

TESTIMONY OF  
PETER BARTON HUTT  
BEFORE  
THE SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE  
ON  
THE NATIONAL UNIFORMITY FOR FOOD ACT  
S. 3128

JULY 27, 2006

Mr. Chairman and members of the Committee:

I am Peter Barton Hutt, senior counsel at the Washington, DC 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 100<sup>th</sup> 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 decision making 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 public 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 ten 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 ten sections must be identical. The ten 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 fifty 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 essential 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 (\$2500 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 elected 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 one 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 two-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 two 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.

