Title 63, Chapter 1, Article 11

	Statutory provision governing the safety of milk (including raw milk). (Oregon Revised Statutes, Volume 13, Title 49, Chapter 621, §§621.003- 621.300). Statutory provision governing the safety of food in restaurants and other food service establishments. (Oregon Revised Statutes, Volume 13, Title 49, Chapter 624, §624.005- 624.992). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Oregon Revised Statutes, Volume 12, Title 37, Chapter 471, §471.551).
Pennsylvania	Statutory provision governing the safety of milk. (Purdon's Pennsylvania Statutes, Title 31, Chapter 13, §§645-660f). Regulatory provision governing the safety of food in restaurants and other food service establishments. (Pennsylvania Administrative Code, Title 28, Part II, Chapter 17, §§17-81-17.85). Statutory provision governing the use of "honey" on the label of a food that is not pure honey. (Purdon's Pennsylvania Statutes, Title 31, Chapter 9A, §382). Statutory provision prohibiting the sale of a confectionary containing more than ½ of one percent alcohol.13 (Purdon's Pennsylvania Statutes, Title 31, Chapter 1A, §20.3(13)). Statutory provision prohibiting the sale of a food containing eggs or egg products derived from a process wherein whole eggs are broken using a centrifuge-type egg breaking machine that separates the egg's liquid interior from the shell. 13 (Purdon's Pennsylvania Statutes, Title 31, Chapter 1A, §20.8(12)).
Rhode Island	Statutory provision permitting ingredients of carbonated beverages to be disclosed in an affidavit to the Director of Health. (Rhode Island General Laws, Title 21, Chapter 21-31, §21-31-11(9)(ii)). Statutory provision requiring packaging or labeling to comply with the regulations of the Poison Prevention Packaging Act. (Rhode Island General Laws, Title 21, Chapter 21-31, §21-31-11(13)). Statutory provision requiring disclosure of whether uncooked fish and shellfish have ever been frozen. (Rhode Island Food General Laws, Title 21, Chapter 21-31, §21-31-3(13)). Statutory provisions regulating packing of various kinds of fish in casks. (Rhode Island General Laws, Title 21, Chapter 21-15, §§21-15-3 *et seq.*).

13 May not be preempted by S. 3128 because part of Pennsylvania's Food Act (Title 31, Chapter 1A, §§20.1- 20.18).

	Statutory provision regulating labeling of closed packages of apples. (Rhode Island General Laws, Title 21, Chapter 21-18, §21-18-2). Statutory provision governing the safety of milk. (Rhode Island General Laws, Title 21, Chapter 21-2). Statutory provision governing the safety of food in restaurants and other food service establishments. (Rhode Island General Laws, Title 21, Chapter 21-27, §§21-27-1- 21-27-11.13). Regulatory provision that eggs, milk, and molluscan shell stock be cooled to no more than 41 degrees Fahrenheit. (Rhode Island Food Code, Chapter 3, §3-501.14 (c)).
South Carolina	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (South Carolina Code of Laws, Title 39, Chapter 25, §39-25-130(b)). Statutory provision governing the safety of milk. (South Carolina Code of Laws, Title 46, Chapter 49, §§46-49-10- 46-49-90). Statutory provision governing the safety of food in restaurants and other food service establishments. (South Carolina Code of Laws, Title 44, Chapter 1, §44-1-140(2)). Statutory provision governing the safety of shellfish (South Carolina Code of Laws, Title 44, Chapter 1, §§44-1-150- 44-1-155).
South Dakota	Statutory provision deeming confectionaries adulterated if they contact any vinous, malt, or spirituous liquor or compound or narcotic drug. 14 (South Dakota Codified Laws, Title 39, Chapter 4, §39-4-3(2)). Statutory provision requiring food label to disclose when food contains chloroform and various narcotics. (South Dakota Codified Laws, Title 39, Chapter 4, §39-4-10). Statutory provision governing the safety of milk (including raw milk). (South Dakota Codified Laws, Title 39, Chapter 6, §§39-6-1- 39-6-22). Statutory provision governing the safety of food in restaurants and other food service establishments. (South Dakota Codified Laws, Title 34, Chapter 18, §§34-18-25- 34-18-33). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (South Dakota Codified Laws, Title 35, Chapter 4, §§35-4-99- 35-4-100).

14 May not be preempted by S. 3128 because part of South Dakota's Food and Drug Law (Title 39, Chapter 4).

Tennessee	Statutory provision governing the safety of milk. (Tennessee Code, Title 53, Chapter 3, Part 1, §§53-3-101- 53-3-118). Statutory provision governing the safety of food in restaurants and other food service establishments. (Tennessee Code, Title 68, Chapter 14, Part 3, §§68-14-301- 68-14-323). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (Tennessee Code, Title 57, Chapter 1, Part 2, §57-1-211).
Texas	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Texas Health and Safety Code, Title 6, Chapter 431, §431.161(b)). Regulatory provision requiring that the internal temperature of potentially hazardous foods shall be no higher than 41 degrees Fahrenheit. (Texas Administrative Code, Title 25, Part 1, Chapter 229, Subchapter N, §229.219 (2)(C)(i)). Statutory provision governing the safety of milk. (Texas Health and Safety Code, Title 6, Chapter 435, §§435.001- 435.021). Regulations governing the safety of molluscan shellfish. (Texas Administrative Code, Title 25, Part 1, Chapter 241, Subchapter B, §§241.50-241.71) Regulatory provision governing the safety of food in restaurants and other food service establishments. (Texas Administrative Code, Title 25, Part 1, Chapter 229, Subchapter K, §§ 229.161- 229.177). Regulatory provision requiring a minimum chlorine residual of 0.5 mg./l in water being hauled (Texas Administrative Code, Title 25, Part 1, Chapter 229, Subchapter F, §229.83(3)(D).
Utah	Statutory provisions allowing the state to adopt tolerances for food additives and color additives that are more protective of human health than the applicable federal tolerances. (Utah Agricultural Code, Title 4, Chapter 5, §§4-5-17(3) - (5)). Statutory provision governing the safety of milk (including raw milk). (Utah Agricultural Code, Title 4, Chapter 3, §§4-3-1- 4-3-14). Statutory provision governing the safety of food in restaurants and other food service establishments. (Utah Health Code, Title 26, Chapters15 and 15a, §§26-15-l- 26-15a-107).

	Statutory provision governing the safety of bees and honey. (Utah Agricultural Code, Title 4, Chapter 11, §§4-11-1- 4-11-15).
Vermont	Statutory provision governing the safety of milk. (Vermont Statutes, Title 6, Chapter 151, §§2671- 2768). Statutory provision governing the safety of food in restaurants and other food service establishments. (Vermont Statutes, Title 18, Chapter 85, §§4301-4309). Statutory provision prohibiting the carrying of unwrapped bread if it is to be sold. 15 (Vermont Statutes, Title 18, Chapter 81, §4023). Statutory provision governing the labeling of maple products. (Vermont Statutes, Title 6, Chapter 32, §490).
Virginia	Statutory provision banning the use of sulfiting agents in restaurants. (Virginia Code, Title 35.1, Chapter 2, §35.1-14.1). Statutory provision governing the safety of milk. (Virginia Code, Title 3.1, Chapter 21, §§3.1-420- 3.1-425). Statutory provision governing the safety of food in restaurants and other food service establishments. (Virginia Code, Title 35.1, Chapters 1-5, §§35.1-1 to 35.1-28). Statutory provision governing shellfish safety (Virginia Code, Title 28.2, Chapter 8, §§28.2-800- 28.2-826).
Washington	Statutory provision governing the safety of milk (including raw milk). (Revised Code of Washington, Title 15, Chapter 15.36, §§15.36.002- 15.36.561). Statutory provision governing the safety of food in restaurants and other food service establishments. (Revised Code of Washington, Title 43, Chapter 43.20, §§43.20.050(2)(c) and 43.20.145). Statutory provision governing the safety of shellfish. (Revised Code of Washington, Title 69, Chapter 69.30, §69.30.050). Statutory provision requiring the posting of a sign in state liquor stores warning pregnant women of the risk of drinking alcoholic beverages. (Revised Code of Washington, Title 66, Chapter 66.16, §66.16.110). Statutory provision prohibiting the use of "honey" on a food if it is not pure honey. (Revised Code of Washington, Title 69, Chapter 69.28, §69.28.400(5)).

15 May not be preempted by S. 3128 because part of Vermont's Title 18, Chapters 81 and 82.

West Virginia	Statutory provision governing the safety of milk. (West Virginia Code, Chapter 19, §19-11A-1- 19-11A-10). Statutory provision governing the safety of food in restaurants and other food service establishments. (West Virginia Code, Chapter 16, §§16-6-3- 16-6-11). Statutory provision requiring the posting of a sign in bars and other establishments warning pregnant women of the risk of drinking alcoholic beverages. (West Virginia Code, Chapter 60, §60-6-25). Statutory provision prohibiting sale of soft drinks in certain schools at certain times. (West Virginia Code, Chapter 18, §18-2-6a).
Wisconsin	Statutory provision requiring label showing age of cheese made in Wisconsin. (Wisconsin Statutes, Chapter 97, §97.177(3)). Statutory provision requiring that a food containing whole fish flour bear a label saying it is made only from edible portions of fish. (Wisconsin Statutes, Chapter 97, §97.13). Regulations regarding processing of smoked fish and a warning label for smoked fish. (Wisconsin Administrative Code, Agriculture, Trade and Consumer Protection, Chapter ATCP 70, §§ATCP 70.21 *et seq.*). Statutory provision governing the safety of milk. 16 (Wisconsin Statutes, Chapter 97, §§97.20- 97.25). Statutory provision governing the safety of food in restaurants and other food service establishments. 16 (Wisconsin Statutes, Chapter 97, §§97.30(1)- 97.30(2).
Wyoming	Regulatory provision governing the safety of milk. (Regulations of Department of Agriculture, Chapter 3, §§8(a)(i)-(iii)). Statutory provision governing the safety of food in restaurants and other food service establishments.17 (Wyoming Statutes, Title 35, Chapter 7, Article 1, §§35-7-120, 35-7-123, 35-7-125).

16 May not be preempted by S. 3128 because part of Wisconsin's Chapter 97.
17 May not be preempted by S. 3128 because part of Wyoming's Food, Drug and Cosmetic Act (Title 35, Chapter 7).

QUESTIONS OF SENATOR JEFFORDS TO PANEL II

Question 1. I am concerned that S. 3128 would undermine Vermont's food labeling laws, particularly those that control what may or may not be labeled as maple syrup. Some testimony states that S. 3128 would only affect State warnings that address the safety of food. On most containers of Vermont maple syrup, the word "pure" is used, and is widely understood, to indicate an absence of impurities or pollutants. According to S. 3128, a "warning" is a direct or implied indication of a food's risk to health or safety. Would S. 3128, should it become law, prohibit Vermont from regulating what is considered "pure?"

Answer 1. Response not available.

Question 2. In Vermont, maple syrup must be "100 percent maple syrup which is entirely produced within the State of Vermont." According to the FDA, however, maple syrup may contain one or more "optional ingredients," including salt or chemical preservatives, as long as the optional ingredient is "safe and suitable." Since the FDA allows other ingredients to be present in maple syrup, and since this bill prohibits State food laws that result in "materially different requirements," would S. 3128 override Vermont's higher standards?

Answer 2. Response not available.

Question 3. When the FDA uses "safe and suitable" to describe a food ingredient, as it does with optional ingredients allowed for maple syrup, it seems that a judgment on that ingredient's healthfulness has been made. If S. 3128 prohibits States from issuing warnings about food safety, would this judgment by the FDA on an optional ingredient's healthfulness affect Vermont's ability to regulate the labeling of maple syrup or other maple products?

Answer 3. Response not available.

RESPONSE TO QUESTIONS OF SENATOR ENZI, SENATOR KENNEDY, AND SENATOR REED BY WILLIAM STADTLANDER

QUESTIONS OF SENATOR ENZI

Question 1. Your product, Wheatena, bears an FDA-approved health claim to the effect that Wheatena may help reduce the risk of cancer. At the same time, if I understand the situation correctly, you are being sued in California for failure to warn that your product contains a substance that causes cancer. Do I have that right?

Answer 1. Exactly right. The health benefits of whole grain cereals like Wheatena are well established. Indeed, the reason that Wheatena can make these claims is that FDA has rigorously reviewed the data and determined that fiber-rich whole grain foods like Wheatena may help reduce the risk of cancer.

Question 2. What would happen to your company and your employees if you had to pay out the $250,000 to settle the California Prop 65 law suit? What are your other options? Couldn't you just decide not to sell your product in California?

Answer 2. Homestat Farm is a small company. Having to pay that kind of money to settle a lawsuit would have a huge impact on my ability to continue offering healthy products to consumers and jobs to my employees.

As I understand them, my options in this litigation are to pay to settle these claims or to pay my attorneys to defend me in court. Since Proposition 65 puts the burden on defendants, winning this case (and I'm confident that I will win) will cost a tremendous amount of money that will be lost to my company forever because I can't get it back from the people who are bringing these claims against me.

These costs won't necessarily go away even if I agreed to put a cancer warning on my product or to pull the products off California shelves. In fact, I'm told that some plaintiffs (even the California Attorney General) could sue me if someone sold the product in California without my authorization, *even if I tried my best to prevent that from happening*.

Therefore, I could be forced to put a warning on the product, regardless of where it is sold. Aside from the injury to my business, that warning could discourage consumers in all 50 States from eating these products and deprive them of these well established benefits, all in order to give warnings about miniscule amounts of a naturally created chemical that poses little or no risk to people.

Question 3. In your testimony, you stated that Wheatena has been sold since 1879. Have you changed the way you make Wheatena since it was first marketed? If you have not, doesn't that suggest there has been acrylamide in Wheatena for over 100 years?

Answer 3. Wheatena is and always has been a pure and simple product—toasted wheat. Of course, people have been eating roasted, toasted, and baked wheat- and grain-based products for hundreds if not thousands of years. Since these basic cooking methods create acrylamide, you're right that it's been part of the human diet all of that time.

In addition, calcium has been added for building strong bones.

QUESTIONS OF SENATOR KENNEDY

Question 1. Wheatena.—You state on page 3 of your testimony that "FDA specifically determined that Wheatena may reduce the risk of cancer." This statement surprises me, because FDA health claims don't typically identify a specific food product,

but instead talk about food types, or foods that contain certain substances, usually as part of a certain diet, as reducing the risk of a disease.

For example, a health claim under 21 CFR 101.76 relates the risk of cancer to low fat diets rich in fiber-containing grain products, fruits, and vegetables. The health claim under 21 CFR 101.77 is similar: it relates the risk of heart disease to diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly dietary fiber.

Could you please provide the committee with a copy of, or citation to, the document in which FDA "specifically determined that Wheatena may reduce the risk of cancer?"

Answer 1. FDA has specifically determined that fiber-rich grain products are components of a healthy diet associated with a reduced risk of cancer. 21 CFR § 101.76(a)(2). Wheatena is a fiber-rich grain product.

There are many other cereals as components of a healthy diet that reduce the risk of cancer.

Question 2. Status of Acrylamide.—The following are some statements from the FDA Action Plan for Acrylamide in Food, March 2004 (*http://www.cfsan.fda.gov/dms/acrypla3.html*):

> "[A]crylamide is a potential human carcinogen and genotoxicant, based on high-dose animal studies, and a known human neurotoxicant."
>
> "Acrylamide causes cancer in laboratory animals in high doses. As a result, acrylamide is considered a potential human carcinogen. However, it is not clear whether acrylamide causes cancer in humans at the much lower levels found in food. Scientists have conducted epidemiological studies of people exposed to acrylamide in the workplace and through the diet. The studies did not show increased cancer risk with acrylamide exposure. However, these studies do not rule out the possibility that acrylamide in food can cause cancer because they have limited power to detect this effect. Also, we do not have enough information to rule out the possibility that subtle effects can occur on the developing nervous system at acrylamide doses lower than those that have been studied so far in animals and humans."
>
> "In June 2002, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) convened an expert consultation on acrylamide. The consultation, in which three FDA experts participated, concluded that the presence of acrylamide in food is a major concern, and recommended more research on mechanisms of formation and toxicity. Both the WHO/FAO consultation and the FDA have recommended that people continue to eat a balanced diet rich in fruits and vegetables. The WHO/FAO consultation advised that food should not be cooked excessively, i.e., for too long a time or at too high a temperature, but also advised that it is important to cook all food thoroughly—particularly meat and meat products—to destroy foodborne pathogens (bacteria, viruses, etc.) that might be present."

The FDA Web site (*http://www.cfsan.fda.gov/dms/acrydata.html*) also includes reports on its sampling of foods with acrylamide, and FDA tested Wheatena three different times as having 1057, 689, and 467 ppb acrylamide. Although some foods had higher levels than these—some considerably higher—most foods tested had much lower levels.

Considering these statements and assuming there were foods that provided the nutritional benefits of Wheatena that contain less acrylamide than does Wheatena, do you believe that a consumer could reasonably choose to eat the other foods and not eat Wheatena? How do you think a consumer who might consider these statements relevant to a decision to eat Wheatena or not should be informed of such statements?

Answer 2. As FDA has pointed out, people who are frightened away from eating certain foods because of an acrylamide warning will not necessarily substitute foods that are more wholesome or healthful. In the case of Wheatena, they almost certainly would not (since there aren't many more healthful foods around).

Wheatena offers the following nutritional benefits:

- All Natural, High Fiber (25 percent more fiber than the leading brand), Low fat, Cholesterol free, Sodium Free, Calcium fortified;
- Wheatena is Heart Healthy, Bone Healthy and May reduce the risk of cancer;

Healthy whole grain cereals, breads and bagels contain acrylamide.

More importantly, the numbers you mention are expressed in parts per billion—these amounts are *extremely small*. FDA has said that the levels of acrylamide present in foods as the result of cooking do not warrant a change in diet. Differences between the levels present in my products and others on the market are therefore

so insignificant that they simply do not provide any meaningful information regarding differences in actual risk. These warnings don't help consumers choose one product over another based on a comparison of such small numbers, they do the opposite—they mislead.

The levels of acrylamide in Wheatena are smaller than the FDA reports based on our testing through an independent lab. In addition, Wheatena was tested in raw form versus mixed with a liquid to make hot cereal and Wheatena's serving size is 24 percent greater than other hot cereals.

Question 3. Acrylamide Labeling.—In your testimony on page 2, you say, "I know now that FDA actually says there should not be warnings on foods just because they contain acrylamide." I'm not aware of any statement to that effect from the agency—certainly not a formal advisory opinion. Would you please submit for the record any information that you have suggesting the FDA took a formal position on the issue, including any written statement from FDA?

Answer 3. Representatives of FDA have twice written to government agencies in California indicating that Proposition 65 warnings on foods based on acrylamide are unwarranted and may confuse consumers or conflict with Federal policy. The first was a July 14, 2003 letter from acting director Lester Crawford to the director of the California Environmental Health Hazard Assessment. This view was recently reiterated in a March 21, 2006 letter from the FDA's Dr. Terry Troxell to the California Deputy Attorney General Ed Weil.

Question 4. Regulations adopted under Proposition 65 provide that a warning need not be given for a chemical that causes cancer where "sound considerations of public health" support using a standard more favorable to businesses.

1. Were you aware of this provision prior to your testimony?
2. Have you done anything to raise this issue in your case?
3. Do you plan to follow-up on this provision and potentially use it in the future?

Answer 4. I am aware of this provision, and it is among the defenses that make me confident that the claims in the lawsuit against my company are without merit. However, proving it will require me to hire expert witnesses to develop a risk assessment and to engage in a "battle of experts" with the plaintiff if my case goes to trial. These things are enormously expensive, particularly for a small business such as mine.

QUESTIONS OF SENATOR REED

Question 1. Food Manufacturing Facility Inspections.—As a food manufacturer, you are inspected regularly by a variety of different State and Federal agencies. How often are you inspected by State entities and how often does the FDA come to inspect your manufacturing sites presently?

Answer 1. I can not speak to either State or Federal inspections prior to my ownership of Homestat Farm, however, in the nearly 5 years of ownership the FDA has conducted one inspection resulting in the FDA inspector stating the facility "looked good." While I am in compliance with State requirements, no State inspection has taken place since I have owned the company.

Question 2. Acrylamide.—I understand that acrylamide is a naturally occurring substance contained in Wheatena as well as numerous other products consumed by millions of Americans. Does the amount of acrylamide contained in Wheatena differ from similar products? Does the California law or its regulations specify a particular threshold for consumption of acrylamide, and if so, how does Wheatena measure up to that standard?

Answer 2. As I've stated, there are differences between the concentrations found in one food product or another (and between one sample and another of the *same* food product). However, because the numbers are so small, the differences between them are immaterial and do not provide a sound basis for choosing between one product and another.

The appropriate warning threshold for acrylamide in foods is one that is supported by sound considerations of public health. For all of the reasons I've discussed here and in my testimony before the committee, I am confident that sound considerations of public health support a warning threshold that does not require warnings that could scare people away from foods that they have been eating for hundreds of years without ill effect.

Acrylamide is a naturally occurring substance and is in approximately 40 percent of the food people consume. Many of these products are considered healthy by the FDA and nutritionists. Toasters, microwaves and ovens all create acrylamide when starches and carbohydrates are cooked. In addition, coffee contains acrylamide. As

a result of small quantities of naturally occurring acrylamide in food, and the total percent of foods with acrylamide I do not believe there should be any acrylamide warning.

RESPONSE TO QUESTIONS OF SENATOR ENZI, SENATOR KENNEDY, SENATOR HARKIN, SENATOR REED, AND SENATOR CLINTON BY PETER BARTON HUTT

QUESTIONS OF SENATOR ENZI

Question 1. How do you respond to the charges that suggest State officials have the primary responsibility for protecting the food supply and that this legislation would impair their ability to ensure the safety of the food supply?

Answer 1. Under the Federal Food and Drugs Act of 1906 and then the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938, Congress has entrusted to FDA the primary responsibility for protecting the nationwide food supply for the past 100 years. Under State and local food and drug laws, State and local officials are given the primary responsibility for protecting the food supply within their own local jurisdictions. Thus, regulation of the food supply necessarily requires a cooperative and collaborate approach between Federal and State officials. In order to have a nationwide food supply, one nationwide policy must be established to govern both the labeling and the safety of our food. That policy can then be implemented at both the Federal and State levels. Permitting every State and local jurisdiction to have their own conflicting and inconsistent rules would destroy interstate commerce in food and directly violate the intent of Congress in establishing FDA with primary jurisdiction over nationwide food issues.

As the National Uniformity for Food Act recognizes, however, there are food issues that are essentially local in nature. These include, as examples, regulation of milk, shellfish, and restaurants. That is the reason why the National Uniformity for Food Act excludes these type of local activities from the requirement of national uniformity. The cooperative Federal/State/industry/academic programs that cover these local issues will not in any way be affected. It is only nationwide issues that are subject to the requirement of national uniformity, and the legislation makes it clear that every State and local jurisdiction will retain full authority to enforce compliance with nationwide policy on a local level.

Question 2. Your testimony mentioned that there were only six petitions for an exemption under NLEA. What process did NLEA use for petitions? It has been suggested that the Citizen Petition process would be used under the National Uniformity for Food Act, but I don't see that requirement anywhere in the legislation. Could FDA use a different process?

Answer 2. As enacted by the Nutrition Labeling and Education Act (NLEA) of 1990, Section 403A(b) of the FD&C Act provides that a State or political subdivision may petition FDA for an exemption from national uniformity. FDA has by regulation established a form in 21 CFR 10.30(b) for all citizen petitions, regardless of the subject matter. Because the NLEA did not specify any particular form to be used for an exemption petition, the form established by FDA in 21 CFR 10.30(b) was used for the six submitted petitions. It is reasonable to anticipate that FDA would use the same form for exemption petitions under the National Uniformity for Food Act. The process that FDA uses in considering such petitions is also established by FDA in its administrative regulations set forth in 21 CFR Subpart B. FDA could lawfully adopt a different process if it chose to do so, but it is standard FDA practice to use the forms and procedures set forth in 21 CFR Part 10 except in unusual circumstances where a more detailed or targeted petition may be appropriate.

Question 3. There has been considerable disagreement about the number of State laws that would or would not be preempted by this proposed legislation. I have heard numbers ranging from 11 to 240. While I have heard a lot of back and forth about which number is right, and whether a particular law would or would not be preempted, I have not heard anything definitive about the sources of the confusion. For example, some have suggested the definition of "identical" is unclear. Others have indicated that the problem lies with distinguishing between a State law and a State regulation. Please discuss what you believe to be the sources of disagreement and confusion in this debate, and any suggestions or recommendations to clarify the proposed language.

Answer 3. There are a number of reasons for the disagreement regarding the number of State laws that would be affected by the National Uniformity for Food Act.

First, the people who oppose the legislation argue that it would affect a very large number of State laws, hoping that this will give strength to their argument. They

contend that the bill is ambiguous and thus could have a very broad impact on State laws. On not one occasion, however, have these critics ever suggested ways that the language could be improved and clarified. Their strategy, instead, is simply to repeat vague allegations and not to respond to requests for specific details.

Second, an analysis of the list of 240 State laws that would supposedly be affected by the legislation demonstrates in detail why in fact only 11 State laws would be affected. The proof of the validity of this analysis lies in the fact that the critics who have put forth the list of 240 State laws have been unable to respond substantively to the analysis which shows their list to be inaccurate. If their list was accurate, they would have responded.

Third, the definition of the word "identical" is a good example. In response to criticism that this word was not defined, Senator Burr added a specific definition in order to make clear that it requires only that the State law be substantially the same as the Federal law and that any differences in language do not result in the imposition of materially different requirements. Nonetheless, the critics continue to say the provision is ambiguous—but, importantly, offer no clarifying language. The purpose of the critics is simply to oppose the legislation, not to offer meaningful clarifying language.

Fourth, the problem does not lie with distinguishing between a State law and a State regulation. A State regulation cannot exceed the authority granted by a State law. Because a State regulation only implements a State law, the National Uniformity for Food Act refers only to the State laws themselves and not to the various regulations promulgated to implement them.

Fifth, the only suggestion I have to clarify the proposed language would be for the committee to request all of the critics of the legislation for their suggestions to clarify the language of the bill in order to implement—not change—the stated purpose of the legislation. I believe this would quickly reveal that the purpose of the critics is to defeat the legislation, not to clarify it.

Sixth, part of the confusion is also caused by the fact that critics either do not read or do not wish to understand the clear words of the bill. For example, William Hubbard, who appeared before the committee and initially criticized the legislation, later admitted that he had not read the bill at all. He relied upon the March 1, 2006 letter from the National Association of Attorneys General raising concerns about 10 specific examples of State laws that would be affected. I am attaching an analysis of those 10 examples which demonstrates that none of them is valid. NAAG simply failed to conduct the research and analysis necessary to understand the provisions of the legislation.

NATIONAL UNIFORMITY FOR FOOD ACT

ANALYSIS OF CONCERNS RAISED BY THE NATIONAL ASSOCIATION OF ATTORNEYS GENERAL LETTER OF MARCH 1, 2006

In a letter dated March 1, 2006, the National Association of Attorneys General (NAAG) raised 10 specific concerns about H.R. 4167, the National Uniformity for Food Act, which would amend the current national uniformity provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). A close review of these 10 concerns, however, reveals a serious misunderstanding of the impact of the National Uniformity for Food Act on the authority of States to regulate the food supply. The following analysis corrects the record and demonstrates that the National Uniformity for Food Act would have none of the consequences that were erroneously alleged in the NAAG letter.

1. *Mercury in fish.*—The NAAG letter states in two places that the national uniformity legislation would prevent a State from requiring a consumer warning with respect to the mercury content in tuna fish. The letter fails to point out that FDA has determined—and sent a letter to California explicitly stating its determination—that there is no valid scientific or public policy basis for such a warning. On April 7, 2006, the San Francisco Superior Court issued an opinion in *California* v. *Tri-Union Seafoods*, LLC concluding that mercury is naturally occurring throughout the environment, that it does not present a significant human risk at the levels involved, that the FDA determination to handle the matter through consumer advisories rather than safety warnings must be given deference in California, and therefore that there is no legal basis for the consumer warnings proposed by the State. Accordingly, the example of mercury in fish simply reinforces the legal and factual basis for the National Uniformity for Food Act.

2. *Arsenic in drinking water.*—The NAAG letter states that the national uniformity legislation would remove the authority of a State to require a warning about the level of arsenic in drinking water. This is incorrect, because the national uni-

formity legislation does not involve the regulation of drinking water in any way. The legislation only covers food regulated by FDA. Regulation of drinking water is handled by EPA, not FDA. Accordingly, consumer warnings about arsenic in drinking water are not affected by the national uniformity legislation. Research has uncovered no State law requiring a consumer warning about arsenic in drinking water.

3. *Lead in cans used to package food.*—The NAAG letter states that the national uniformity legislation would prevent a State from requiring consumer warnings about the lead content in cans used to package food. This is incorrect, because FDA banned lead soldered food cans more than a decade ago. 21 CFR 189.240. FDA also banned lead foil for wine bottles a year later. 21 CFR 189.301. California is the only State that has an explicit law permitting the continued use of lead foil for wine bottle closures.

4. *Arsenic in bottled water.*—NAAG argues that the National Uniformity for Food Act takes away from the States the authority to require consumer warnings about arsenic in bottled water. This is incorrect, because FDA regulates the amount of arsenic permitted in bottled water under a standard of identity promulgated by the agency. 21 CFR 165.110(4)(i)(A). Under the national uniformity provisions of the Nutrition Labeling and Education Act of 1990, this FDA standard of identity is already subject to national uniformity. 21 U.S.C. 343-1(a)(1).

5. *Lead in ceramic tableware.*—The NAAG letter contends that the national uniformity legislation would prevent a State from requiring consumer warnings about lead in ceramic tableware. Following a landmark court decision holding that FDA has jurisdiction over lead in ceramic tableware, the agency has established and enforced stringent regulations and action levels governing the migration of lead from food utensils and ceramic ware, 21 CFR 109.16, and has determined that the trace amounts of lead that do migrate are safe and should not be the subject of consumer warnings.

6. *Alcohol in candy.*—The NAAG letter contends that a State will be precluded from consumer warnings about the alcohol content of candy within its jurisdiction. This is incorrect, for two separate reasons. First, the provisions regarding the regulation of alcohol in candy, under Section 402(d) of the FD&C Act, 21 U.S.C. 342(d), explicitly state that each State is permitted either to ban or permit the use of alcohol in candy. Second, the national uniformity legislation does not cover this provision of the FD&C Act. Thus, the pending legislation would not change current law with respect to the authority of a State to require a consumer warning about the alcohol content of candy within its own borders. Research has uncovered no State law that requires such a warning.

7. *The fat and oil content of a food.*—The NAAG letter states that the national uniformity legislation would take away the right of a State to require a consumer warning about the fat and oil content of food. This is also incorrect, for three reasons. First, to the extent that the NAAG letter relates to the labeling of the content of fat and oil in food, the national uniformity legislation does not cover this subject. The labeling of food ingredients and nutrients is subject to national uniformity that was enacted by Congress in the Nutrition Labeling and Education Act of 1990, 21 U.S.C. 343-1(a). Second, to the extent that the NAAG letter relates to regulating the safety of the content of fat and oil in food, because FDA has no specific regulation governing these matters States would be free to impose safety limitations under their own State statutes in compliance with new section 403A(c)(3) unless and until FDA issued its own contrary determination. Third, to the extent that the NAAG letter relates to consumer safety warnings about the safety of fat and oil in food, new section 403B(a)(3) explicitly preserves the right of any State to issue any consumer warning that it determines appropriate although it cannot require the food industry to disseminate such warnings unless it obtains FDA approval of a local exemption or a new national standard. Research has uncovered no State law governing the safety or consumer warnings relating to the fat and oil content of food.

8. *Post-harvest pesticide application to fruits and vegetables.*—The NAAG letter argues that the national uniformity legislation would take away the authority of a State to require consumer warnings about post-harvest pesticide applications to fruits and vegetables. This is incorrect, because FDA has no statutory authority to establish pesticide tolerances or require consumer warnings about pesticide residues. EPA has sole jurisdiction over pesticides, under Section 408 of the FD&C Act, 21 U.S.C. 346a, and this provision is not covered by the National Uniformity for Food Act. National uniformity has already been established for pesticides under the Food Quality Protection Act of 1996, 21 U.S.C. 346a(n). Accordingly, the national uniformity legislation has no impact on the authority of a State to require warnings about post-harvest pesticide applications to food.

9. *False claims of health benefits.*—The NAAG letter states that the national uniformity legislation would eliminate the ability of a State to regulate false claims re-

lating to the health benefits of food. This is incorrect, because the national uniformity legislation only covers safety warnings, and does not in any way relate to claims for the health benefits of food. Congress enacted national uniformity governing claims for the health benefits of food as part of the Nutrition Labeling and Education Act of 1990, 21 U.S.C. 343-1(a)(5). Accordingly, the current legislation has no impact on this matter.

10. *Inadequate warnings for children.*—Finally, the NAAG letter argues that the national uniformity legislation will prevent a State from imposing adequate warnings for children with respect to food products. The letter gives no specific examples of appropriate warnings that are not already required by FDA, and cites no State law or regulation that imposes such warnings. The NAAG letter also fails to recognize that new section 403B(c)(3)(C) of the legislation would grant expedited consideration by FDA to any State petition for a local exemption or a national standard governing warnings that could affect the health of children. Thus, the pending legislation fully recognizes the importance of any appropriate warnings to protect the health of children.

QUESTIONS OF SENATOR KENNEDY

Question 1. Implied Warnings.—Under the bill, a warning includes a statement "that indicates, directly or by implication," that the food presents or may present a hazard to health or safety.

In a notice published in the Federal Register in February 1994, FDA stated:

> "[T]he concept would better be formulated as 'from cows not treated with rbST' or in other similar ways. However, even such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading."

Farm-raised salmon has more PCBs than wild salmon. Therefore, by the reasoning FDA applied to statements about mild from rbST treated cows, a statement that salmon is farm-raised implies that the fish may be less safe than wild salmon, and is a warning under this bill. Do you agree? If not, why not? Please explain what "by implication" means? Why won't a food industry lawyer at least be able to argue that "farm-raised" is an implied statement about safety?

Answer 1. Under the National Uniformity for Food Act, not all statements regarding the origin or composition of food are subject to national uniformity. Simple statements that provide information to consumers without in any way stating or implying that the food presents or may present a hazard to health or safety are not included within this legislation. Thus, a statement that is not in the nature of a warning is not covered by the legislation.

Your question raises two examples: "From cows not treated with rbST" and "farm-raised salmon." Taken by themselves, without a negative context, neither of these statements is in the nature of a warning. For the same reason, "contains no caffeine" on a soft drink or any other of a large number of other "avoidance"statements do not, by themselves, inherently imply a warning. An avoidance statement is intended to appeal to people who, for whatever reason, do not wish to ingest a given type of substance or product. People have widely variable reasons for preferring substances or food products, wholly apart from safety reasons. Providing truthful, accurate, and nonmisleading information about food is therefore useful to consumers who wish to be able to make informed decisions in the marketplace.

Any of these types of avoidance statements can, on the other hand, quickly be turned into safety warnings if the context is different. If the statement about rbST were conjoined with safety concerns or if the issue of PCBs were directly raised with regard to farm-raised salmon—or if the safety of caffeine is questioned in conjunction with a statement that a soft drink contains no caffeine—the result would be a warning. Thus, this legislation unequivocally preserves the right of a consumer to obtain accurate and nonmisleading information about the composition of the food supply without confusing consumers about warnings that are not imposed on a national basis.

Question 2. Preemption Defense.—Under the proposed section 403A(c)(1) in the Federal Food, Drug, and Cosmetic Act (page 2 of the bill), every time language in a State requirement does not use exactly the "same language" as the comparable provision under the Federal Food, Drug, and Cosmetic Act, a food company lawyer will be able to argue that the State provision is not "substantially the same language" or that the "differences in language . . . result in the imposition of materi-

ally different requirements," especially when there is no FDA standard for the substance at issue.

In fact, a food company lawyer would likely be committing malpractice not to use a preemption defense in such a State enforcement action following passage of S. 3128 if his or her client wanted him or her to do so. Food company lawyers would even potentially try to remove the cases to Federal court. How do you respond?

Answer 2. The FD&C Act is filled with broad and general terminology that is designed to achieve the statutory purpose. Indeed, there is no regulatory statute in American history for which this is not true. For example, Section 402(a)(1) of the FD&C Act states that a food is deemed adulterated if it bears or contains "any poisonous or deleterious substance which may render it injurious to health." Section 403(a)(1) of the FD&C Act states that a food is deemed to be misbranded if its labeling is "false or misleading in any particular." The language in these two provisions is far broader and less clear in its scope and impact than is the definition of "identical" in the National Uniformity for Food Act. In fact, the statutory terms for adulteration and misbranding are not defined at all, whereas the statutory term "identical" is defined in a very clear and precise way. A State statute will be deemed identical if it uses substantially the same language and there is no materially different requirement. Compared to other provisions in the FD&C Act, the intent is extremely clear and the courts should have no difficulty whatever in implementing it.

Question 3. Guidance Documents.—Section 701(h) of the Federal Food, Drug, and Cosmetic Act states that guidance documents are "not binding on the Secretary" and requires that guidance documents indicate their "nonbinding nature."

S. 3128 doesn't change that guidance documents aren't binding on FDA or the industry. But it says that guidance documents are binding on States and localities, because they may only enforce a State requirement when it "conforms" to an FDA guidance.

Under this bill, a company is not required to comply with a guidance document but a State can only act if it is alleging that the company hasn't complied with the guidance. Could you please explain why a State or locality should be bound by a guidance document that binds neither the FDA nor a food company?

Answer 3. There are two answers to your question.

First, if there is no FDA regulation or guidance, a State is entirely free to implement a statutory provision that is identical to the same provision in the FD&C Act in any way that it believes is justified. Thus, a State requirement imposed under a State statute identical to the Federal statute is completely lawful unless FDA has taken a contrary position in a regulation or guidance.

Second, Section 701(h) of the FD&C Act explicitly states that guidance documents "present the views" of FDA on matters under its jurisdiction. It requires FDA to ensure that agency employees do not deviate from such guidances without appropriate justification and supervisory concurrence. Thus, as FDA has often said, guidance documents represent the enforcement position of the agency. The agency deviates from them only on rare occasions and under unusual circumstances.

FDA guidance documents therefore represent national policy. They establish tolerances for food contaminants that the agency intends to enforce in court and related food safety and labeling positions that represent national policy established by the agency designated by Congress as the primary regulatory agency for our nationwide food supply.

Although a guidance is not legally binding in the way that a statute or regulation is binding, it nonetheless represents FDA enforcement policy. It is rare that a company would willfully violate such a guidance. It is an informal substitute for a formal regulation. FDA uses guidances rather than regulations in situations where the formal procedures now required for promulgating regulations make that form of policy statement infeasible. A guidance represents FDA nationwide policy, however, and thus States should follow it or should petition FDA to change it. If States were permitted to ignore FDA guidance, FDA would be required to promulgate many more regulations in order to assure national uniformity, thus making regulation far more costly and difficult.

Question 4. Seafood HACCP.—In 1995, the FDA issued final regulations under both section 402(a)(1) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act to ensure the safe and sanitary processing of fish and fishery products, known as Seafood HACCP, for Hazard Analysis and Critical Control Point.

S. 3128 gives preemptive effect to section 402(a)(1) and it gives no preemptive effect to section 402(a)(4). So what is the effect of the HACCP regulations, which were issued under both of these statutory requirements? It seems that any State that has

a safety standard of any sort related to fish, including shellfish, is preempted by this FDA regulation, because those State standards are obviously not identical to the FDA HACCP regulation. In any case, there is some real ambiguity here that a food industry lawyer could exploit, isn't there?

Answer 4. The seafood HACCP regulations codified in 21 CFR Part 123 are unquestionably directed at the safety of seafood, to implement Section 402(a)(1) of the FD&C Act. As often occurs, FDA included the sanitation provisions of section 402(a)(4) as additional statutory justification for these regulations. Even if FDA had not cited section 402(a)(4), however, all of the regulatory requirements in part 123 would be fully justified. Accordingly, to the extent that any State enacts a competing or different seafood HACCP regulation, it could not lawfully be enforced. This would be true whether the State law sought to increase or reduce the seafood HACCP requirements. Thus, consumers throughout the country are assured of a comprehensive, nationally-applicable HACCP regulation protecting the safety of seafood products.

You ask whether any State that has a safety standard of any sort related to fish is preempted by this regulation. The answer is that in some circumstances it would be and in some circumstances it would not. Such a State law would be subject to national uniformity if it attempted to reduce or increase safety requirements addressed by part 123. If it addressed other issues relating to fish, however, national uniformity would not apply. For example, the National Shellfish Sanitation Program (NSSP) is not subject to national uniformity. The NSSP program has been implemented for years under the authority of the Public Health Service Act, not the FD&C Act. And the National Uniformity for Food Act explicitly provides that shellfish warnings established under the Food Code are not subject to national uniformity. Thus, there is no ambiguity on what aspects of FDA regulations governing seafood are and are not subject to the pending legislation.

Question 5. Preemption of Proposition 65.—Mr. Hutt, on page 6 of your written testimony, you say that it is a "conspicuous anomaly" and an "historic accident" that there is not uniformity for foods, as there is for other products, such as nonprescription drugs, cosmetics, nutrition labeling, and pesticides. You seem to think the main point of this bill is to pre-empt California's Proposition 65. It is therefore interesting to note that both the Reagan and Bush I administrations opposed preemption of Proposition 65. It is therefore not an "accident" that Proposition 65 is not preempted.

Nor is it an anomaly, as consideration of the preemptive actions of Congress makes clear. When Congress gave preemptive effect to FDA's regulation of over-the-counter drugs, cosmetic packaging and labeling, pesticides, and nutrition labeling, it always protected Proposition 65.

Sections 751 and 752 of the Federal Food, Drug, and Cosmetic Act, as added in 1997, include the following provision:

> "This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997."

In fact, Congress added this provision to protect California's Proposition 65 from preemption.

Similarly, paragraph (8) of the pesticide preemption provision, section 408(n) of the Federal Food, Drug, and Cosmetic Act, says:

> "Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide residue in or on such food."

Again, Congress protected Proposition 65 from preemption.

Finally, section 6(c)(2) of the Nutrition Labeling and Education Act states:

> "The amendment made by subsection (a) and the provisions of subsection (b) [both of which provided for preemption of certain State laws] shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food."

Once again, Congress protected Proposition 65.

With respect to prescription drugs, Congress has never given preemptive effect to FDA regulation. It is true that Congress gave preemptive effect to FDA regulation of medical devices in section 521 of the Federal Food, Drug, and Cosmetic Act, but the effect of this provision is still being debated, and besides, it was passed in 1976, before the citizens of California adopted Proposition 65 by referendum in 1986. It cannot be argued that Congress explicitly intended section 520 to preempt a proposition that California had not yet adopted. Certainly, as the Senate author of the

1976 medical device legislation, it was not my intent to preempt Proposition 65 (nor any State product liability claims, for that matter).

You argue that Congress should preempt Proposition 65 because you suggest it has done so in the past, when in fact Congress has not. Please comment.

Answer 5. I have not stated, and I do not believe, that the "main point" of this legislation is to preempt California Proposition 65. The purpose of the legislation is to establish national policy regarding food safety in general and food warnings in particular. It is intended to make certain that every citizen of our country, wherever located, has access to the same safe and wholesome food that is clearly and conspicuously labeled with whatever warnings are appropriate. Uniformity in food warnings is uniquely important because of the consumer confusion that would result if each State imposed its own separate and different system of warnings.

The lack of uniformity in regulating food under the FD&C Act is indeed an anomaly. When the Association of Official Agricultural (now Analytical) Chemists (AOAC) was formed in 1884, its constitution stated that the objectives were "to secure, as far as possible, uniformity in legislation . . . and uniformity and accuracy in the methods and results" of analysis. When the Association of Food and Drug Officials (AFDO) was formed in 1897, the constitution of the new organization stated that its purpose was "to promote uniformity in legislation and rulings." In 1898, the Chief of the USDA Food Laboratory (which later became part of FDA) stated that national legislation was needed because, "By no other means can we hope to secure laws uniform in their scope, requirements and penalties." The Director of the Bureau of Chemistry of the New York State Department of Health stated in 1903 that "uniformity in our food laws is much to be desired." Indeed, the House Report on the Food and Drugs Act of 1906 stated that:

> "The laws and regulations of the different States are diverse, confusing, and often contradictory. . . . One of the hoped-for good results of a national law on the subject of pure foods is the bringing about of a uniformity of laws and regulations on the part of the States within their own several boundaries."

Similarly, the 1935 Senate Report on the legislation that ultimately became the FD&C Act of 1938 expressly recognized the importance of enacting legislation that would result in greater uniformity between Federal and State requirements.

Your question does not reflect the fact that numerous laws have been enacted by Congress to achieve national uniformity in the regulation of food products as well as in the regulation of other products subject to FDA jurisdiction. These laws include the statutes that govern meat, poultry, and eggs, the packaging and labeling requirements for all food, and the misbranding provisions for food enacted under the Nutrition Labeling and Education Act of 1990. It also includes such other areas as medical devices. Most recently national uniformity was included in the Food Allergy Labeling and Consumer Protection Act of 2004, which you supported.

As you point out, California Proposition 65 was excluded from three other provisions of law. These provisions were the result of political compromise in order to expedite pending legislation. They represent extremely unwise public policy. In effect, they permit one State to dictate food safety requirements for the rest of the country. The mistakes made in that prior legislation should not be repeated.

Question 6. Local Requirements.—I'd like you to explain why the bill completely preempts localities from enforcing local requirements, even those that are identical to Federal requirements.

Paragraphs (2), (3), and (4) of the proposed section 403A(c) (pages 2 and 3 of the bill) say when a State or political subdivision of a State may or may not enforce a State law, but they don't say when the law of a political subdivision may be enforced. Similarly, the proposed section 403B(a)(3) (page 5) permits States to act under certain State authorities, but it doesn't say that a locality may act under its own, comparable authorities.

Proposed section 403B(b) (pages 6–9) provides for the review of preempted State requirements, but not preempted local requirements. Proposed section 403B(c) (pages 9–12) allows States to petition for exemptions and national standards, but not localities. Proposed section 403B(d) (pages 12–14) gives States a so-called imminent hazard authority, but not localities.

S. 3128 completely preempts local laws that are not identical to Federal requirements, and it blocks localities from enforcing local laws that are identical. Why?

Answer 6. The National Uniformity for Food Act does not completely preempt localities from enforcing local requirements that are identical to Federal requirements.

Section 403B(a)(1) explicitly provides that any political subdivision of a State may enforce a local food safety warning that is identical to a Federal warning. Section 403A(c) also explicitly provides that a political subdivision of a State may enforce

a State law that contains a requirement that is identical to a Federal requirement. I am unaware of any situation where a local jurisdiction within a State has enacted a law governing food safety that is identical to the Federal law but for which there is no comparable State law. Your question does not identify any such situation, nor has AFDO or other interested organizations stated that this has ever occurred. Perhaps that is the reason why Senator Burr has not covered this hypothetical situation in the legislation.

Nonetheless, there is a simple answer to this hypothetical question. If the local jurisdiction has identified a provision of Federal law governing food safety that has no State counterpart and has enacted its own identical provision on a local level, it will be quite simple for that local jurisdiction to persuade the State to enact it into State law. Once that is done, it may be enforced by both State and local officials.

Finally, the National Uniformity for Food Act funnels all State issues relating to FDA review, petitions for exemption, national standards, and imminent hazard action, through the appropriate State officials rather than through each individual local jurisdiction, for several reasons. First, as already stated, no one has thus far identified the type of local laws that you hypothesize in this question. Second, it is sound public policy to require each State to coordinate whatever petitions may be appropriate within its own jurisdiction, rather than to have a variety of viewpoints expressed by different local authorities. For the same reasons that uniformity is appropriate at the Federal level on nationwide issues, it is equally justified at the State level on statewide issues. Assuming that there are local laws governing food safety that are not applicable on a statewide basis, the State has an interest in assuring both that those laws are appropriate and that they should be advanced either as an exemption or as a national standard.

Question 7. The Effect of Proposition 65.—On pages 14–15 of your testimony, Mr. Hutt, you state that California's Proposition 65 "has resulted in a veritable flood of warnings in restaurants, bars, grocery stores, hotel lobbies, and elsewhere, as well as major litigation about its applicability to various food products."

The implication of this statement is that Proposition 65 has resulted in warnings on signs or placards in various places of business in California, but not actual warnings on food labels. A bit later on page 15, you concede that many companies have reformulated their foods, rather than engage in litigation (or, implicitly, place a warning on their food products).

First, there is obviously no burden on food manufacturers of a requirement that signs be posted at points of sale in California. Please respond.

Second, you obviously think that certain substances reduced as ingredients or reformulated out of foods because of Proposition 65 should be reintroduced or increased in levels in foods. Please list each substance for which a warning is required under Proposition 65 that is in your view improperly excluded from food or reduced in levels in food. Provide all substantiating science for your views.

Third, you state on page 16 of your testimony that "the claims that Proposition 65 has resulted in safer food are often not correct." By implication, sometimes such claims are correct. Please list each substance that Proposition 65 has properly reduced in, or excluded from, foods, making them safer.

Answer 7. As you point out, I have testified that California Proposition 65 "has resulted in a variable flood of warnings in restaurants, bars, grocery stores, hotel lobbies, and elsewhere, as well as major litigation about its applicability to various food products." Your question implicitly agrees with that statement. I also testified that FDA has disagreed both with Proposition 65 itself and with its applicability to several food products. Your question does not disagree with that testimony. Thus, the real issue is whether this "flood of warnings"—which has occurred in only 1 of 50 States in our country and has not occurred anywhere else in the rest of the world—represents sound public policy.

Your question implies that, because warnings have not been placed on food labels and companies have simply reformulated in order to avoid litigation rather than because of any concern about the safety of their products, there is no impact on the food industry or on consumers. This is wrong. There has been a major impact on the food industry and on consumers. Forcing industry to promulgate warnings in California, even if not on food labels, has a large impact on the food industry as well as on consumers. First, it undermines the credibility and authority of one of our most important Federal agencies, the Food and Drug Administration. Second, it leads to enormous public concern about issues that FDA and the rest of the world have determined do not represent a significant health hazard. Third, it undermines our nationwide food distribution system. Fourth, it forces food companies either to engage in protracted expensive litigation in California (like the recent tuna fish liti-

gation) or else cave in to private bounty hunters who have no interest in food safety but rather are focused on extorting fines from food companies.

The recent tuna fish litigation responds to all three of your specific questions. In *California* v. *Tri-Union Seafoods*, LLC (April 7, 2006), the San Francisco Superior Court issued an opinion concluding that mercury is naturally occurring throughout the environment, that it does not present a significant risk at the levels involved, that the FDA determination to handle the matter through consumer advisories rather than safety warnings must be given deference in California, and therefore that there is no legal or policy basis for the consumer warnings sought by the State. That decision illustrates the burden on food manufacturers involved under signs posted at points of sale in California, the existence of substances in food for which California would require a warning even when FDA determines that no warning is appropriate, and the false illusion that is created that any reduction in substances like mercury will necessarily make the food safer. The California court decision details the scientific evidence demonstrating the lack of harm from existing mercury levels in fish. The court determined that the testimony offered by the State was not credible. Yet manufacturers were forced to spend millions upon millions of dollars in defense of a case that should never have been brought. This is but one example where FDA has opposed a warning that would be required under Proposition 65, but it is the only one that has thus far been litigated with respect to food products.

Question 8. Status of State Requirements Subject To a Petition.—On page 17 of your testimony, you state: "State requirement that are the subject of State petitions to FDA remain in effect until FDA takes action on the petition, however long that takes." The proposed section 403B(b)(2), on page 6 of the bill, says that if a State submits a petition within 180 days after the date of enactment of the bill, "the notification of food safety requirement shall remain in effect in accordance with subparagraph (C) of paragraph (3)." Paragraph (3)(C) of the proposed section 403B(b) says in clause (I) that the State requirement stays in effect until FDA denies the petition, which makes sense. Clause (II) says the State requirement stays in effect until FDA approves the petition, which makes no sense: Shouldn't the State requirement remain in effect after the petition is granted?

Answer 8. Sections 403B(b)(3)(C)(i)(I) & (II) provide that a State requirement that is the subject of a petition submitted to FDA within 180 days after the date of enactment shall remain in effect until either FDA denies the petition or, if the petition is approved, the effective date of the final rule promulgating an exemption or national standard, except that there is no applicable ending date if the final rule does not establish any condition regarding the State law provision. The State requirement remains in affect after the petition is granted, except to the extent that the FDA determination modifies the State requirement in some respect. Accordingly, there is no need to revise this provision of the National Uniformity for Food Act.

Question 9. Number of Petitions for Proposition 65.—On page 18, you suggest that the number of State petitions will be small. Everyone agrees that the bill would preempt Proposition 65 and presumably also every warning with respect to a substance in food required under it. California could of course petition FDA to create an exemption for Proposition 65 itself.

Do you believe that FDA could grant an exemption from preemption for Proposition 65? If it could, would each of the current food warning requirements under Proposition 65 be preserved from preemption, or not?

If FDA weren't to grant an exemption for Proposition 65, or if such an exemption wouldn't preserve each of the Proposition 65 food warnings, isn't it reasonable to assume that California would pursue a petition for each such food warning? How many such warnings are there? Please list each one. Would you agree that each such petition would require FDA scientists to review an extensive scientific record, and that FDA action on such petitions could not be addressed "summarily?"

Answer 9. Sections 403B(b)(1) & (2) provide that the State may petition within 180 days after the date of enactment with respect to any State food safety warning "that expressly applies to a specified food or food component" and "that does not meet the uniformity requirement." A petition by California to create an exemption for all of Proposition 65 would therefore violate this provision and could not lawfully be granted. California could, of course, file separate petitions regarding safety warning requirements that are imposed under Proposition 65 for each specified food or food component. Any such petition would be required to demonstrate the scientific basis for the warning. As I have already noted above, FDA has opposed Proposition 65 generally and the specific warnings for food products that have been the subject of potential or actual litigation thus far. It is highly doubtful that responsible toxicologists in California would conclude that the types of warnings that FDA has op-

posed can be justified on a scientific basis. Indeed, it is unclear that responsible scientists would be able to mount a persuasive argument that cancer and reproductive toxicity warnings under Proposition 65 should be applied to any significant items in the food supply. Once the rules of science are imposed, rather than the arbitrary political determinations set forth in Proposition 65, the number of petitions is likely to be extremely small. In fact, it is not clear that even a single petition, backed by a strong scientific rationale, could be prepared for any Proposition 65 food safety warning.

I fully agree that any California petition relating to a food safety warning that is backed by substantial scientific data would be, and should be, treated very seriously by FDA. Under no circumstances could it be summarily dismissed. The length and depth of any scientific analysis by FDA will, of course, depend upon the length and depth of the scientific analysis presented in a State petition.

Question 10. Alcohol-Pregnancy Warnings.—At the food industry's April 24, 2006, press conference, the industry conceded that H.R. 4167 threatened Nevada's law requiring that food establishments selling alcoholic beverages post a sign warning pregnant women of the risk of drinking such beverages (Analysis of State Laws Cited in CSPI Report Shredding the Food Safety Net, www.uniformityforfood.org/statelawanalysissummarydetails.pdf at 21). I believe at least 18 States have such requirements. How do you explain this discrepancy with your testimony that such warnings would not be preempted?

Answer 10. It is clear that State laws requiring food establishments selling alcoholic beverages to post a sign warning pregnant women of the risk of drinking alcoholic beverages is not subject to the National Uniformity for Food Act. The National Uniformity for Food Act only applies to food that is subject to the jurisdiction of FDA under the FD&C Act. In *Brown-Forman Distillers Corp.* v. *Mathews*, 435 F. Supp. 5 (W.D.Ky. 1976), the District Court held that alcoholic beverages are exempt from the labeling requirements of the FD&C Act. Alcoholic beverage labeling is instead subject to the sole jurisdiction of the Federal Alcohol Administration Act, which is administered by the Alcohol and Tobacco Tax and Trade Bureau (ATTTB, formerly BATF). ATTTB also has exclusive jurisdiction over the advertising of alcoholic beverages, and FDA does not have jurisdiction over the advertising of any food that is subject to the National Uniformity for Food Act. Accordingly, the State laws referenced in your question are not covered by the National Uniformity for Food Act and are not in any way affected by this legislation. I did not attend the press conference that you reference and have no information about what was said at that time.

Question 11. Number of Laws Preempted.—The same document identified 26 State laws that would be threatened by the House bill, whereas you state on page 18 of your testimony that only 11 would be affected. Please explain the discrepancy.

Answer 11. I base the statement in my testimony that only 11 State laws would be potentially affected by the National Uniformity for Food Act on the April 24, 2006 analysis of State laws cited in the CSPI Report "Shredding the Food Safety Net." That analysis explicitly identifies the 11 State laws that would be affected. My own review of that analysis confirms that conclusion. Perhaps the discrepancy occurs because a number of State statutes authorize the State to adopt tolerances for food additives and color additives that are more protective of human health than the applicable FDA tolerances. I do not include those statutes in my analysis because no State has ever taken action under one of these provisions in the 48 years that they have been in existence.

Question 12. Meaning of "Requirement".—I would like you to clarify what a "requirement" is under the bill. You seem to suggest that individual phrases can be preempted, leaving the remaining provisions of a State requirement that is "identical" to a Federal Requirement in effect. Yet there is nothing in the bill language to suggest that this is what "requirement" means.

Consider two examples. First is Chapter 94, Section 13 of the General Laws of Massachusetts, which provides for rules for milk and raw milk products. It consists of three sentences. The first of these gives the State the authority to issue rules and regulations with respect to milk and milk products. The second sentence requires that these rules be consistent with FDA's Grade "A" Pasteurized Milk Ordinance, and adds a proviso that the State may impose more stringent bacterial and temperature standards. The third sentence provides for fines for violations of the regulations.

So what is the State requirement here? The food industry seems to argue that these provisions should be spliced up into various phrases and that only the proviso in the second sentence would be preempted, yet I see nothing in S. 3128 that com-

pels this result. Indeed, it would seem that S. 3128 would allow the requirement at issue to be the entire section. The entire provision is by no means identical to anything in the Federal Food, Drug, and Cosmetic Act, and would therefore be preempted. At a minimum, it would seem that the entire second sentence must be preempted. The bottom line is that there is at least a reasonable argument that all of section 13 is preempted by S. 3128, which would leave Massachusetts with no authority to enforce safe standards for milk products.

There is a similarly troubling ambiguity with respect to Massachusetts laws governing the safety of pesticides, food additives, and color additives. The relevant provisions are found in Chapter 94, Section 186. The second Paragraph relating to foods includes subparagraphs (2) (pesticides), (3) (food additives), and (4) (color additives) that say a substance adulterates a food if it is unsafe under the corresponding provisions of the Federal Food, Drug, and Cosmetic Act, with a proviso clause that the State may, by regulation, prohibit pesticides, food additives, and color additives deemed safe under Federal law. So is just the proviso preempted, or are all three provisions preempted entirely? There appears to be nothing in the language of S. 3128 to clarify the issue, which is arguable either way. Please comment.

Answer 12. The term "requirement" is explicitly defined in Section 403B(g)(1) of the National Uniformity for Food Act. It is defined to mean a mandatory action or prohibition established under the FD&C Act or the Fair Packaging and Labeling Act or by a regulation or a court order. Thus, you are correct that the part of a State statute that is identical to a Federal statute would remain in effect, but the part that is not identical would no longer be effective (assuming that it is not the subject of a State petition and FDA acceptance).

Your example of the Massachusetts law relating to milk and raw milk products is not applicable. Beginning in 1923, the Pasteurized Milk Ordinance (PMO) and Code were developed by the Public Health Service under the Public Health Service Act, not the FD&C Act. FDA at one time contemplated codifying the PMO in regulations under the FD&C Act, but abandoned this approach at the request of State officials. Thus, the PMO continues to be implemented under the Public Health Service Act, which is not subject to the provisions of the National Uniformity for Food Act. If at some point in the future FDA were to implement the PMO under the FD&C Act, rather than the Public Health Service Act, the following analysis would result. The State would continue to have full authority to issue rules and regulations with respect to milk and milk products that are identical with the PMO. The State would no longer have authority to impose more stringent bacterial and temperature standards than those required by FDA, but could petition FDA for an exemption or a national standard adopting the Massachusetts requirements. Because nothing in the National Uniformity for Food Act affects enforcement mechanisms, Massachusetts would continue to be able to impose fines for violations. This analysis is completely consistent with the statutory definition of the term "requirement," which unambiguously refers to a mandatory action or prohibition and not to an entire statutory provision. Your analysis is incorrect because it does not refer to the statutory definition of "requirement" in the National Uniformity for Food Act.

The second part of your question refers to Massachusetts laws governing the safety of pesticides, food additives, and color additives. First, the National Uniformity for Food Act does not cover pesticides. Section 408 of the FD&C Act, which governs pesticides, is not one of the provisions that is made subject to this legislation. The Food Quality Protection Act of 1996 governs national uniformity for pesticides. Accordingly, the rules governing national uniformity for pesticides were enacted by Congress 10 years ago.

With respect to food additives and color additives, as I have pointed out above, neither Massachusetts nor any other State has ever utilized the authority to promulgate regulations for food additives or color additives differing from the FDA regulations, in the past 48 years. Indeed, States do not bother to promulgate specific food additive or color additive regulations identical to those adopted by FDA. This is an area where States appropriately have deferred to FDA for the past 5 decades. Nonetheless, in light of the statutory definition of the term "requirement," it is clear that States would retain their authority to issue food additive and color additive regulations identical to those promulgated by FDA, and to enforce those requirements, under the National Uniformity for Food Act. It is only the proviso in the State laws authorizing different regulatory requirements that would be subject to national uniformity.

Question 13. Conforms.—Please explain the meaning of the word "conforms" in the proposed section 403A(c)(2) of the bill (page 3), especially in light of *Processed Apples Institute* v. *Department of Public Health*, 522 N.E.2d 965 (1988). Why doesn't

that case compel the preemption of both the second paragraph on foods of Chapter 94, Section 186 and Section 192?

Answer 13. Section 403A(c) contains provisions that confirm the authority of both a State and a political subdivision to enforce any requirement in a State or local law that is identical to a requirement in the Federal law. If FDA has promulgated a regulation or guidance relating to that requirement, the State or local government must conform its requirement to the Federal requirement. If FDA has not promulgated a regulation or guidance, the State or local government may implement the identical provision in any way that it believes appropriate.

The term "conforms" in Section 403A(c)(2) has its customary English meaning, i.e., the State requirement must be in accord or agreement with the Federal requirement. Once again, because of the statutory definition of the term "requirement," which makes it clear that it refers to a specific action or prohibition and not to a sentence or entire section, the meaning of "conforms" is very clear. If the Federal and State statutes are identical, it is the specific State requirement and not the entire statutory provision that must conform to the Federal regulation or guidance.

Nothing in the *Processed Apples Institute* decision indicates a contrary interpretation of the National Uniformity for Food Act. That decision arose in a context where the court concluded that the State had the authority to ban the pesticide completely. That situation could not arise under the National Uniformity for Food Act. The court in that case reasoned that, if the State could impose a complete ban, it could also take the lesser action of imposing a more stringent tolerance. Because the National Uniformity for Food Act expressly prohibits a complete ban, that court's reasoning could not be applicable, and conformity would be given its common and clear meaning.

Question 14. No FDA or State Regulation.—The proposed section 403A(c) allows a State or locality to enforce a State (but not a local) requirement identical to a Federal requirement when FDA has issued a regulation or guidance and the State or locality enforce the Federal regulation or guidance (paragraph (2)), and when FDA has not issued a final regulation or guidance and the State has its own "policy" such as a regulation or "administrative decision" (paragraph (3)). S. 3128 doesn't say what a State or locality can do when neither the FDA nor the State have a regulation, guidance, or "policy" in place.

It seems to me the better reading is that a State or locality may not enforce in that instance, and, at a minimum, it is clear that a food industry lawyer will be able to argue that the enforcement action is not permitted under the bill. This seems to me a particular concern when neither FDA nor a State may have anticipated a substance that terrorists have put in food. Please respond.

Answer 14. Section 403A(c)(3) governs when a State and the FDA are operating under an identical statute, FDA has taken no action in the form of a regulation or guidance on a particular issue, and the State wishes to enforce its State law in a particular way. For example, let us assume that the State determines that a contaminant in the food supply violates the "poisonous or deleterious substance" provision in both the Federal and the State law, and FDA has expressed no opinion on the matter. Under those circumstances, the State is completely free to take action unless and until FDA takes its own action in the form of a regulation or guidance and makes a different determination. The State's "policy," under this hypothetical, consists of the determination that the contaminant represents a "poisonous or deleterious substance" at the level involved. Indeed, it would be impossible for the State to take any form of action until it had reached the policy position that the particular level of the contaminant that is involved constitutes a "poisonous or deleterious substance." If, as you suggest, the contaminant has been placed in the food by terrorists, it is unquestionable that both FDA and the State would act, and in fact the State would act under the imminent hazard provisions of the National Uniformity for Food Act.

Question 15. Aborted FDA Action.—The proposed section 403A(c)(4) blocks a State or locality from enforcing a policy rejected by FDA. If FDA has rejected a tolerance of X for substance Y, it seems clear that the State may not enforce the tolerance of X. What about twice X? X plus a tenth X? X plus a hundredth X? It is entirely unclear what this provision means. Suppose FDA rejected the policy 10 years ago, and since that time new science supports the tolerance of X for substance Y. Why should a State be prohibited from enforcing it? What if the new science supports a tolerance of one tenth or one hundredth X? Why should the State be blocked from acting until FDA has acted?

Answer 15. FDA is constantly reviewing contaminants and ingredients in the U.S. food supply, and adopting formal and informal determinations regarding the level

at which a given contaminant is and is not a hazard to public health. The hypothetical posed in your question is not realistic. FDA does not determine that a particular level of a contaminant or ingredient is safe and therefore all levels are safe. In almost all instances, it determines the upper limit of safety, so that anything above that limit would not be regarded as safe. Thus your examples of contamination at levels in excess of the FDA tolerance are easily answered. If FDA has said that X level is safe, the simple answer is that in virtually all instances FDA has determined either that this level is the upper limit of safety or that some higher level is the upper limit and that this level falls within it. It would be extremely unusual for FDA to make a safety determination about a particular level and to stop at that point without further analysis. If a State believes that FDA has in fact done this, it is a simple matter for the State to discuss it with FDA in order to obtain clarification, or to submit a petition for an exemption or a national standard.

Without doubt, all regulatory standards are worthy of review and reconsideration as time progresses. You ask what should be done if FDA rejected a tolerance for a contaminant 10 years ago and new science now supports such a tolerance. The National Uniformity for Food Act anticipates exactly this type of circumstance. The State should then discuss the matter with FDA and submit a petition for exemption or, undoubtedly more appropriate, a new national standard. If the science demonstrating the toxicity of the contaminant is compelling, and the hazard is very serious, the State may utilize the imminent hazard provision as well.

You ask why a State should be prohibited from simply adopting whatever contaminant level it wishes, without regard to the FDA determination. The answer to this is very clear and compelling. Tolerances for food contaminants must be established on a national level, not a local level, if we are to maintain a nationwide market in food. If every State were to adopt its own tolerances in the light of new scientific data, there would be chaos in the marketplace. It is precisely for this reason that Congress delegated to FDA primary authority to deal with nationwide food safety problems. This legislation simply permits that delegation to have its intended purpose.

QUESTIONS OF SENATOR HARKIN

Question 1. Exemption From Preemption.—The proposed section 403B(f) exempts from preemption certain types of State required notifications such as open date labeling, religious dietary labeling, organic or natural designation, and statements of geographic origin, among others. Please explain why such exemption is needed for each of the particular exemptions contained in this subsection. What provisions in the bill imply that these sorts of provisions are preempted absent the exemption? Does the clear exemption for these specific State-required notifications create the implication that all other State-required notifications are preempted?

Answer 1. The State laws you identify in Section 403B(f)(1)—open date labeling and so forth—are not food safety provisions, are not food warnings, and would not be covered by the legislation even without the specific statutory exemption. I am told that Senator Burr included them in the legislation because critics persisted in using each one of these types of State required notifications as an example of State laws that would be preempted by this legislation. Even though that was a demonstrably incorrect interpretation of the bill, Senator Burr apparently felt that it was easier to put in a specific exemption in order to cut off this erroneous criticism. There would be no way to interpret the legislation to imply that these sorts of provisions are preempted absent the exemption. Thus, this specific exemption for these types of non-warning statements does not create an implication that other similar non-safety statements are subject to national uniformity.

Question 2. Scope of the Bill.—Mr. Hutt, you state in your testimony that Proposition 65 is the overarching problem that necessitates this uniformity legislation. But you also state that "existing differences between Federal and State food safety law are few and generally of a minor nature." Can you please explain how you reconcile your opinions on this matter, which seem somewhat at odds with one another?

In addition, if Proposition 65 is the problem that needs to be addressed, can you tell me if there are there alternative and more circumscribed means by which to address these matters? Is it possible to create a mechanism by which to avoid the kind of situation in which Mr. Stadtlander finds himself without such broad preemption?

Answer 2. As I have stated in response to a question from Senator Kennedy, the main purpose of this legislation is to assure a cohesive national approach to food safety. It is not directed primarily or exclusively at Proposition 65.

In 1997, Congress directed USDA to fund a study by the National Academy of Sciences to evaluate our current food safety system in the United States. The Institute of Medicine undertook this study and produced its report in 1998. The report found that "Federal activities are not well integrated with State and local activities" and called for a "national food safety plan" that would "integrate Federal, State, and local food safety activities." As the report recognized, "officials at all levels of government must work together in support of common goals of a science-based system." The report emphasized the need for statutory authority "to integrate State and local activities regarding food safety into an effective national system." The President's Council on Food Safety, which President Clinton established in August 1998 in response to the Institute of Medicine report, strongly endorsed this approach. President Clinton's Council issued its own report in March 1999 stating that Federal and State food safety agencies "have expertise and resources that, when combined in an integrated program, would significantly enhance the impact of food safety programs." The Council's report concluded that there needs to be "public assurance that State and local activities are integrated with, and an extension of, the Federal responsibility in order to assure consistency, accountability, and above all, enhanced consumer protection." This legislation provides the critical element to assure an integrated national food safety program.

As I said in my testimony, existing differences between Federal and State food safety laws are few and generally of a minor nature. This means that there will be no wholesale revocation of existing food safety laws. Most are presently identical to the Federal law, and thus may continue to be enforced under the provisions of this legislation. It is only the few that differ substantially from Federal law that will no longer be enforceable.

Merely addressing California Proposition 65 would not meet the mandate of President Clinton's Food Safety Council. A comprehensive national food safety system is needed in order to assure maximum consumer protection, and this legislation provides for just such a system.

Question 3. Multiple Labels.—With regard to warning labels and notification requirements, supporters of this bill, have complained about a patchwork quilt of food safety warnings required by different States. Yet I have not yet seen a specific food product that contains multiple labels—one required by Federal law and another required by State law. Can you provide me with such an example or multiple examples?

Answer 3. I did not testify that food safety warnings have appeared in food labeling. Rather, I said that they appear "in restaurants, bars, grocery stores, hotel lobbies, and elsewhere." None of these warnings are required in any other State or by FDA or by any other country in the world. Obviously, the ingredients required to be the subject of a warning in California are not unsafe in California and safe in 49 other States. There is a strong need to rationalize safety decisions in order not to confound the public.

For example, a law suit was brought under Proposition 65 to require a warning regarding the natural lead content of calcium in dietary supplement products. The industry had only two options. Either it could spend millions of dollars litigating the issue, with the always uncertain result in a California court, or it could cave in and find a way to use only low lead calcium in California. At no time did FDA suggest that the lead content in calcium deserved a warning. Nonetheless, the industry concluded that it was less expensive to find a low-lead source of calcium for California than it was to litigate the matter. In the view of FDA, this entire process did not in any way advance the health and safety of consumers. It disrupted the dietary supplement industry and cost them millions of dollars, for no public health reason.

Question 4. Warning vs. *Notification.*—On the issue of what constitutes a warning, there is some disagreement. The Center for Science in the Public Interest asserts that nearly 200 State laws would be affected by this legislation. Mr. Hutt, you have reviewed the CSPI report on this matter and believe that the CSPI report is incorrect because it doesn't distinguish between "warnings" and "notification." You state that if one looks only at warnings and not at notifications more broadly, that the number of State laws affected would be significantly less. You also state that S. 3128 clearly pertains only to notification requirements that contain food-related warnings and not notification more broadly.

However, I am unclear as to whether the term "warning," as defined by the bill, is nearly as clear as has been asserted. The bill says that "warning," used with respect to a food, means any statement, vignette, or other representation that indicates, directly or by implication, that the food presents or may present a hazard to health or safety.

Do you see any uncertainly under this definition, especially the "by implication" portion? Can you explain to me more precisely the legal import and effect of this "by implication" language? Why it is important to have the "by implication" language included in the bill at all?

By way of example, what if a State adopts a requirement that grass-fed beef be labeled as such? Directly, this may be only a notification. But what if research definitively shows that grass-fed has health benefits relative to grain-fed beef. By implication, wouldn't a grass-fed beef notification then become a warning regarding grain-fed beef? Perhaps this isn't the best illustration. My point is not to comment on grass-fed beef or the state of science pertaining to it, but to ask whether the definition of warning in the legislation is altogether clear.

Answer 4. As I have said in response to your first question above, the National Uniformity for Food Act covers only notifications that are in the nature of a warning, and does not cover notifications that do not state or imply a safety problem.

You have asked why it is necessary to impose national uniformity both for direct warnings and for implied warnings. The answer is clear. If only direct warnings were subject to national uniformity, it would be very simple to convert them into implied warnings and thus escape national uniformity. Let us take the example of farm-raised fish. State laws that require farm-raised fish to be so labeled are not subject to national uniformity because, as I have pointed out in response to question No. 1 from Senator Kennedy, this type of statement is merely an "avoidance" claim. Some people prefer wild fish to farm-raised fish because they prefer "natural" food. Companies are entitled to give this type of information on the source of the fish so that consumers can satisfy their own personal eating preferences.

If a State were to decide that it wanted to discourage the sale of farm-raised fish (because it could be in an ocean State's interest to encourage the sale of wild fish), it could easily devise a statement such as "farm-raised fish contain PCBs." It would not include the required use of the term "warning" and would not allege the lack of safety of the product. It would, however, clearly imply that there was a significant safety issue. Accordingly, it is important to harmonize implied as well as direct food safety warnings throughout the country.

Question 5. Cost-Benefit Analysis.—Issues like food safety often involve cost-benefit analyses. Are you aware of any cost-benefit analysis showing the costs and benefits of a single national regulatory scheme as envisioned under S. 3128 compared to the costs and benefits under the current relationship?

Answer 5. Both the Report of the Institute of Medicine and the Report of President Clinton's Food Safety Council strongly recommended a nationally integrated food safety system. They argued that a coordinated national regulatory scheme such as that envisioned under the National Uniformity for Food Act would increase efficiency and maximize consumer benefit. I am not aware whether they conducted formal cost-benefit analyses in reaching their conclusions, but it seems very clear that a single national food standard, enforced uniformly by every Federal, State, county, and city regulatory agency, will be far more efficient than a patchwork of requirements of the type that now exist.

Question 6. National Response to Local Issues.—Right now, State and local officials are not preempted from taking action when food-related health concerns arise that are limited to their jurisdictions. How can we be sure that a national regulatory regime will: (a) be able to respond in a timely fashion to what is a local concern; and (b) be willing to respond to localized issues, when other matters will compete for limited Federal resources?

Answer 6. The National Uniformity for Food Act balances the need of the Federal Government to assert primary jurisdiction over national issues and the right of State and local governments to take primary responsibility for local issues. The legislation explicitly excludes such food sanitation matters as regulation of milk, seafood, and restaurants, which are quintessential local issues. Moreover, local food safety officials will always be authorized under the National Uniformity for Food Act to take immediate enforcement action under their own State provisions that are identical to Federal law in order to address local concerns promptly. And if those localized issues present a serious health hazard, the State may act immediately under the imminent hazard authority in this legislation. Thus, the National Uniformity for Food Act explicitly provides for several ways in which State and local officials can immediately respond to localized food safety problems.

Question 7. Imminent Hazard Authority.—Could you please explain the imminent hazard authority to me more fully? First, explain to me the legal definition and standing of the term "imminent hazard" as well as the term "adverse health con-

sequences." Are these terms defined in statute, regulations, or guidance or, alternatively, have they been further explicated in existing case law?

If a State determines that there is an imminent hazard, why is it necessary for them to notify FDA and to determine if FDA has or has not initiated enforcement action on the matter? And how do you envision that this process would operate? Would a State have to receive word from the FDA that they are not initiating enforcement? How long would a State have to wait to determine whether or not the FDA has initiated or plans to initiate enforcement action? And if there is truly an imminent hazard that requires immediate action by State authorities, is this process of notification, waiting, and clarification truly the best process, in terms of expediency and therefore, in terms of human health?

Answer 7. The imminent hazard provision in section 403B(d) is patterned on two other provisions in the FD&C Act: (1) the imminent hazard provision for new drugs in Section 505(e) of the FD&C Act and (2) the standard of "serious adverse health consequences" that is used in Sections 515(e)(3), 518(e)(1), and 522(a) of the FD&C Act and in a number of FDA regulations. Thus, both of these statutory terms have substantial FDA precedent.

For example, the term "imminent hazard" is defined in 21 CFR 2.5 and has been the subject of judicial interpretation in the decision in *Forsham* v. *Califano*, 442 F. Supp. 203 (D.C.D.C. 1997). The term "serious adverse health consequences or death" has similarly been defined by FDA in 21 CFR 810.2(1) & 814.3(1). Thus, these are not new or undefined terms.

Under the imminent hazard provision in the legislation, once the State notifies FDA and determines that FDA has not already initiated enforcement action, it may immediately take its own action. It need not wait another minute. No clarification by FDA is needed. The State must later submit a petition to FDA relating to the matter, but in the meanwhile it can take whatever action is necessary in order to address the imminent hazard. Thus, the type of delay and confusion that you envision is explicitly avoided under the legislative provisions.

As you know, the imminent hazard provision applies only where the State action conflicts with the uniformity provisions of the legislation. If the State wishes to take emergency action under a State law that is identical to the Federal law and there is no contrary FDA regulation or guidance, the State may proceed immediately without consulting FDA.

Question 8. Restaurant Labeling.—This country has now required food manufacturers to provide nutrition information on packaged foods for about 15 years. I think most people agree that the nutrition information provided on packaged foods has been successful. Americans appreciate the information and rely on it to make informed choices about what they eat.

However, more and more, Americans spend their food dollars away from home, mostly in restaurants. As a result, individuals who have good nutrition information when cooking at home are totally in the dark when they go out to a restaurant. That's why I've proposed a bill that would require chain restaurants to provide basic nutrition information (calories, salt, fat, trans fat) on standard menu items at the point of sale.

I'm hopeful that Congress will take up and pass my bill for restaurant nutrition labeling. But if it doesn't happen, there is always the possibility of a State or a municipality passing a similar law on restaurant labeling. If a State were to pass a law that required chain restaurants to provide nutrition information on calories, salt, fat, and trans fat at the point of sale, would such a law, in your view, be preempted by passage of the proposed National Uniformity legislation?

Alternatively, what if, in addition to the required information on calories, salt, fat, and trans fat, a State or municipality required restaurants to also post the following notice, "The National Academy of Sciences has concluded that trans fats provide no known benefit to human health and recommends that consumption of trans fats be as low as possible." Would such a notification be preempted by passage of S. 3128?

Answer 8. Congress established the current statutory provisions regarding national uniformity for nutrition labeling in the Nutrition Labeling and Education Act of 1990. The National Uniformity for Food Act does not in any way deal with nutrition labeling, whether on food packages or in restaurants.

You ask whether a State requirement that a restaurant post a notice that "the National Academy of Sciences has concluded that trans fats provide no known benefit to human health and recommends that consumption of trans fats be as low as possible" would be subject to national uniformity under this legislation. In my opinion, such a notice would be an implied safety warning. In contrast, a simple restaurant statement that a food "contains trans fats" without an implication that they are unsafe, like the "avoidance" claim that a product "contains no trans fats," would

not be subject to uniformity. I believe that this is consistent with my response above to your question number 4 and illustrates why implied as well as direct food warnings are properly covered by the National Uniformity for Food Act.

Question 9. School Nutrition Standards.—In testimony before the committee, you raised the issue of State and local laws regarding school food sales. In particular, these are laws that govern what and when food can be sold at schools, especially unhealthy foods such as soft drinks and snack foods. Your assertion, which I hope is correct, is that because school nutrition issues are typically governed by USDA rather than the FDA, then these State and local laws would not be preempted by S. 3128.

But other than the simple argument that school nutrition is traditionally the purview of USDA, are there other substantive reasons why S. 3128 wouldn't or couldn't be applicable to State and local school nutrition laws? Is there, for instance, any case law that you can cite that would further support this assertion? Wouldn't it still be possible that someone could challenge such laws by arguing that S. 3128, if passed, has preempted them?

Furthermore, if areas that are traditionally the jurisdiction of USDA wouldn't be affected by this bill, why is it that organic designations, which are the purview of USDA, are specifically preempted by the proposed section 403B(f) of S. 3128? Does the clear exemption of organic, even though it is traditionally governed and regulated by the Department of Agriculture, create the implication that all other requirements are therefore affected, even those that are under the purview of USDA? Is it possible that someone could cite this language in an action challenging State school nutrition laws following passage of S. 3128?

Answer 9. State and local laws regarding school food sales are not subject to national uniformity under this legislation. The FD&C Act has no provision authorizing FDA to permit or prohibit the type of food sold in schools. The laws that govern such programs—the National School Lunch Act and the Child Nutrition Act of 1966—are under the jurisdiction of USDA, not FDA, and are not in any way included under the FD&C Act. Accordingly, it is absolutely clear that the National Uniformity for Food Act has no impact of any kind on these laws.

It is not just a matter that school nutrition is "traditionally" the purview of USDA. It is the clear legal situation that school nutrition matters do not fall within the FD&C Act. Rather, they fall within the two specific statutes referred to above that are separate and distinct from the FD&C Act and that are not included in the list of statutory provisions to which the National Uniformity for Food Act applies. Thus, the fact that State and local laws regarding school food sales are not affected by the National Uniformity for Food Act is a matter of statutory law, not a matter of simple tradition. It would be impossible for anyone seriously to suggest that the National Uniformity for Food Act applies to State and local laws regarding school food sales, because the laws administered by USDA are not listed as subject to uniformity under Section 403A or Section 403B as they are written under the pending legislation.

The matter of organic labeling, however, is an entirely different matter. As I have noted in response to your question No. 1, Section 403B(f)(1) included nonsafety food statements as a specific exemption only because critics of the legislation persisted in erroneously contending that otherwise they would be subjected to national uniformity. In short, the provision was included for absolute clarity in order to avoid giving critics yet another erroneous reason for attacking the legislation.

You are correct that it was USDA who was given the statutory authority to develop an organic food certification program under the Farm bill of 1990. Because FDA has jurisdiction under the FD&C Act over all food labeling statements, however, FDA is charged with enforcing the USDA requirements for organic food labeling, even though it is USDA who promulgates the implementing regulations. Thus, this is quite different from the school nutrition programs. Quite simply, FDA has no jurisdiction over school nutrition programs, has not been delegated by Congress with any authority with respect to school nutrition, and has never in its entire history taken any action with respect to school nutrition. FDA has jurisdiction over the safety and labeling of the entire food supply, but does not have authority to determine which safe and properly labeled food may be sold in local school systems.

QUESTIONS OF SENATOR REED

Question 1. FDA Guidance Documents Versus State Food Safety Laws.—The Federal Food, Drug, and Cosmetic Act (Section 701(h)) states that guidance documents are "not binding on the Secretary" and requires that guidance documents indicate their "nonbinding nature." This bill doesn't change the fact that guidance documents aren't binding on FDA or the industry. But it says that guidance documents are

binding on the States and localities, because they may only bring an enforcement action when it "conforms" to the guidance. As a practical matter, a company is not required to comply with a guidance document but the State can only act if it is alleging that the company hasn't complied with the guidance. Would any of you care to comment on whether this makes any sense?

Answer 1. Senator Kennedy has raised the identical question. My response follows.

There are two answers to your question. First, if there is no FDA regulation or guidance, a State is entirely free to implement a statutory provision that is identical to the same provision in the FD&C Act in any way that it believes is justified. Thus, a State requirement imposed under a State statute identical to the Federal statute is completely lawful unless FDA has taken a contrary position in a regulation or guidance.

Second, Section 701(h) of the FD&C Act explicitly states that guidance documents "present the views" of FDA on matters under its jurisdiction. It requires FDA to ensure that agency employees do not deviate from such guidances without appropriate justification and supervisory concurrence. Thus, as FDA has often said, guidance documents represent the enforcement position of the agency. The agency deviates from them only on rare occasions and under unusual circumstances.

FDA guidance documents therefore represent national policy. They establish tolerances for food contaminants that the agency intends to enforce in court and related food safety and labeling positions that represent national policy established by the agency designated by Congress as the primary regulatory agency for our nationwide food supply.

Although a guidance is not legally binding in the way that a statute or regulation is binding, it nonetheless represents FDA enforcement policy. It is rare that a company would willfully violate such a guidance. It is an informal substitute for a formal regulation. FDA uses guidances rather than regulations in situations where the formal procedures now required for promulgating regulations make that form of policy statement infeasible. A guidance represents FDA nationwide policy, however, and thus States should follow it or should petition FDA to change it. If States were permitted to ignore FDA guidance, FDA would be required to promulgate many more regulations in order to assure national uniformity, thus making regulation far more costly and difficult.

Question 2. Definition of "identical" in S. 3128.—Mr. Hutt, you contend that most State laws will not be preempted by S. 3128 because they will not have to exactly mirror the FDA standard. It is estimated, however, that anywhere between 11 and 200 State and local laws would be preempted by S. 3128. Won't the fact that identical means something other than identical under this bill just result in a battle in the courts to define what "identical" actually means?

Answer 2. It is extremely unlikely that there will be any significant litigation regarding the scope of the term "identical" as set forth in new section 403A(c)(1) of the National Uniformity for Food Act, for several reasons. First, the definition is much clearer than most definitions in the FD&C Act. It unambiguously states that it does not require identical language, just the imposition of identical requirements. It also explicitly excludes procedural requirements, and section 403B(a)(3) explicitly excludes enforcement requirements.

Second, the 11 State laws that will be impacted by the National Uniformity for Food Act are unlikely to be the subject of State petitions. A review of these State statutes shows that most are obsolete or represent minor deviations from existing FDA requirements and are unlikely to survive rigorous scientific analysis.

QUESTIONS OF SENATOR CLINTON

Question 1. Local Agencies and Food Safety.—As you state in your testimony,

> "States must be given the right to collaborate with FDA in assuring that appropriate food safety and warning requirements are imposed and, where uniquely local matters are involved, to assume the predominant role in public protection."

However, S. 3128 only allows States, not local governments, to petition the Federal Government for exemptions or to establish a national standard. Furthermore, State governments are allowed to act when the Federal Government has not set a standard, but local governments are not allowed to take such action.

In New York City, a proactive local government, has identified and addressed hazards for which Federal regulation does not exist. For example, when imported candies contaminated with lead were found in New York City, a city law was enacted banning the sale of such products.

In addition, New York City recently embargoed certain imported herbal products that contained lead after several cases of adult lead poisoning were confirmed among residents who used these products. This action was taken despite the fact that there were—and continue to be—no specific Federal standards about adult tolerance levels for adult lead poisoning.

Given these facts, how can we ensure that food uniformity will not constrain this important local role? Under the restrictions of S. 3128, how can localities respond rapidly to products that pose an imminent hazard to their population and do not affect the entire State?

Answer 1. Senator Kennedy has raised the identical question. My response follows. The National Uniformity for Food Act does not completely preempt localities from enforcing local requirements that are identical to Federal requirements.

Section 403B(a)(1) explicitly provides that any political subdivision of a State may enforce a local food safety warning that is identical to a Federal warning. Section 403A(c) also explicitly provides that a political subdivision of a State may enforce a State law that contains a requirement that is identical to a Federal requirement. I am unaware of any situation where a local jurisdiction within a State has enacted a law governing food safety that is identical to the Federal law but for which there is no comparable State law. Your question does not identify any such situation, nor has AFDO or other interested organizations stated that this has ever occurred. Perhaps that is the reason why Senator Burr has not covered this hypothetical situation in the legislation.

Nonetheless, there is a simple answer to this hypothetical question. If the local jurisdiction has identified a provision of Federal law governing food safety that has no State counterpart and has enacted its own identical provision on a local level, it will be quite simple for that local jurisdiction to persuade the State to enact it into State law. Once that is done, it may be enforced by both State and local officials.

Finally, the National Uniformity for Food Act funnels all State issues relating to FDA review, petitions for exemption, national standards, and imminent hazard action, through the appropriate State officials rather than through each individual local jurisdiction, for several reasons. First, as already stated, no one has thus far identified the type of local laws that you hypothesize in this question. Second, it is sound public policy to require each State to coordinate whatever petitions may be appropriate within its own jurisdiction, rather than to have a variety of viewpoints expressed by different local authorities. For the same reasons that uniformity is appropriate at the Federal level on nationwide issues, it is equally justified at the State level on statewide issues. Assuming that there are local laws governing food safety that are not applicable on a statewide basis, the State has an interest in assuring both that those laws are appropriate and that they should be advanced either as an exemption or as a national standard.

You specifically refer to a New York City law banning the sale of imported candies contaminated with high levels of lead. In that instance, FDA also took enforcement action directly to prevent importation of lead-contaminated candies under the prohibition of poisonous or deleterious substances in Section 402(a)(1) of the FD&C Act. New York State law contains an identical prohibition. Accordingly, under the provisions of new Section 403A(c)(3) of the National Uniformity for Food Act New York City would be fully authorized to enforce the State law provisions banning these lead-contaminated candies. The same is true in the situation of imported herbal products with high levels of lead. Where there is no specific Federal standard, New York City may enforce the State law prohibiting poisonous or deleterious substances because that law is identical to the Federal law. Thus, this is an excellent example of the collaboration and cooperation among Federal, State, and local food regulatory agencies that I emphasized in my testimony before the committee.

Question 2. Compensation for Testimony.—Did you or your law firm receive compensation for the testimony you gave to the HELP Committee on Thursday July 27, 2006? Please outline the amount of your compensation together with the details of what companies, groups, associations, or other parties provided that compensation.

Answer 2. I am told that the staff of the HELP Committee asked the Grocery Manufacturers Association to suggest the names of experts in the area of FDA regulation of food safety. GMA suggested me because I have spent the past 45 years practicing food and drug law both as Chief Counsel for FDA and in private practice, I teach food safety law at Harvard Law School each Winter Term, and I am the co-author of the casebook used to teach this subject at law schools throughout the country. It was the HELP Committee that extended an invitation for me to testify. I will be paid by GMA for the amount of time I spent preparing for the hearing,

testifying before the committee, and responding to these questions, at my standard billable rate. At this moment I do not know the amount of compensation that will be involved.

RESPONSE TO QUESTIONS OF SENATOR ENZI, SENATOR KENNEDY, SENATOR HARKIN, SENATOR REED, AND SENATOR CLINTON BY ELSA A. MURANO

QUESTIONS OF SENATOR ENZI

Question 1. I am told that under this legislation, States and localities retain their enforcement authorities and the ability to set food safety standards where FDA hasn't. Furthermore, States would continue to conduct inspections, use their embargo and other enforcement authorities. Do you see anything in the bill that will prevent the States from doing the things they now do in terms of food safety?

Answer 1. It is extremely important that the States retain their inspection, embargo, and other enforcement authorities. The National Uniformity for Food Act does not cover procedural authority states that it does not cover inspection, recall, civil orders, embargo, detention, or court proceedings. I support these provisions. I can find nothing in the bill that will prevent the States from doing the things they do now in terms of food safety.

Question 2. In your testimony, you discussed how when you were Undersecretary, USDA worked with FDA on inspections and could be deputized under Memoranda of Understanding to help FDA. This sounds sensible to me. Do you think it makes sense to expand this approach?

Answer 2. Both USDA and the States have at times been deputized to assist FDA, by conducting inspections, analyzing products, and undertaking other related regulatory work. This has been going on for decades, and I support continuing it and expanding it in the future.

QUESTIONS OF SENATOR KENNEDY

Question 1. Proposition 65.—Which of the ingredients requiring a warning under Proposition 65 do you think should be put back into food, or added to food at higher levels? On which ingredients did California get it right? Please provide a complete list of each class of substances.

Answer 1. To my knowledge, only one food warning case has been litigated under Proposition 65. That case would have required a warning for mercury levels where FDA has determined that a warning is not appropriate. This is, I believe, a sufficient answer to your question. I do not have a complete list of all substances for which warnings have been sought, nor am I familiar with the negotiations that have taken place. I am aware that FDA has opposed warnings that have been sought under Proposition 65. In my opinion, California should follow the lead of FDA in food safety matters, and should not try to set the rules for the entire country.

Question 2. USDA-FDA.—How does Federal preemption on meat inspections justify preemption on the FDA side of things, when USDA is in the plant inspecting basically 24/7 and FDA gets to a food plant to inspect perhaps every 5–10 years?

Answer 2. The justification for continuous factory inspection for meat does not exist when it comes to the kind of processed food that FDA regulates. USDA oversees the slaughter of live animals. FDA does not. Instead, FDA focuses on issues of food toxicology in determining whether safety warnings are appropriate. Accordingly, national uniformity makes as much sense for FDA safety decisions as it does for USDA safety decisions.

QUESTIONS OF SENATOR HARKIN

Question 1. Exemption From Preemption.—The proposed section 403B(f) exempts from preemption certain types of State required notifications such as open date labeling, religious dietary labeling, organic or natural designation, and statements of geographic origin, among others. Please explain why such exemption is needed for each of the particular exemptions contained in this subsection. What provisions in the bill imply that these sorts of provisions are preempted absent the exemption? Does the clear exemption for these specific State-required notifications create the implication that all other State-required notifications are preempted?

Answer 1. I agree with you that these particular exemptions are not needed. I asked why they are there and was told that they were put there to appease critics who insisted that otherwise the types of State laws identified in that provision could possibly be included within national uniformity. Since none of these State laws involves a safety warning, they clearly would not be included under the bill even if

this section were not a part of the legislation. I do not believe there is any implication that other non-safety State-required notifications are subject to national uniformity.

Question 2. Multiple Labels.—With regards to warning labels and notification requirements, supporters of this bill, have complained about a patchwork quilt of food safety warnings required by different States. Yet I have not yet seen a specific food product that contains multiple labels—one required by Federal law and another required by State law. Can you provide me with such an example or multiple examples?

Answer 2. I have asked the same question, and I have been told that the food industry prefers to put any required food safety warnings on store posters rather than on labels. We are therefore unlikely to see any food labels that contain a safety warning imposed by State law but not required by Federal law.

Question 3. Cost-Benefit Analysis.—Issues like food safety often involve cost-benefit analyses. Are you aware of any cost-benefit analysis showing the costs and benefits of a single national regulatory scheme as envisioned under S. 3128 compared to the costs and benefits under the current relationship?

Answer 3. I have undertaken no research to determine whether cost-benefit analyses of a single national regulatory scheme have been performed. It is common sense, however, that one national safety standard, as contrasted with numerous State standards, will be far more effective and efficient. We do not need a study to understand that. It is instructive that the European Union has adopted a common market in food, and has abandoned its centuries-old balkanized approach of individual country regulations, precisely in order to obtain the benefits of a single standard that the National Uniformity for Food Act would confirm.

QUESTION OF SENATOR REED

Question. USDA Meat Inspections Versus FDA Inspections.—How many inspectors does the USDA have to conduct meat inspections? How many inspectors does the FDA have for the thousands of food products under its jurisdiction? How does Federal preemption on meat inspections justify preemption on the FDA side of things, when USDA is in the plant inspecting basically 24/7 and FDA gets to a food plant to inspect every 5–10 years?

Answer. USDA has about 9,000 meat inspectors, because of the Federal statutory requirement of continuous factory inspection over the slaughter of live animals. Comparing USDA inspection of the slaughter of live animals with FDA inspection of processed food is like comparing apples and oranges. The two have nothing in common. USDA must be concerned with the safety of each individual animal. FDA is concerned with the safety of ingredients, which can be used in thousands of different types of products. Thus, while USDA focuses on one animal at a time, FDA can cover thousands of food products by reviewing just a single ingredient. For this reason, the two agencies properly conduct their statutory responsibilities in extremely different ways.

QUESTION OF SENATOR CLINTON

Question. AFDO and the Food Code.—As you stated in your testimony, 48 of the 56 States and territories have adopted their own food codes from the Food Code. You draw parallels between this code and the National Uniformity for Food Act.

According to your testimony,

> "there is nothing in proposed S. 3128 that would limit, restrict or compromise the Food Code or the State or territorial codes modeled on it . . . [nor] anything that would impact FDA's or USDA's other cooperative food safety programs with the States."

It stands to reason that if this statement were true, the National Uniformity for Food would enjoy the support of the organizations that support the Food Code.

However, the Association of Food and Drug Officials (AFDO), the non-profit organization whose mission is to foster "uniformity in the adoption and enforcement of food, drug, medical devices, cosmetics and product safety laws and regulations," is opposed to H.R. 4167, the House companion of S. 3128. In a letter to the House of Representatives last January the AFDO addresses "serious concerns" regarding H.R. 4167 and its impact on State sanction laws and programs. The AFDO calls the bill "a disastrous step backwards in ensuring the safety of our Nation's food supply."

Considering the AFDO fully supports the Food Code but stands in opposition to the National Uniformity for Food Act, how do you justify your argument that the

two are somehow equal? What differences exist between the Food Code and the food uniformity legislation?

Answer. The Food Code began with a cooperative program undertaken in 1935 by the Public Health Service in cooperation with State health officials. It encompasses food service, vending, and retail food store sanitation. It is a cooperative program with the States, and it is not affected in any way by the National Uniformity for Food Act. In fact, over the past 70 years the Food Code and its predecessor programs have fostered uniformity in these areas that are uniquely the responsibility of local health officials, and I expect that this will continue. I regret that AFDO has seen fit to oppose the National Uniformity for Food Act. This opposition seems to go against the stated mission of this important organization. I see no difference between the Food Code approach and the National Uniformity for Food Act. Both are consistent with the mission of AFDO.

RESPONSE TO QUESTIONS OF SENATOR ENZI, SENATOR KENNEDY, SENATOR HARKIN, AND SENATOR REED BY WILLIAM K. HUBBARD

QUESTIONS FROM SENATOR ENZI

Question 1. On what basis do you conclude that such a large number of petitions would be submitted? Mr. Hutt testified that many of the State laws that were listed as vulnerable to preemption were not even under the FDA's jurisdiction. How do you respond to this?

Answer 1. I based my conclusion on the assumptions made by the Congressional Budget Office, which I understand is charged with guiding legislators in gauging the impact of proposed legislation. The food industry is on record as saying that there will be *more* petitions coming to FDA than the CBO estimated. Whomever is correct, it appears that there will likely be many petitions addressed to the FDA under the bill, and even a much smaller number than estimated will result in significant budgetary problems for the FDA.

Question 2. The Congressional Budget Office scored a similar House bill, H.R. 4167 at $100 million over 5 years, using an estimated cost of $400,000 per petition, 240 petitions and associated regulatory costs of about 4.2 percent. You have suggested that FDA could not accommodate such responsibilities in its current budgetary state. I, too, am concerned about FDA's budget. However, if we stipulate to CBO's model for the cost per petition and the add-on for any regulatory actions, but take the lower number of 11 laws preempted, we would come up with a cost estimate for this bill of a little under $5 million. Could FDA handle that?

Answer 2. A $5 million estimate would assume that only about 20 petitions would be received by FDA in the first year. It is difficult to conceive of so small a number of petitions, given the large number of contaminants that California alone has listed under Proposition 65. It might be useful to ask that State how many petitions it would expect to submit. Further, even if California submitted just *one* petition to cover the hundreds of contaminants it has regulated under Proposition 65, FDA would be forced to undertake the same expensive process for assessing those contaminants as it would if the State had submitted a separate petition for each hazardous substance.

Given FDA's precarious budget situation in its foods program, even a $5M reallocation would be difficult for the agency to accommodate. In essence, it would mean the assignment of perhaps 40 to 50 scientists away from their public health mission to the review of petitions, for no discernible public health gain.

Question 3. Dr. Murano's testimony discussed how when she was Undersecretary, USDA worked with FDA on inspections and USDA staff could be deputized under agreements between the two agencies to help FDA. You indicated that deputization worked in combating bioterrorism. Why wouldn't it work here?

Answer 3. The Bioterrorism Act authorized FDA to "commission" officials from other regulatory agencies with like missions to assist FDA in its food safety oversight role—in essence, to empower those agencies, where FDA determined it appropriate, to share FDA's regulatory authority. For example, FDA has already commissioned Customs officials who can assist in inspecting imported foods. However, the act also required FDA to reimburse agencies for such commissioning efforts where necessary, so there would need to be funding to allow USDA staff to review petitions, if the purpose of this question is to inquire about USDA doing petition review under the uniformity legislation. Moreover, the meat inspectors that were under Dr. Murano's supervision, while highly trained in their particular field, would not likely have the scientific expertise to review the safety of contaminants that would be the subject of uniformity petitions. Indeed, Congress recognized that fact by assigning

to FDA the principal authority to approve new food additives, including those used in meat production. If the question is aimed more at suggesting that USDA inspectors would pick up any slack caused by FDA's inspection reduction due to their having to reallocate inspectors to petition review, such reallocations would not likely occur. Petition review would need to be done by the scientists in FDA's headquarters food program, who would be best qualified to conduct petition review.

QUESTIONS OF SENATOR KENNEDY

Question 1. FDA Inspections.—State officials, from attorneys general to public health and agriculture officials, have expressed concern that S. 3128 will disrupt their authority to inspect and enforce the safety of food. States presently conduct 80 percent of all domestic food inspections. Does it unsettle you that S. 3128 might disrupt these inspections? What resources could FDA bring to bear to replace lost State inspections?

Answer 1. FDA would have no resources to make up for lost State efforts. Indeed, States do far more now than FDA does to enforce food safety laws, and much of that enforcement is directly on FDA's behalf. If States are allowed to continue their inspections, as S. 3128 contemplates, but not enforce the standards that those inspections are intended to enforce, as S. 3128 appears to intend, it would be logical to assume that States would simply stop inspecting altogether in many instances. The result would be a significant diminution of food safety protection nationwide.

Question 2. Petitions.—How do you think the FDA will be able to afford the hundreds of millions of dollars it will take to implement S. 3128 over the next 5 years, when its budget is currently being cut?

Answer 2. The agency will not be able to afford to implement S. 3128. If enacted, and if FDA were to make a sincere effort to implement it, I believe S. 3128 would force FDA to reallocate most of the efforts of its headquarters scientists to petition review, for no discernible public health gain. FDA's food budget needs to be doubled, not drastically cut, as is already happening (and which would be exacerbated by S. 3128).

Question 3. Implied Warnings.—Under the bill (page 5, paragraph (B)), a warning includes a statement "that indicates, directly or by implication," that the food presents or may present a hazard to health or safety. Because farm-raised salmon has more PCBs than wild salmon, isn't a statement that salmon is farm-raised a warning under this bill?

Answer 3. FDA has interpreted similar circumstances in the past as implied warnings. For example, when some States expressed their intention to require that milk resulting from the use of the hormone BST in milk cows bear a notification of that fact, FDA concluded that consumers would view that notification as a warning. A farm-raised salmon notification could easily be assumed to refer to fish that contained higher levels of PCBs or a wild salmon notification could refer to fish that contained higher levels of mercury. So viewed, these notifications would be preempted by S. 3128.

Question 4. State Embargoes.—Given what you know about how State embargo is used, including in coordination with FDA, what is your view of the restrictions on such embargo authority under the proposed section 403B(a)(3)?

Answer 4. Currently, State health officials can detain or "embargo" a food that they believe posed a health risk, by essentially demanding that the food be held pending sampling or other examination to affirm its safety. The Bioterrorism Act of 2002 attempted to give FDA detention authority as well, but so many procedural requirements were imposed that the authority is essentially unused and impractical. S. 3128 preserves various State authorities—including embargo and detention authorities—but only when they "involve food adulteration under a State statutory requirement identical to a food adulteration requirement under this Act." So the bill seems to result in diminution of States' current detention authority, an authority that States have often used to deal with critical food safety threats. If the intention is to retain current State embargo authority, any ambiguity on this point should be explicitly removed.

Question 5. Imminent Hazard.—What is your reaction to how the imminent hazard provision in proposed section 403B(d)? Is it at all realistic to think that a State can use this provision to respond quickly to a food emergency?

Answer 5. The very term "imminent hazard" implies a public health threat that must be addressed with alacrity. Under S. 3128, a State wishing to use its imminent hazard authority would first be expected to ask the FDA to deal with the issue (and

perhaps engage in the development of a scientific standard). Such a process would not allow expeditious solution of an imminent hazard, and thus would be a negative public health provision.

QUESTIONS OF SENATOR HARKIN

Question 1. Exemption From Preemption.—The proposed section 403B(f) exempts from preemption certain types of State required notifications such as open date labeling, religious dietary labeling, organic or natural designation, and statements of geographic origin, among others. Please explain why such exemption is needed for each of the particular exemptions contained in this subsection. What provisions in the bill imply that these sorts of provisions are preempted absent the exemption? Does the clear exemption for these specific State-required notifications create the implication that all other State-required notifications are preempted?

Answer 1. I am not a lawyer, but it appears to me that by clearly listing certain things that are not preempted, one is left with the impression that everything else is *not* exempted from preemption. So, yes, I agree with you that the clear exemption for these specific State-required notifications create the implication that all other State-required notifications are preempted.

Question 2. Scope of the Bill.—Can you comment on the scope of the bill compared to the scope of the problem? Most importantly, are there alternative and more circumscribed means by which to address these matters? Is it possible to create a mechanism by which to avoid the kind of situation in which Mr. Stadtlander finds himself without such broad preemption?

Answer 2. The bill's scope certainly implies that there is a major, nationwide problem with consumer confusion and excessive costs to the food industry. Such a problem has not, to my knowledge, been shown. Mr. Stadtlander, however, certainly finds himself in a bind, due to the so-called "bounty hunter" provision embodied in Proposition 65, which allows private parties to sue if the State has not taken action. On the one hand, Mr. Stadtlander's cereal is alleged to contain much higher levels of acrylamide than other cereals, and public health officials at international, national, and State levels are trying to lower acrylamide levels in food across the board; so some would argue that Mr. Stadtlander needs whatever urging possible to change his production processes so as to lower acrylamide levels in his food. On the other hand, California is engaged in a process to address acrylamide in all foods, and, as I testified at the hearing, I would hope that the judge in Mr. Stadtlander's case would defer further action on his case until his product can be brought under the auspices of the State (and Federal) actions that will be taken more broadly to lower acrylamide levels.

Question 3. Multiple Labels.—With regards to warning labels and notification requirements, supporters of this bill, have complained about a patchwork quilt of food safety warnings required by different States. Yet I have not yet seen a specific food product that contains multiple labels—one required by Federal law and another required by State law. Can you provide me with such an example or multiple examples?

Answer 3. The food industry has long feared that individual State actions will result in differing State labeling requirements that will impose massive costs on them with regard to the distribution and labeling of their products. In theory, their fears are legitimate. However, States have acted responsibly on such matters, such conflicting and confusing labels on foods have generally not appeared, and thus the substantial consumer confusion and production costs have not been seen. The Reagan administration conducted a lengthy study looking for such adverse effects, and did not find them (and those conclusions were affirmed by the first Bush and Clinton administrations. If Congress believes those examinations are no longer up to date, perhaps a better course than pursuing this legislation at this time would be to sponsor another, independent, examination to determine if such costs are being incurred.

Question 4. Warning vs. Notification.—On the issue of what constitutes a warning, there is some disagreement. The Center for Science in the Public Interest asserts that nearly 200 State laws would be affected by this legislation. Mr. Hutt has reviewed the CSPI report on this matter and states that the CSPI report is incorrect because it doesn't distinguish between "warnings" and "notification." He argues that if one looks only at warnings and not at notifications more broadly, that the number of State laws affected would be significantly less and also asserts that S. 3128 clearly pertains only to notification requirements that contain food-related warnings and not notification more broadly.

However, I am unclear as to whether the term "warning," as defined by the bill, is as clear as has been asserted. The bill says that "warning," used with respect to a food, means any statement, vignette, or other representation that indicates, directly or by implication, that the food presents or may present a hazard to health or safety.

Do you see any uncertainty under this definition, especially the "by implication" portion? Can you explain to me more precisely the legal import and effect of this "by implication" language? Why is it important to have the "by implication" language included in the bill at all?

By way of example, what if a State adopts a requirement that grass-fed beef be labeled as such? Directly, this may be only a notification. But what if research definitively shows that grass-fed has health benefits relative to grain-fed beef. By implication, wouldn't a grass-fed beef notification then become a warning regarding grain-fed beef? Perhaps this isn't the best illustration. My point is not to comment on grass-fed beef or the State of science pertaining to it, but to ask whether the definition of warning in the legislation is altogether clear.

Answer 4. It appears that there is indeed ambiguity in whether a notification is a safety warning. FDA concluded years ago that the proposed "notification" by some States that some milk might contain the animal hormone BST was, in fact, a "warning," as it implied that such milk might pose a safety risk (if the milk cow had been given BST to promote milk production). Similarly, a "grass-fed" beef notification would/could be felt to imply that the beef cattle were free of beef hormones commonly used in beef cattle husbandry. Thus, under that view, the term "grass-fed" would be an implied warning and covered by S. 3128.

Question 5. Cost-Benefit Analysis.—Issues like food safety often involve cost-benefit analyses. Are you aware of any cost-benefit analysis showing the costs and benefits of a single national regulatory scheme as envisioned under S. 3128 compared to the costs and benefits under the current relationship?

Answer 5. I served on a Reagan administration task force, led by the President's Council of Economic Advisors that was charged in the late 1980s with carefully examining the costs of Proposition 65 and similar State initiatives. Despite a long and detailed search for excessive costs imposed on the food industry resulting from consumer confusion and conflicting State labeling and warning requirements, that analysis concluded that the costs were only theoretical and that preemptive action to address State food safety warnings should be considered only if substantial costs were to actually occur. The Administrations of G.H.W. Bush and Bill Clinton also studied the issue and reached the same conclusions as the original Reagan study—that preemption was not warranted absent clear, proven negative effects on the food production system.

Question 6. State Innovation.—States and local regulatory efforts have often put State and local actors out ahead of Federal agencies in discovering more efficient and effective means to accomplish the goal of public protection. Enacting a single, national regulatory scheme may mean the loss of these resources and of State and local innovation. How can we be sure that a single Federal system will lead to the most effective and efficient approaches to ensuring better public health?

Answer 6. As I said in my formal testimony at the committee's recent hearing on this matter, the States have been a valuable complement to Federal food safety protections, and have often taken the lead in identifying public health threats that they have brought to the attention of Federal officials. That synergistic system should be protected and nurtured, and I fear that S. 3128 will have the opposite effect, by weakening the ability of States to protect their citizens (and thus to some extent remove the "canary in the coal mine"). Preemption can be quite appropriate where the States have not taken action in the past, such as with allergen and nutrition labeling for processed foods. But States have a long, distinguished, and effective history in food safety, which should not be undermined.

Question 7. Imminent Hazard Authority.—Could you please explain the imminent hazard authority to me more fully? First, explain to me the legal definition and standing of the term "imminent hazard" as well as the term "adverse health consequences?" Are these terms defined in statute, regulations, or guidance or, alternatively, have they been further explicated in existing case law?

If a State determines that there is an imminent hazard, why is it necessary for them to notify FDA and to determine if FDA has or has not initiated enforcement action on the matter? How do you envision that this process would operate? Would a State have to receive word from the FDA that they are not initiating enforcement? How long would a State have to wait to determine whether or not the FDA has initiated or plans to initiate enforcement action? If there is truly an imminent hazard

that requires immediate action by State authorities, is this process of notification, waiting, and clarification truly the best process, in terms of expediency and therefore, in terms of human health?

Answer 7. S. 3128 appears to require a State to come to the FDA before it can act upon an identified "imminent hazard," which is generally meant to refer to a public health threat that needs prompt and decisive action. Forcing a State to present its evidence to the FDA, then perhaps await FDA's procedural efforts to regulate the "hazard," would deprive the State of its ability to promptly protect its citizens. Thus, it is difficult to see how the "imminent hazard" authority would, in fact, be what it claims to be.

Question 8. Restaurant Labeling.—This country has now required food manufacturers to provide nutrition information on packaged foods for about 15 years. I think most people agree that the nutrition information provided on packaged foods has been successful. Americans appreciate the information and rely on it to make informed choices about what they eat.

However, more and more, Americans spend their food dollars away from home, mostly in restaurants. As a result, individuals who have good nutrition information when cooking at home are totally in the dark when they go out to a restaurant. That's why I've proposed a bill that would require chain restaurants to provide basic nutrition information (calories, salt, fat, trans fat) on standard menu items at the point of sale.

I'm hopeful that Congress will take up and pass my bill for restaurant nutrition labeling. But, if it doesn't happen, there is always the possibility of a State or a municipality passing a similar law on restaurant labeling. If a State were to pass a law that required chain restaurants to provide nutrition information on calories, salt, fat, and trans fat at the point of sale, would such a law, in your view, be preempted by passage of the proposed National Uniformity legislation?

Alternatively, what if, in addition to the required information on calories, salt, fat, and trans fat, a State or municipality required restaurants to also post the following notice, "The National Academy of Sciences has concluded that trans fats provide no known benefit to human health and recommends that consumption of trans fats be as low as possible." Would such a notification be preempted by passage of S. 3128?

Answer 8. When the Nutrition Labeling and Education Act was enacted by Congress in 1990, it preempted States from imposing separate nutrition labeling requirements on packaged foods (correctly, in my judgment, as States had not been active in that area and national standards were appropriate). But the act also exempted restaurants, including so-called "fast food" and other chain restaurants, from nutritional labeling. Thus, States presumably have the authority to require nutrition labeling for restaurants, and there is a public health justification for doing so for restaurants with standard menu items (and, indeed, most fast food chain restaurants do so voluntarily now, with varying degrees of public display). However, if notification of such food constituents as trans fats were required by States, and considered "warnings," then it would be logical to assume that the States would be preempted from requiring such notifications.

Question 9. School Nutrition Standards.—Mr. Hutt, in his testimony before the committee, raised the issue of State and local laws regarding school food sales. In particular, these are laws that govern what and when food can be sold at schools, especially unhealthy foods such as soft drinks and snack foods. Mr. Hutt's assertion, which I hope is correct, is that because school nutrition issues are typically governed by USDA rather than the FDA, then these State and local laws would not be preempted by S. 3128.

But other than the simple argument that school nutrition is traditionally the purview of USDA, are there other substantive reasons why S. 3128 wouldn't or couldn't be applicable to State and local school nutrition laws? Is there, for instance, any case law that you can cite that would further support this assertion? Wouldn't it still be possible that someone could challenge such laws by arguing that S. 3128, if passed, has preempted them?

Furthermore, if areas that are traditionally the jurisdiction of USDA wouldn't be affected by this bill, why is it that organic designations, which are the purview of USDA, are specifically preempted by the proposed section 403B(f) of S. 3128? Does the clear exemption of organic, even though it is traditionally governed and regulated by the Department of Agriculture, create the implication that all other requirements are therefore affected, even those that are under the purview of USDA? Is it possible that someone could cite this language in an action challenging State school nutrition laws following passage of S. 3128?

Answer 9. I am not a lawyer, and am certainly not familiar with case law on this issue. But I would agree with you that the exemption for organic descriptors creates the impression that other USDA-related items may be covered by S. 3128, including State school lunch requirements.

QUESTIONS OF SENATOR REED

Question 1. Previous Administrations have rejected Food Uniformity.—Is it true that previous Administrations have considered the issue of Federal standards for food uniformity and rejected it? Could you please elaborate on which Administrations contemplated food uniformity and their reasons for maintaining the current State food safety framework?

Answer 1. The administrations of Presidents Reagan, G.H.W. Bush, and Clinton explicitly examined this issue and rejected it, concluding that preemption of State food safety standards was not warranted absent a showing of significant adverse economic effects caused by conflicting State requirements (which they concluded did not exist).

Question 2. Disruption of State Efforts.—States presently conduct 80 percent of all domestic food inspections. State inspection authorities generally understand the intricacies of the local food industries. For instance, seafood and shellfish in particular are big business in my little State. Under this bill, responsibility for inspection and oversight of these local manufacturers would fall under the authority of FDA officials. Does it unsettle you that S. 3128 might disrupt these inspections, especially as the Federal Government will not be able to step in?

Answer 2. I would not read S. 3128 as specifically preempting a State's ability to inspect food processors. However, if a State could not set or enforce its food safety standards, as contemplated by S. 3128, why would they continue to inspect? Accordingly, the only inspection system would be the FDA's. Let me give you an example of what that would mean. FDA now has over 200,000 registrants of food producers, each and every one of which should be inspected with some regularity (even if only every year or two). This year, FDA will conduct about 5,000 inspections. This means that a food producer in a given State would be inspected only once every 40 years by the FDA. So, the practical effect of removing State inspections would be eliminating the likelihood that a given food processor would *ever* be inspected.

LETTERS OF SUPPORT

NATIONAL BLACK CHAMBER OF COMMERCE,
WASHINGTON, DC 20036,
July 3, 2006.

Hon. BILL FRIST,
Senate Majority Leader,
Washington, DC 20510.

Re: S. 3128, National Uniformity for Food Act of 2006

DEAR MAJORITY LEADER FRIST: The National Black Chamber of Commerce joins the U.S. Chamber of Commerce, the Grocery Manufacturers Association and many other organizations in support of the National Uniformity for Food Act of 2006, S. 3128. This bill is to amend the Federal Food, Drug and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes. This is consistent with the NBCC philosophy that mainstreaming regulation avoids needless costs and bureaucracy. This will benefit American citizens as well as businesses.

Under the current system, food regulations are composed of different and sometimes contradictory requirements. This imposes unnecessary complexity and cost on makers of food throughout the United States. By bringing a uniform code to our industry, the legislation represents a major step forward in assuring consumer confidence in the food they buy for their families.

As you know, the House of Representatives overwhelmingly supported their version of this bill by a vote of 283 to 139. Your support of this bill when it hits the floor will be very appreciated by the 1.4 million Black-owned businesses which we represent.

Sincerely,

HARRY C. ALFORD,
President and CEO.

U.S. HISPANIC CHAMBER OF COMMERCE,
WASHINGTON, DC 20037,
June 19, 2006.

U.S. Senate,
Washington, DC 20510.

DEAR MEMBERS OF THE U.S. SENATE: On behalf of the 2 million Hispanic-owned businesses in the country, we are writing to you to vote YES on S. 3128, the "National Uniformity for Food Act of 2006." This important piece of legislation will establish a single standard for food safety, helping consumers, families and businesses in an ever-changing and currently confusing food labeling environment.

Under the current system, food regulation is composed of a variety of different and sometimes inconsistent requirements. This "patchwork" of different State laws adopting different regulatory requirements on identical food products is confusing to consumers and burdensome for businesses that distribute products across State lines. This imposes unnecessary complexity and cost on food producers and distributors throughout the United States. By bringing a uniform code to our industry, the National Uniformity for Food Act represents a major step forward in assuring that there are rational, scientifically-based and consistent standards in all 50 States.

The National Uniformity for Food Act also takes a measured approach to national uniformity for food labeling by providing a mechanism for a thorough, orderly review of existing State regulations that may differ from Federal regulations. By granting States the ability to have the Federal Government adopt their State standard, this bill carefully balances the need for uniformity while respecting the important role State and local governments have in ensuring the safety of the food supply.

Once again, the United States Hispanic Chamber of Commerce strongly urges you to support S. 3128, the National Uniformity for Food Act of 2006, if you have any questions, please feel free to contact me at (202) 842–1212.

Sincerely,

MICHAEL L. BARRERA,
President and CEO.

WYOMING RETAIL MERCHANTS ASSOCIATION (WRMA),
CHEYENNE, WY 82003.

Hon. MICHAEL B. ENZI,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR ENZI: On behalf of the Wyoming Retail Merchants Association, I am writing to urge you to cosponsor and support S. 3128, the "National Uniformity for Food Act of 2006." Senators Richard Burr (R-NC), Pat Roberts (R-KA), and Ben Nelson (D-NE) introduced the legislation on May 25, 2006. On March 8, the House passed the legislation (H.R. 4167) with a strong bipartisan vote of 283–139. I urge you to cosponsor this critical piece of legislation.

The legislation provides for science-based uniform food safety standards and warning requirements so that Americans in every State are protected equally. It is common-sense legislation that will help consumers make educated decisions for themselves and their families in an ever-changing and confusing food labeling environment. Consumers deserve a single standard when it comes to food safety, and this bill will allow States and the FDA to work collaboratively in establishing sound food safety policies that benefit—not confuse—consumers.

The "National Uniformity for Food Act" is top priority for Wyoming Retailers. It recognizes that it makes no sense to have different States adopting different regulatory requirements for identical food products. This legislation will instead provide consumers with a single set of consistent, science-based food safety regulations for food products sold in all 50 States.

Successful passage of the "National Uniformity for Food Act" is absolutely critical. We urge you to make its passage a top priority.

Sincerely,

LYNN BIRLEFFI,
Executive Director.

STATE OF NEBRASKA,
OFFICE OF THE ATTORNEY GENERAL,
LINCOLN, NE 68509,
April 19, 2006.

Hon. BEN NELSON,
U.S. Senate,
Washington, DC 20510.

Re: H.R. 4167—Food Labeling Legislation

DEAR SENATOR NELSON: I am writing to urge you to support The National Uniformity for Food Act when it is introduced in the Senate. Last month, 39 Attorneys General signed a NAAG letter to Congress urging you to oppose the House bill, H.R. 4167, which passed in the House by a large and bipartisan margin on March 8. I respectfully disagree with my colleagues regarding the effect of the bill and believe it would establish a consistent, science-based framework to ensure the security and safety of our food supply.

I am satisfied that H.R. 4167 in its current form will not compromise the ability of State and local officials to act decisively when faced with a food safety threat of any kind. Rather, the bill fosters consistency in the regulation of our food supply and ensures a framework in which State Attorneys General and our State agriculture and health officials will remain unencumbered and effective in protecting consumers.

Attorneys General across the country are generally protective of States' rights. However, food label warnings seem to be one area in which it makes sense to have a national standard. I do not believe that food manufacturers that ship their food all around the world should be required to potentially develop a different label for each State in the union. H.R. 4167 recognizes and preserves the essential role that States play in the day-to-day business of ensuring a safe food supply. For example, the bill would keep all existing State warning requirements in place while States petition the U.S. Food and Drug Administration (FDA) and both a public comment period and transparent review process are completed.

A similar petition procedure is also established for warnings requirements that are not currently the subject of State law. Expedited review is specifically required for petitions involving notifications relating to cancer, reproductive or birth defects, or that furnish information to parents that allows them to limit a child's exposure to cancer-causing agents, or reproductive or developmental toxins.

It is noteworthy that the bill specifically applies only to mandated warning statements. Nothing in H.R. 4167 infringes upon the right of any State agency or official to share food safety concerns (e.g., public education campaign) with their citizens. The sum of the parts of H.R. 4167 that address warning statements ensures that States participate in, and the Federal Government ultimately sets, national food safety policy. A close reading of the proposed legislation confirms that this balance would be achieved by H.R. 4167.

Certain food safety and adulteration provisions of the Federal Food, Drug, and Cosmetic Act are also subject to national uniformity under the bill, with several important limitations. is my understanding that nearly all States have food statutes comparable to the food safety and adulteration provisions of Federal law that are covered by the bill. The bill is not likely to have any practical impact on the content or application of such State food laws. Separately, I would note that H.R. 4167 completely excludes—and thus would not affect the Federal and corresponding State provisions that are most often relied upon by State and local inspectors to seize, embargo or otherwise take immediate action against unsafe food (e.g., food held under unsanitary conditions, product unfit for food).

Where State food safety and adulteration law is the same as the Federal, States are only restricted in adopting adulteration-related requirements that are already the subject of an FDA regulation or "final guidance" as that term is defined by Federal regulation. If there is no FDA regulation or "final guidance," States would be free to apply their food safety laws to a circumstance as they see fit.

Finally, the bill, once enacted, cannot become effective until the U.S. Department of Health and Human Services, in consultation with the U.S. Department of Homeland Security certifies to Congress that implementation of the new law would pose no additional risk to public health or safety from terrorist attacks on the food supply. State and local officials remain on the front-line in protecting our food supply and their rapid response is left intact under H.R. 4167. Accordingly, this office does not foresee any significant changes in how State and local officials protect consumers.

I urge your support for the Senate version of H.R. 4167, when introduced. The plain language of the bill suggests that a proper balance between uniform, con-

sistent Federal food safety policies and requirements can be achieved without compromising the critical role States play day-in and day-out in the marketplace.

Sincerely,

JON BRUNING,
Attorney General.

BIMBO BAKERIES USA, INC.,
FORT WORTH, TX 76155–2861,
June 28, 2006.

Hon. MICHAEL B. ENZI,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR ENZI: On behalf of **Bimbo Bakeries USA, Inc.,** I am writing to urge you to support S. 3128, the "National Uniformity for Food Act of 2006." Senators Richard Burr (R-NC), Pat Roberts (R-KS), and Ben Nelson (D-NE) introduced the legislation on May 25, 2006. On March 8, the House passed their version of this legislation (H.R. 4167) with a strong bipartisan vote of 283–139. I urge you to support this critical piece of legislation.

S. 3128 provides for science-based uniform food safety standards and warning requirements so that Americans in every State are protected equally. It is commonsense legislation that will help consumers make educated decisions for themselves and their families in an ever-changing and confusing food labeling environment. Consumers deserve a single standard when it comes to food safety, and this bill will allow States and the FDA to work collaboratively in establishing sound food safety policies that will benefit—not confuse—consumers.

The "National Uniformity for Food Act" is a top priority for the baking industry. This critical legislation recognizes that it makes no sense to have different States adopting various regulatory requirements for identical food products. S. 3128 will instead provide consumers with a single set of consistent, science-based food safety regulations for food products sold in all 50 States.

Successful passage of the "National Uniformity for Food Act" is absolutely critical to **Bimbo Bakeries USA, Inc.** and our employees. I urge you to make its passage a top priority.

Thank you in advance for your consideration of my request to support S. 3128.

Sincerely,

JOE T. DANGELMAIER,
Senior Vice President of Operations,
Bimbo Bakeries USA, Inc.

NATIONAL ASSOCIATION OF MANUFACTURERS (NAM),
WASHINGTON, DC 20004–1790,
July 13, 2006.

Hon. MICHAEL B. ENZI,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR ENZI: On behalf of the National Association of Manufacturers (NAM), I urge you to cosponsor and strongly support S. 3128, the National Uniformity for Food Act.

The National Uniformity for Food Act will create national, uniform standards for food safety labeling. Under current policy, there could be 50 or more labeling standards, causing logistical and distribution inefficiencies and, potentially, drawing concerns from our international trading partners about labeling being used as a nontariff barrier to trade. Thus, S. 3128 is an appropriate congressional exercise of the Constitution's Interstate Commerce Clause.

Some State officials have wrongly argued that their citizens will lose protections if S. 3128 becomes law. Actually, States will retain their ability to contribute to food safety information by petitioning to have their current and new standards approved by the FDA. If a petitioned standard is warranted, all consumers nationwide would benefit rather than just the citizens of certain States.

Your cosponsorship of and support for S. 3128 would be appreciated. Please let me or Larry Fineran, the NAM's vice president for legal and regulatory reform, know

if you have any questions or need additional information. Mr. Fineran can be reached at (202) 637–3174 or lfineran@nam.org.

Sincerely,

JOHN ENGLER,
President and CEO.

STATE OF ARKANSAS,
STATE CAPITOL BUILDING,
LITTLE ROCK, AR, 72201,
April 17, 2006.

Hon. MARK PRYOR,
Hon. BLANCHE LINCOLN,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR PRYOR AND SENATOR LINCOLN: I am contacting you to ask for your support for legislation that has been introduced in the Senate that would provide national, uniform food safety standards and warning requirements for food. The National Uniformity for Food Act passed the U.S. House of Representatives on March 8th by a vote of 283–139 with bipartisan support.

If approved by the Senate, States could petition the U.S. Food and Drug Administration (FDA) to adopt their food safety standards and warning requirements nationally. If approved by the FDA, food manufacturers would incorporate the requirements, thus providing all consumers nationwide with the same information.

This is an opportunity for Congress to embrace a measure that would ensure critical safety information about food products delivered to consumers nationwide in a simplified fashion. Arkansas consumers deserve more than a mixed message when it comes to important information regarding food safety.

I have spent a great deal of time in recent years looking at wellness and obesity issues in America. Maintaining a consistent labeling system is important to all our citizens. This policy will also protect Arkansas-based food manufacturers from having to deal with the logistical nightmare of 50 labels for each product sold in the United States.

Maintaining consumer confidence in food safety is an important goal. The National Uniformity for Food Act is a step in the right direction. For this reason, I respectfully ask for your support on this measure.

Sincerely yours,

MIKE HUCKABEE,
Governor.

CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,
WASHINGTON, DC 20062–2000,
June 13, 2006.

TO THE MEMBERS OF THE UNITED STATES SENATE: The U.S. Chamber of Commerce, the world's largest business federation representing more than 3 million businesses and organizations of every size, sector, and region, strongly urges you to consider cosponsoring S. 3128, the National Uniformity for Food Act, a similar version of which recently passed the House with strong bi-partisan support. This legislation would amend the Federal Food, Drug, and Cosmetic Act by extending national uniformity to food safety and warning label laws.

With the enactment of this legislation, national uniformity would be extended to one of the very few areas where it has been lacking: food safety and warning labeling. Meat and poultry regulations, nutritional labeling, and pesticide tolerance standards are all regulated at the Federal level. Food safety and warning label requirements, on the other hand, have been governed by a "patchwork quilt" of State and local regulations. This collection of inconsistent requirements is burdensome for food businesses and confusing for consumers.

The National Uniformity for Food Act takes a commonsense, measured approach to achieving national uniformity for food safety and warning label requirements, striking an appropriate balance between national and State interests. The legislation provides ample time for review and harmonization of preexisting State rules, and establishes procedures under which States can opt out of uniformity requirements. Furthermore, this legislation does not impact the States' inspection and enforcement authority over food safety and warning label requirements.

With the increase in new food sources from overseas, thousands of new products introduced each year by domestic manufacturers, and faster communications and transportation, the need for a national food safety system is greater today than it was even 10 years ago. Consumers should not have to endure conflicting standards that declare an identical food product safe in one State, but hazardous in another.

The Chamber strongly urges you to consider cosponsoring S. 3128, the National Uniformity for Food Act, and looks forward to a hearing on this bill in the near future.

Sincerely,

R. BRUCE JOSTEN,
Execitive Vice President,
Government Affairs.

INTERNATIONAL DAIRY FOODS ASSOCIATION (IDFA),
July 25, 2006.

Hon. MICHAEL ENZI,
Chairman,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

Hon. EDWARD KENNEDY,
Ranking Member,
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR CHAIRMAN ENZI AND RANKING MEMBER KENNEDY: On behalf of the International Dairy Foods Association, I am writing to ask for your support of the National Uniformity for Food Act, S. 3128, which was referred to the Senate Health, Education, Labor, and Pensions Committee (HELP) in March. This important bill would create a uniform, national system that recognizes the role of State and local governments in the regulation of food products and integrates them into the national system.

The International Dairy Foods Association (IDFA) represents the Nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 530 companies representing a $90-billion a year industry. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's 220 dairy processing members run more than 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese and frozen desserts produced and marketed in the United States.

We ask you to consider the following points when the HELP Committee hears S. 3128 on Thursday, July 27. Current individual State regulations create an unwieldy national patchwork of standards, which oftentimes confuse consumers about the food they eat and the beverages they drink. Under the current system, food regulation is composed of a variety of different and sometimes inconsistent requirements. S. 3128 seeks to harmonize these differences to achieve a more uniform and national system. Consistency in labeling is vital to dairy processors that sell their products in multiple States and want to provide the clearest information to American consumers.

This legislation provides for science-based uniform food safety standards and warning requirements so that Americans in every State are protected equally. Under the bill, the Federal requirements would take effect gradually and provide for thorough review of existing State regulations. The bill allows for the States to petition the Food and Drug Administration to adopt their regulations as national requirements or exempt them from national uniformity. This legislation would not undo current safety regulations, as opponents have claimed, for products such as milk.

Congress has repeatedly recognized the importance of uniformity in food regulation. The Nutrition Labeling and Education Act (1990), the Food Quality Protection Act (1996), the Poultry Products Inspection Act and the Meat Inspection Act are examples of policies containing uniformity provisions. The House has already acted on this important legislation and passed the bill with a strong bipartisan vote of 283–139.

I urge you to join the list of cosponsors of S. 3128, the National Uniformity for Food Act, and ultimately vote "yes" on this critical legislation. Feel free to contact me directly for more information at (202) 737–4332.

Sincerely,

CHIP KUNDE,
Senior Vice President,
Legislative and Economic Affairs.

HISPANIC ASSOCIATION ON CORPORATE RESPONSIBILITY (HACR),
WASHINGTON, DC 20005,
June 22, 2006.

Hon. BILL FRIST,
Majority Leader,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR FRIST: On behalf of the Hispanic Association on Corporate Responsibility (HACR), one of the most influential advocacy organizations in the Nation representing 14 national Hispanic organizations, I am writing to urge you to support S. 3128, the "National Uniformity for Food Act of 2006." Senators Richard Burr (R-NC), Pat Roberts (R-RA), and Ben Nelson (D-NE) introduced the legislation on May 25, 2006. On March 8, the House passed the legislation (H.R. 4167) with a strong bipartisan vote of 283–139.

This legislation recognizes that it makes no sense to have different States adopting different regulatory requirements on identical food products. S. 3128 will instead provide consumers with a single set of consistent, science-based food safety regulations for food products sold in all 50 States.

Under the current system, food regulations are composed of different and sometimes contradictory requirements. This imposes unnecessary complexity and cost on makers of food throughout the United States. These costs are most often passed on to consumers. By bringing a uniform code, the legislation represents a major step towards ensuring consumer confidence in the food they buy for their families.

S. 3128 takes a measured approach to national uniformity for food by providing a mechanism for a thorough, orderly review of existing State regulations that may differ from Federal regulations. By granting States the ability to have the Federal Government adopt their standard, this bill carefully balances the need for uniformity while respecting the important role State and local governments have in ensuring the safety of the food supply.

Founded in 1986, HACR is one of the most influential advocacy organizations in the Nation representing 14 national Hispanic organizations in the United States and Puerto Rico. Our mission is to advance the inclusion of Hispanics in corporate America at a level commensurate with our economic contributions. To that end, HACR focuses on four areas of corporate responsibility and community reciprocity: employment, procurement, philanthropy, and governance.

Once again, we urge you to support this legislation. Thank you for your time and consideration.

Sincerely,

CARLOS F. ORTA,
President and CEO.

COUNCIL FOR CITIZENS AGAINST GOVERNMENT WASTE,
WASHINGTON, DC 20036,
June 19, 2006.

U.S. Senate,
Washington, DC 20510.

DEAR SENATOR: On behalf of the more than 1.2 million members and supporters of the Council for Citizens Against Government Waste (CCAGW), I urge you to support S. 3128, the "National Uniformity for Food Act of 2005." S. 3128 would harmonize inconsistent State requirements by providing national, uniform food safety standards and warning requirements.

Under the current system, States may impose different, and sometimes contradictory, regulations. This imposes unnecessary complexity and cost on food processors and manufacturers throughout the United States. These costs are most often passed

on to consumers. In addition, taxpayers in the various States bear the burden for administration of these unnecessary and duplicative regulations.

It does not make sense to have States adopting different regulatory requirements on identical food products. S. 3128 will provide consumers with a single set of consistent, science-based safety regulations for food products in the entire country. The legislation provides that where the Food and Drug Administration (FDA) has established a safety standard, the States would adopt and enforce the same standard. If the FDA has not set a safety standard for a particular food ingredient, the States would remain free to set and enforce their own standards.

The National Uniformity for Food Act takes a measured approach by providing a mechanism for a thorough, orderly review of existing State regulations that may differ from Federal regulations. By providing States with the ability to petition for adoption at the Federal level any existing State food safety or warning requirements, the legislation carefully balances the need for uniformity while at the same time recognizing the role that State and local governments have in ensuring the safety of the Nation's food supply.

Any votes on S. 3128 will be among those considered in CCAGW's *2006 Congressional Ratings*.

Sincerely,

THOMAS A. SCHATZ,
President.

LETTERS OF OPPOSITION

CALIFORNIA LEAGUE OF CONSERVATION VOTERS, CALIFORNIA LEAGUE FOR ENVIRONMENTAL ENFORCEMENT NOW, CALPIRG, CENTER FOR FOOD SAFETY, CENTER OF SCIENCE IN THE PUBLIC INTEREST, COALITION FOR CLEAN AIR, CONSUMER ACTION, CONSUMER FEDERATION OF CALIFORNIA, CONSUMERS UNION, ENVIRONMENT CALIFORNIA, ENVIRONMENT LAW FOUNDATION, ENVIRONMENTAL WORKING GROUP & EWG ACTION FUND, FRIENDS OF THE EARTH, GOTMERCURY.ORG, GREENPEACE, HEALTHY CHILDREN ORGANIZING PROJECT, NATIONAL ENVIRONMENTAL TRUST, NATURAL RESOURCES DEFENSE COUNCIL, OCEANA, PHYSICIANS FOR SOCIAL RESPONSIBILITY, SIERRA CLUB, UNION OF CONCERNED SCIENTISTS, U.S. PUBLIC INTEREST RESEARCH GROUP, UNITED STEELWORKERS

June 7, 2006.

U.S. Senate,
Washington, D.C. 20510.

DEAR SENATOR: On behalf of our millions of members and supporters, we strongly urge you to support the safety of America's food supply by *opposing* and refusing to cosponsor the so-called "National Uniformity for Food Act of 2005," S. 3128. This legislation, more appropriately labeled the "State Food Safety Preemption Act," tinkers with—but in some respects is actually *worse* than—the hastily-passed House food safety preemption bill, H.R. 4167.

For example, the Senate bill explicitly deletes the House's provision—adopted on the floor as the Wasserman-Shultz amendment by a vote of 253–168—allowing States to retain warnings to pregnant women and parents about the significant risks to the brains of fetuses and young children from high levels of mercury in certain kinds of fish. *Consumer Reports* (published by Consumers Union) just published an article on the risk of mercury in tuna, which we have attached to this letter. The U.S. Food and Drug Administration (FDA) warns on its Web site that pregnant women and young children should avoid certain fish due to high mercury levels, but under S. 3128 State-required warnings about these risks—even one identical to the Federal FDA warning—would be preempted.

In this and many other ways, S. 3128 undermines public health protection. The Senate bill makes other minor changes to the House legislation, but none alter the fundamental thrust of the bill, which is to stop States from protecting their citizens from dangers in the food supply when the Federal Government is not doing so. This bill has been introduced repeatedly for many years, yet no public hearings have been held on it, and we are confident it cannot withstand public scrutiny.

The vast majority of editorial writers, State officials, environmental, consumer, health, labor and other groups strongly oppose this problematic legislation (see attached). For example, State and local food safety officials and 39 Attorneys General have weighed in against the House bill because it would nullify critically-important consumer and health protections and right-to-know requirements. Similarly, at least eight governors, including Governor Schwarzenegger, oppose the bill. The preempted

State and local rules protect consumers by filling the gaps left by the understaffed and underfunded FDA. States would no longer have the authority to provide important protections for the public, such as shellfish, milk, and egg safety standards—unless the FDA grants a State waiver. This seriously undermines food safety and offends longstanding principles of federalism. Preemption of State food safety laws is opposed by the National Association of State Departments of Agriculture and the Association of Food and Drug Officials (AFDO). AFDO points out that this bill, if enacted, "will effectively eliminate our Nation's biosecurity shield, and will undermine our whole food safety and biosurveillance capability."

The waiver process of the legislation would impose huge financial burdens on the financially-strapped FDA and States. The CBO estimated that this legislation would require the FDA to spend $100 million (over 5 years) reviewing over 240 waiver requests. Moreover, States would incur substantial legal and technical expenses in seeking an FDA waiver. These Federal and State resources could be better used in promoting food safety.

We urge you to oppose this rollback of State and local food safety programs.

Sincerely,

Susan Smartt, Executive Director, California League of Conservation Voters; Joseph H. Guth, J.D., Ph.D., Executive Director, California League for Environmental Enforcement Now; Emily Clayton, Public Health Advocate, CALPIRG; Will Rostov, Senior Attorney, Center for Food Safety; Benjamin Cohen, Senior Staff Attorney, Center of Science in the Public Interest; Tim Carmichael, President and CEO, Coalition for Clean Air; Linda Sherry, Director of National Priorities, Consumer Action; Richard Holober, Consumer Federation of California; Susanna Montezemolo, Policy Analyst, Consumers Union; Rachel L. Gibson, Environmental Health Advocate & Staff Attorney, Environment California; James R. Wheaton, Esq., President, Environment Law Foundation; Bill Walker, Vice President/West Coast, Environmental Working Group & EWG Action Fund; Sara Zdeb, Legislative Director, Friends of the Earth; Eli Saddler, JD, MPH, MA, Public Health Analyst, GotMercury.Org; Rick Hind, Legislative Director, Greenpeace; Neil Gendel, Project Director, Healthy Children Organizing Project; Karen Steuer, Vice President, National Environmental Trust; Erik Olson, Advocacy Center Director, Natural Resources Defense Council; Ted Morton, Legislative Director, Oceana; Will Callaway, Legislative Director, Physicians for Social Responsibility; Ed Hopkins, Director of the Environmental Quality Program, Sierra Club; Susan Prolman, J.D., Washington Representative, Union of Concerned Scientists; Anna Aurillio, Legislative Director, U.S. Public Interest Research Group; Roxanne D. Brown, Legislative Representative, United Steelworkers.

[Editor's Note: Due to the high cost of printing, previously published materials submitted by witnesses are not reproduced. The article, "Mercury in Tuna" may be found at ConsumerReport.org®.]

U.S. PUBLIC INTEREST RESEARCH GROUP,
WASHINGTON, DC 20003,
May 4, 2006.

DEAR SENATOR: On behalf of the 30 State Public Interest Research Groups (PIRGs) across the country, we are writing to urge you to **oppose the National Uniformity for Food Act**, which passed the House on March 8. This bill, as passed by the House, would nullify at least 200 effective State and local food safety and right-to-know requirements, leaving a critical gap in the food safety net that protects public health and consumer choice.

This bill does **not** establish uniform food safety and labeling requirements; instead, it simply eliminates proven food safety and labeling standards that are more protective than Federal standards, even when the Federal Government has done nothing. In effect, the bill asks American consumers to trust that an increasingly unresponsive and under-funded Federal bureaucracy will enact adequate food safety and labeling standards that fully inform and protect them. Unfortunately, this often is not the case.

In the absence of adequate Federal regulations, numerous State and local governments have passed strong laws designed to safeguard public health, ensure a safe supply of food, and give consumers the information they need and deserve. Laws at risk of preemption include milk safety and restaurant sanitation standards in all 50 States; shellfish safety standards in 16 States; laws in 17 States requiring bars and liquor stores to post signs warning pregnant women of the effects of drinking alcohol; laws in 15 States allowing the States to enact stricter standards for food

additives; and scores of laws that require food manufacturers to truthfully label their products.

In addition to nullifying proven food safety laws already on the books, this bill would forever tie the hands of States and municipalities on a range of emerging food safety issues, whether or not the Federal Government has addressed public health concerns.

Federal legislation preempting State law would affect dozens of States, but the law that started the food industry's crusade is California's Proposition 65. In 1986, California voters approved Proposition 65, which requires warning labels on products containing chemicals known to cause cancer or birth defects. Consumers have the right to know if their food contains dangerous chemicals, and States and localities have the right to provide this information in the absence of strong Federal standards. Although critics of Proposition 65 say varying State standards pose a burden to food manufacturers, past administrations have dismissed this claim. When asked by the food industry to preempt California's law, President George H.W. Bush's administration concluded in 1989 that "no Federal preemptive action—either by regulation or otherwise—is warranted." The Reagan-Bush administration came to the same conclusion, and this is why Governor Arnold Schwarzenegger of California has opposed this bill.

Although the bill provides States with a limited opportunity to petition the Food and Drug Administration (FDA) to keep State laws on the books, the petition process is slow, uncertain, and expensive. In fact, the Congressional Budget Office estimates that this bill would cost FDA at least $100 million over a 5-year period. FDA does not have the staff or financial resources to absorb these costs. In fact, the number of full-time FDA employees dealing with food safety has fallen steadily from 3,167 in fiscal year 2003 to 2,843 in fiscal year 2006; the president's proposed fiscal year 2007 budget for FDA would further reduce that number to 2,757.

Eight Governors, 39 Attorneys General, the National Conference of State Legislatures, National Association of State Departments of Agriculture, Association of Food and Drug Officials, and others from both political parties have come out in sharp opposition to this bill, as it would usurp power from those best-positioned to serve as the first line of defense against threats to our food supply: States and localities. **Oppose the National Uniformity for Food Act** to preserve the State and local laws so critical to the safety of our food supply.

Sincerely,

ANNA AURILIO,
Legislative Director.

STATE OF NEW YORK,
DEPARTMENT OF AGRICULTURE AND MARKETS,
March 1, 2006.

DEAR MEMBER OF NEW YORK STATE DELEGATION: I am writing to express my concern for H.R. 4167, the National Uniformity for Food Act, as currently written. This bill could make it more difficult for States like New York with strict food safety regulations to protect our food supply.

As you know, the current food safety regulatory system in the United States is the shared responsibility of local, State and Federal partners. Local and State agencies currently perform approximately 80 percent of the food safety work across the Nation and Federal agencies often seek assistance from local/state partners in dealing with imminent health hazards. Therefore, it is imperative that States have the right to act quickly to enact laws and issue rules that address local and statewide public health concerns that cannot be anticipated or are not adequately addressed nationally.

In addition to preempting State laws relating to food safety warnings, H.R. 4167 would require States to change their laws to be identical to the Federal Food, Drug, and Cosmetic Act (FDCA).

If this proposed legislation is enacted, the Association of Food and Drug Officials anticipates the following:

State enforcement action related to adulterated food or misbranding would be open to challenge. Variations in language currently exist between many of New York's food laws, relating to adulterated food and additives, and the respective Federal counterpart. Under this proposed legislation, States will be required to seek clarity to determine if New York laws are "identical" to Federal law through an appeals process with the U.S. Food and Drug Administration (FDA). During this process, the States' enforcement attempts to ensure food safety and security will be open to legal challenge by anyone who violates State food safety provi-

sions. This fact is problematic at a time when the Nation is forced to address current problems such as "mad cow" disease (State food safety laws cover adulterated animal feed), unsafe food or food ingredients, and possible terrorist threats to the Nation's food supply. If passed into law, H.R. 4167 has the potential to deregulate food safety requirements at a time when quick food safety action could prove crucial to protecting the public. In the past, FDA has typically acted months after a food safety concern has occurred where New York State has taken action quickly to protect our consumers.

New York State's ability to enforce food safety laws would be hampered. Currently, there is very limited food inspection and corrective action taken in New York by Federal authorities. The New York State Department of Agriculture and Markets has coordinated over 1,000 food recalls in the past 3 years. If H.R. 4167 is passed, the New York law authorizing the quarantine or seizure of misbranded or adulterated food could be unenforceable. Due to the broad wording relating to the "construction" provision in this proposed Federal law, New York could be left without any means to keep contaminated food from entering the Nation's food supply.

Food inspection enforcement laws relating to grade A milk, grocery stores and shellfish would be preempted. Currently there are no Federal laws governing the inspection and regulation of grade A milk production for interstate commerce, shellfish harvesters and processors, or regulation of retail food establishments like grocery stores and restaurants. By failing to specifically reference these code sections in the bill, States are left to assume that State regulations, relating to inspection and enforcement of these programs, may be preempted because there are no Federal laws governing these program areas. These food safety areas would then be left unregulated.

For the above reasons, I ask you to work with us to amend H.R. 4167 to ensure that New York's strong food safety programs remain intact so that our food supply remains as safe as possible. Please let me know if we can provide any additional information or assistance.

Sincerely,

PATRICK H. BRENNAN,
Commissioner.

THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE,
WASHINGTON, DC 20005,
June 1, 2006.

MEMBERS OF THE U.S. SENATE.

DEAR SENATORS: The National Association of State Departments of Agriculture (NASDA) is writing to express our strong opposition to S. 3128, the National Uniformity for Food Act. NASDA represents the commissioners, secretaries and directors of agriculture in the 50 States and four territories, and we are partners in the Nation's food safety system.

The State Departments of Agriculture are very concerned that this legislation goes far beyond its stated purpose of providing uniform food safety warning notification requirements and greatly expands Federal preemption under the Food, Drug and Cosmetics Act. This preemption would seriously compromise our ability to enact laws and issue rules in numerous areas of food safety. Specifically, we believe the bill as currently written threatens existing State food safety programs and jeopardizes State/Federal food safety cooperative programs such as those related to Grade A milk, retail food protection, and shellfish sanitation. We simply disagree with recent analyses which claim that State laws and regulations will not be undermined by this legislation.

Our current food safety regulatory system is the shared responsibility of local, State and Federal partners. Approximately 80 percent of food safety inspections in the United States are completed at the State and local level. It is imperative that States retain their traditional right to address local and statewide public health concerns that cannot be anticipated or are not adequately addressed nationally. The preemption embodied in this legislation is broad, vague and sweeping. It calls into question the authorities of State and local laws that address adulterated foods, animal feed, and antiterrorism and other food defense programs. It will leave a critical gap in the safety net that protects consumers.

We are dismayed that Congress has not held any hearings on these important issues, especially since the legislation would radically change the traditional allocation of power between States and the Federal Government. NASDA urged the House of Representatives to hold hearings on similar legislation, and we were extremely disappointed when this did not happen. We call on the Senate to hold hearings be-

fore taking further action on S. 3128 and to seek full input from State and local partners in our food safety system.

NASDA would welcome the opportunity to discuss ways the legislation could be amended to achieve its intent without dismantling critical food safety regulatory programs at the State and local level. We respectfully request that you oppose S. 3128 until these critical issues are fully addressed.

Sincerely,

J. CARLTON COURTER III,
President, NASDA,
Commissioner, Virginia Department of Agriculture & Consumer Services.

THE CITY OF NEW YORK,
DEPARTMENT OF HEALTH AND MENTAL HYGIENE,
OFFICE OF THE COMMISSIONER,
NEW YORK, NY 10013,
April 11, 2006.

Hon. HILLARY CLINTON,
U.S. Senate,
Washington, DC 20510.

DEAR SENATOR CLINTON: I am writing to advise you of the very serious impact that enactment of H.R. 4167, the "National Uniformity for Food Act," would have on public health and safety in New York City. We join a broad spectrum of groups, including attorneys general and State agriculture commissioners, who strongly oppose this bill.

This act would encroach upon State and local governments' inherent power to act to protect the public health of their citizens. Moreover, by preempting local authority to seize, embargo and condemn adulterated food, it would seriously undermine the ability of New York City and other localities to respond immediately to the threat of terrorist activity affecting the food supply. Enactment of this bill, which passed the House of Representatives without public hearings, would have serious consequences that may not be intended or clearly understood by some of its proponents. I urge you to request that the appropriate Senate committees hold hearings and carefully review its impact. The bill, in its present form, should not be adopted by the Senate.

This legislation would go far beyond regulation of food labeling. It preempts State and local governments from enforcing laws regarding adulterated food that are not "identical" to Federal laws, creating a serious obstacle to our ability to protect the public from dangerous conditions that the Federal Government has not yet regulated. The power to act on local authority is of particular importance to New York City and other localities with multicultural populations that create a market for imported specialty foods and products. These products may be rare and unique to certain nationalities and cultures, and often present hazards that have not been anticipated or adequately addressed either by State or national governments. For example, when imported candies contaminated with lead were found in the city, a city law was enacted banning the sale of such products, because Federal regulatory efforts had been inadequate to stop these contaminated products from entering the country.

In addition, the bill may prevent local governments from enacting and enforcing even laws "identical" to Federal law. The definition of "identical" in section 403A refers to a law "of a State or a political subdivision" that uses "substantially the same language as the comparable provision" under H.R. 4167, and where "any differences in language do not result in the imposition of materially different requirements." This language by itself would create endless challenges, confusion, and litigation as to whether any given law meets the "identical" standard. Moreover, while the definition refers to local as well as State laws, the operative provision states only that a "State or political subdivision of a State may enforce a State law" meeting the "identical" standard; *there is no provision for enforcing a local law which meets that standard*. This inconsistency in the drafting of the statute creates serious doubt about the ability of local governments to enforce a wide range of laws concerning food safety. New York City, which has had a longstanding and critical role in protecting its residents from adulterated food, is particularly impacted by this legislation.

New York City has a comprehensive body of law regarding food safety, and the city's Department of Health and Mental Hygiene has the primary responsibility for

these matters in the city. These activities are at the very core of the mission of local health departments and must be preserved, especially in *view* of New York city's disproportionate risk for future terrorist attacks, including the threat of deliberate contamination of our food supply.

As the Supreme Court stated more than 125 years ago in *Sherlock* v. *Ailing, 93* U.S. *99*, 103 (1876),

> "In conferring upon Congress the regulation of commerce, it was never intended to cut the States off from legislating on all subjects relating to the health, life and safety of their citizens, though the legislation might indirectly affect the commerce of the country."

As recent events have proven, local governments are ultimately responsible for the safety of their citizens, and must continue to have the necessary tools to fulfill this responsibility.

Enclosed is an analysis of the impact of this bill on New York City, as well as news articles and letters from other public officials and experts expressing concerns about this legislation. I appreciate your continued interest in this critical issue.

Sincerely,

THOMAS R. FRIEDEN, M.D., M.P.H.,
Commissioner.

NEW YORK CITY POSITION ON H.R. 4167, THE NATIONAL UNIFORMITY FOR FOOD ACT OF 2005

New York City strongly opposes this legislation. If enacted, H.R. 4167, by preempting local authority to seize, embargo and condemn adulterated food, would seriously undermine the ability of New York City and other localities to protect citizens from unsafe food and to respond immediately to the threat of terrorist activity affecting the food supply.

New York City's Department of Health and Mental Hygiene (DOHMH) is responsible for supervising and regulating the food supply in New York City. [New York City Charter § 556(a)(9)]. Food establishments in New York City are licensed and regulated by DOHMH in accordance with Article 81 of the New York City Health Code.

DOHMH is also authorized by existing local law to seize, embargo or condemn food that is adulterated or otherwise constitutes a danger to public health [New York City Health Code §§ 3.03(a) and 71.11]. These authorities are essential public health tools that DOHMH has used for many decades to protect the citizens of New York City. DOHMH must be able to continue this critical public health activity, especially in light of New York City's disproportionate risk for future terrorist attacks, including the threat of deliberate contamination of our food supply.

The following are examples of actions that New York City's DOHMH has taken and that would be preempted by H.R. 4167 or be subject to legal challenges that would result in dangerous delays and costly litigation. Law in such critical areas of public health should not be left unsettled and unclear. The authority to act needs to be unequivocal.

- In March 2005, DOHMH linked certain imported cheeses to infection by *Mycobacterium bovis, a form of* tuberculosis found in cattle; 35 cases, including the death of an infant, were attributed to *M. bovis* tuberculosis. The city monitored certain markets to assure that no contaminated cheese was sold.
- In December 2005, DOHMH used its powers under the city's Health Code *to embargo certain imported herbal products that contained lead or mercury* after several cases of adult lead poisoning were confirmed among residents who used these products. Although there were National Academy of Science recommendations about tolerance levels, there were—and continue to be—no specific Federal standards. In previous years, DOHMH had also ordered the cessation of sale of an herbal tea that contained high concentrations of lead and arsenic. While an amendment in the House-passed version of H.R. 4617 exempts regulation of dietary supplements from preemption, it is unclear whether food products containing dietary supplements would be similarly exempted.
- In October 2005, following a sewage backup in a manufacturing establishment in which specialty desserts and candies were made, DOHMH used its powers under the city's Health Code to order the owner to cease production and thoroughly clean the processing area. DOHMH embargoed and ultimately destroyed the contaminated products.
- In August 2004, DOHMH issued a warning to city residents to avoid eating certain candies and food products made in Mexico that had been found to contain lead.

DOHMH, based on its authority under the Health Code, and in cooperation with New York State authorities, inspected and tested these products. These actions, along with actions by other States and localities, resulted in a voluntary recall by a candy manufacturer. Because any increase in lead exposure to New York City's children is a serious public health concern, the New York City Council subsequently adopted a law banning sale of candy products containing lead. This action was prompted by concerns about the inadequacy of Federal regulatory efforts to set allowable safety limits for lead in food products and stop contaminated products from entering the country.

• In 1999, reports of food-related illnesses were traced to salmonella bacteria in cheese blintzes prepared and sold by a local retail food manufacturer. DOHMH used the power of the Health Code to order the retailer to cease production of the blintzes and to destroy all contaminated products.

• In 1991, DOHMH, under the authority of the City Charter and the Health Code, ordered the surrender of shellfish that had been identified as the source of several cases of cholera.

KEY PROVISIONS OF H.R. 4167 THAT WOULD IMPACT NEW YORK CITY'S FOOD SAFETY PROGRAM

The bill amends 21 USCA § 343-I, the National Uniform Nutrition Labeling Act. The proposed amendments, however, go well beyond regulation of labeling. The bill would prevent a State or locality from enforcing requirements for adulterated foods that are also regulated by Federal law when the State or local requirement is not "identical" to a Federal requirement. This invites litigation about whether a State or local requirement meets the "identical' standard and will thereby seriously undermine the ability of State and local governments to enforce laws of great importance to public safety.

It is unclear whether a State or locality would continue to have any authority to act regarding adulterated food in the absence of a Federal requirement addressing the relevant type of adulteration. An amendment to section 2 of the bill seemingly authorizes States and localities to act in some such cases, but the amendment is made to a section that still refers to enforcement of a State law that is "identical" to a requirement in Federal law, thereby creating confusion about whether an "identical" Federal requirement is a prerequisite to State or local action. Denying State and local governments the ability to protect their citizens from threats in the food supply that the Federal Government has not addressed is clearly not in the public interest.

Section 403A(c)(2) of H.R. 4167 establishes circumstances under which a State or political subdivision of a State may enforce a *State* law regarding adulteration, and says nothing about enforcement of a local law, even though the definition of "identical" laws does refer to laws of a political subdivision as well as to laws of a State. New York City has a comprehensive body of city law regarding food safety. Given New York City's population, which includes citizens from every part of the world, the unique cultural and ethnic foods that are imported and consumed by these populations, and New York City's disproportionate risk for future attacks or deliberate contamination of food, enforcement of local law must be recognized. Many imported specialty foods may present public health hazards that have not been anticipated or adequately addressed either by State or national governments. Local governments, as first responders, would be in the best position to quickly identify, investigate and remove harmful products from the local food supply.

Section 403B(a)(3) of the bill is also of great concern to DOHMH. This provision states that section 403B should not be construed to prevent a *State* from embargoing adulterated food pursuant to a *State* requirement identical to a Federal food adulteration requirement, but again fails to recognize the need of a locality to take such action, or to act pursuant to a local law. These activities (i.e., seizure, embargo of adulterated food) are at the very core of the mission of local health departments and must be preserved, not preempted.

H.R. 4167 attempts to address the threat of an imminent hazard by explicitly allowing States—but again, not localities—to impose requirements for adulterated foods or take action that would otherwise violate the proposed uniformity requirement in § 403B(a), but only upon satisfying various conditions (for example, submission of a petition). This process would be unduly burdensome and is unreasonable in situations involving an imminent threat to public health, when immediate action is necessary. New York City's health authority must be able to protect its citizens without having to comply with additional layers of bureaucracy.

Immediately after 9/11, DOHMH intensified its surveillance for food-related illnesses because of concern about the potential for terrorist activity involving the food supply. If the provisions of H.R. 4167 had been in effect at that time, the city would likely have been powerless to embargo potentially harmful food, even if our surveillance system had detected a serious threat. We have strengthened and enhanced that system, and it is now a model for the Nation. However, this legislation, if enacted, would compromise our ability to use our model system to respond quickly and preserve the public health.

Enactment of H.R. 41671, which passed the House of Representatives without public hearings, will have serious consequences that may not be intended or clearly understood by some of its proponents. I urge you to request that the appropriate Senate committees hold hearings and carefully review its impact. The bill, in its present form, should not be adopted by the Senate.

STATE OF CONNECTICUT, DEPARTMENT OF AGRICULTURE,
OFFICE OF THE COMMISSIONER,
HARTFORD, CT 06106,
August 4, 2006.

HON. CHRISTOPHER DODD,
Putnam Park,
100 Wethersfield, CT 06109.

DEAR SENATOR DODD: I am writing to you on behalf of Governor Roll to urge your rejection of S. 3128 "National Uniformity for Food Act of 2006."

The Connecticut Department of Agriculture (CT DOA) has the following concerns regarding S. 3128, known as the "National Uniformity for Food Act of 2006":

- Potential preemption of State and local food safety authority particularly in the area of dairy products including yogurt and cheese, more specifically locally produced product, and locally grown and harvested shellfish, all of which CT DOA regulates.
- CT DOA has concerns about the economic impact the passage of this bill may have on its local producers of dairy product and shellfish in terms of new or additional labeling requirements and also Connecticut Grown promotional labeling.
- CT DOA is uncertain about the impact of the bill on intra-state commerce for example labeling of Connecticut grown/produced food products at Connecticut farmers' markets.

At this point in time, we are not convinced that this bill is in the best interests of, primarily Connecticut's agricultural industry, and secondarily, the citizens of the State of Connecticut.

It is my understanding that the Connecticut Department of Consumer Protection also has concerns and you may be hearing from them in a separate communication.

It is for these reasons I urge your careful consideration and rejection of S. 3128. Thank you for the opportunity to comment.

Sincerely,

F. PHILIP PRELLI,
Commissioner.

NATIONAL ASSOCIATION OF ATTORNEYS GENERAL,
WASHINGTON, DC 20002,
March 2, 2006.

DEAR MEMBERS OF CONGRESS: On March 1, 2006, we sent to you a sign-on letter by 37 Attorneys General in opposition to H.R. 4167, the "National Uniformity for Food Act." Attorneys General Wayne Stenehjem of North Dakota and Malaetasi M. Togafau of American Samoa would like to join their colleagues in supporting this issue, so attached is the revised letter which includes their signatures. Thus, a total of 39 Attorneys General have signed on to the March 1 letter.

Sincerely,

LYNNE ROSS,
Executive Director.

NATIONAL ASSOCIATION OF ATTORNEYS GENERAL,
WASHINGTON, DC 20002,
March 1, 2006.

DEAR MEMBERS OF CONGRESS: We write to urge you to oppose the "National Uniformity for Food Act," H.R. 4167, 109th Cong. (2005) which undercuts States' rights and consumer protection. This bill, which the House Energy and Commerce Committee approved on December 15, 2005, would preempt all existing and future State and local food labeling requirements that expressly or indirectly imply that a particular food or its packaging "presents or may present a hazard to health or safety" unless identical to Food and Drug Administration requirements. Indeed, under this bill, States would be forbidden from adopting their own policies, even if the Federal Government had not acted in a particular area or adopted a particular warning. Important consumer warnings dealing with mercury in fish, arsenic in drinking water, and lead in cans are just a few examples of States food labeling requirements that would be eviscerated by this bill.

Food safety has been largely a matter of State law and oversight for well more than a century. State and local agencies perform more than 80 percent of food safety work, with Federal agencies often seeking their assistance. There is nothing in the public record showing that Federal uniformity in this area provides a greater level of protection to consumers or is in the public interest. Indeed, although this bill would radically change the traditional allocation of power between the States and the Federal Government, it has never been the subject of public hearings.

This bill would strip State Governments of the ability to protect their residents through State laws and regulations relating to the safety of food and food packaging. Some of the more obvious state-level warnings that almost certainly would be challenged include consumer warnings about mercury contamination of fish, arsenic in bottled water, lead in ceramic tableware, the alcohol content in candies, the content of fats and oils in foods, and post-harvest pesticide application to fruits and vegetables. Unscrupulous merchants could contend that this bill immunized their false claims of health benefits ascribed to their products from State prohibitions or remedies such as laws barring deceptive advertising of food. The same could occur with regard to inadequate warnings regarding a child's use of a product.

While H.R. 4167 provides States with a limited opportunity to petition the Federal Government for authorization to take action in a particular area, the petition process is slow, expensive and uncertain, and certainly is no substitute for allowing States their traditional role of taking action on their own to protect consumers. The bill would create a new Federal bureaucracy dedicated to evaluating, judging and even invalidating proposed State and local laws, a startling change in State-Federal relations in the food safety area.

Without question, the target of this bill is California's Proposition 65, which was approved by California voters by initiative in 1986 and provides consumers with health and safety information concerning foods they may purchase and eat. There is no evidence that this popular initiative has harmed consumers or merchants.

The Association of Food and Drug Officials, an organization comprised of State regulators with responsibility for ensuring food safety since 1896, strongly opposes this bill and, on January 16, 2006 wrote:

> passage of this bill would undermine proven consumer protection programs . . . [t]he preemption provisions are broad, vague and sweeping and will likely dismantle the authority of State and local laws that address adulterated foods—which include food laws, dairy laws, animal feed laws, other agricultural commodity laws, anti-tampering laws, anti-terrorism laws, etc.:

Letter from Association of Food and Drug Officials regarding H.R. 4167 to the Honorable Mike Rogers, January 16, 2006 (copy attached).

We need all levels of government to work together to protect food safety. State and local governments are often the first line of defense when problems emerge. Prohibiting State and local leadership and action in this area is a serious mistake. We respectfully request that you oppose H.R. 4167.

Sincerely,

Eliot Spitzer, Attorney General, New York; Mark J. Bennett, Attorney General, Hawaii; David W. Marquez, Attorney General, Alaska; Malaetasi M. Togafau, Attorney General, American Samoa; Terry Goddard, Attorney General, Arizona; Bill Lockyer, Attorney General, California; Richard Blumenthal, Attorney General, Connecticut; Carl C. Danberg, Attorney General, Delaware; Robert Spagnoletti, Attorney General, District of Columbia; Lawrence Wasden, Attorney General, Idaho; Lisa Madigan, Attorney General, Illinois; Tom Miller, Attorney General, Iowa; Greg Stumbo, Attorney General, Kentucky; Charles Foti, Attorney General, Louisiana; G.

Steven Rowe, Attorney General, Maine; J. Joseph Curran, Jr. Attorney General, Maryland; Tom Reilly, Attorney General, Massachusetts; Mike Cox, Attorney General, Michigan; Mike Hatch, Attorney General, Minnesota; Jim Hood, Attorney General, Mississippi; Jeremiah W. Nixon Attorney General, Missouri; Mike McGrath, Attorney General, Mississippi; George J. Chanos; Attorney General, Nevada; Kelly Ayotte, Attorney General, New Hampshire; Zulima V. Farber, Attorney General, New Jersey; Patricia A. Madrid, Attorney General, New Mexico; Wayne Stenehjem, Attorney General, North Dakota; W.A. Drew Edmondson, Attorney General, Oklahoma; Hardy Myers, Attorney General, Oregon; Patrick Lynch, Attorney General, Rhode Island; Henry McMaster, Attorney General, South Carolina; Larry Long, Attorney General, South Dakota; Paul G. Summers, Attorney General, Tennessee; Greg Abbott, Attorney General, Texas; Mark Shurtleff, Attorney General, Utah; William H. Sorrell, Attorney General, Vermont; Darrell V. McGraw, Jr. Attorney General, West Virginia; Peg Lautenschlager, Attorney General, Wisconsin; Pat Crank, Attorney General, Wyoming.

ASSOCIATION OF FOOD AND DRUG OFFICIALS (AFDO),
YORK, PA 17402,
January 16, 2006.

U.S. HOUSE OF REPRESENTATIVES,
Washington, DC 20515.

DEAR REPRESENTATIVE: I am writing on behalf of the Association of Food and Drug Officials (AFDO) to express serious concerns regarding H.R. 4167, "The National Uniformity for Foods Act of 2005" introduced by Congressman Mike Rogers (MI-8). Originally introduced in the 108th Congress as H.R. 2699, the bill's stated purpose is to amend the Federal Food, Drug and Cosmetic Act (FFDCA) to provide for uniform food safety warning notification requirements—and for other purposes. It is the phrase "for other purposes" that alarms members of AFDO. The legislation has been reviewed by attorneys for 11 State food safety programs, and unfortunately, all of the reviews are unanimous in their conclusion that the bill will preempt States and local food safety and defense programs from performing their functions to protect citizens.

You may have already received some information concerning this bill's impact from its proponents. This information claims that State regulators, and organizations such as AFDO, are erroneous in their legal evaluation of the bill. However, in addition to AFDO's attorney, attorneys in 11 States, after careful review of this bill (as H.R. 2699), have reached similar conclusions regarding its severe negative impacts to State programs. While it is not uncommon for legal authorities to differently interpret the meaning of a given law, because this disagreement is so profound and has such far-reaching implications, it is imperative to amend this bill and clearly specify Congress' intent to address solely food labeling. I urge you to oppose this bill until these differences can be resolved in Congress, and not leave it to the courts to decide while public health is put at risk.

Proponents of this bill emphasize that H.R. 4167 does not impact State sanitation laws, and thus, will not impact State programs. Nothing could be further from the truth. States perform sanitation inspections in an effort to assist food businesses in preventing contamination or adulteration of products, but one of the States' critical complementary functions is to take action when these preventive measures fail. Whether food becomes contaminated by accident, intent, or act of nature, it is critical that States retain their authorities to contain and remove food from the marketplace. Because we believe that H.R. 4167 compromises these authorities, it is our belief that the impact of this legislation is huge. If enacted, H.R. 4167 would significantly impede resolution of the unsafe conditions and removal of contaminated foods from the human food supply. Sanitation and adulteration are not identical, but rather complementary, and if public health is to be protected, States must retain their authority to respond to contaminated (adulterated) products—without seeking Federal permission.

Please take note that FDA has adopted few adulteration standards for microbial contamination. While some guidance has been issued in the form of Action Levels, adulteration is frequently determined on a case-by-case basis. With States' rulemaking authority in question under H.R. 4167, States cannot take action unless they first confer with FDA and a determination is made, or unless the State concurrently petitions FDA. In 2001 alone, States took action in over 45,000 separate instances to embargo or remove adulterated foods from the market place. No additional resources have been provided to FDA to undertake such review of these petitions, and again—this is an issue that extends well beyond uniform labeling.

A vote in support of H.R. 4167 puts at risk the health and wellbeing of all our citizens. While proponents argue that programs such as the cooperative milk and shellfish programs are not at risk, our attorney, along with 11 other State attorneys, read the bill quite differently. These are cooperative programs. The milk program, based on the Pasteurized Milk Ordinance (PMO), is written under the auspices of the Public Health Service Act. In order to participate in either program, a State must first demonstrate clear authority in adulterated foods—and this authority is lost under H.R. 4167. Under this bill, a State cannot have ANY law, not just a food law, which is not identical to the FFDCA.

Please note the differences in language between this "uniformity bill" and Section 11 of S. 3, the "National Biodefense Act of 2005", which specifically states its intended uniformity applies to the *labeling* of drugs. AFDO does not oppose uniform food labeling; however, H.R. 4167 extends its reach well beyond this, and because of its ambiguity, it would be a disastrous step backwards in ensuring the safety of our Nation's food supply.

Again, with so much at risk, I urge you to oppose this bill and to call for hearings to better delineate the impact and issues that are clouded by the broad, vague, sweeping language that comprises H.R. 4167. AFDO representatives would appreciate and welcome an opportunity to discuss our concerns with you and your staff.

Thank you in advance for your thoughtful consideration of our concerns. Should you or your staff have any questions, please do not hesitate to contact me at (850) 488–0295 or Mr. Cameron Smoak, Assistant Commissioner, GA Department of Agriculture at (404) 656–3627.

Sincerely,

MARION F. ALLER, DVM, DABT,
President.

[Whereupon, at 12:08 p.m., the hearing was adjourned.]

○