

National Uniformity for Food Act of 2003
HR 2699
Impact Analysis

Summary of HR 2699: Known as the National Uniformity for Food Act of 2003, HR 2699 was filed in the House of Representatives by Rep. Burr, on July 10, 2003. The Grocery Manufacturers of America worked to get the bill introduced. Their stated intention is for uniformity in warning statements on food labels (i.e., because of California's Prop 65) but the bill includes many additional sweepingly preemptive features which invalidates a state's laws if its law is not identical to the Federal FD&C Act. By adding '(6) to Sec. 402 Adulterated Food and adding 'Sec. 403B Uniformity in Food Safety Warning Notification Requirements, the bill requires any state or political subdivision's law to be identical to its federal counterpart in the Federal FD&C Act regarding adulterated food containing poisonous or deleterious substances, raw agricultural commodities containing pesticides defined as unsafe, irradiated foods unless approved, unsafe color additives and food additives, tolerances for poisonous ingredients, conditions for emergency permit control, suspension of that permit, promulgation of rules, access for inspection and dietary supplement labeling regulations. Any non-identical state or local law becomes invalidated 180 days after the enactment of this bill. The bill also preempts a state's ability to establish a requirement because of an imminent health hazard unless the state notifies the Secretary of HHS and the Secretary has not initiated enforcement action. The state must then petition the Secretary within 30 days for an exemption to the federal law or establishment of a new federal standard and then initiate enforcement action itself.

The bill has the potential to be interpreted very broadly which could invalidate many state laws and rules and therefore, the programs which get their authority to operate from these laws and rules. There is no mention of, nor allowance for, local health departments, even those operating under home-rule provisions in their state. Under the strictest interpretation of the bill, states without identical laws defining adulterated food and warning statements on food labels, including laws governing the rule-making process could lose their legal foundation for conducting the FDA Cooperative Programs (Milk Safety, Shellfish Sanitation and Retail Food Protection) and then not be able to adopt identical federal regulations if their rule-making process was not identical.

FDA Cooperative Programs: Milk safety, shellfish sanitation and retail food protection are cooperative programs with states (including local city and county agencies with retail food programs) carrying out compliance and enforcement activities and FDA providing training/standardization, oversight and evaluation. All three programs work through a conference body (NCIMS, ISSC or CFP) for presenting issues, arriving at consensus and developing model codes or ordinances. When interstate transport of Grade A milk and shellfish occur, the conferences, through MOUs, also provide for reciprocity of licensing and inspections between states. States adopt these model ordinances/codes into law and some states rely on state revenues funds and license or permit fees to support the operation of the program. FDA's role in the three cooperative programs includes CFSAN's Division of Cooperative Programs (Milk, Shellfish, Retail Food and Lab Quality Assurance) which provide standardization and certification services, evaluations, training and technical assistance to FDA/state field staff and laboratories. CFSAN's Cooperative Programs staff also work with foreign countries on equivalency determinations, laboratory evaluations and program evaluations. OPDF and CVM also provide input and technical assistance to the Cooperative Programs on milk, shellfish, produce and drug residues. ORA's Division of Federal-State Relations, Division of Human Resource Development and Office of Regional Activities (Regional Specialists) perform training, field standardization, program evaluation and technical assistance.

Scope of State and Local Activities: In 2002, the Association of Food and Drug Officials (AFDO) conducted a State Food Safety Resource Survey to capture work done in the area of food safety. This

survey included milk, shellfish, retail food and feed inspections, investigations, enforcement activities and samples analyzed. (Survey results available at <http://www.afdo.org>). While data from all 50 states are available, not all state agencies or all 2900+ local health departments responded to the survey, making the final reported figures less than the actual by an unknown amount. FDA, through cooperative partnerships and contracts, leverages limited resources at the federal, state and local levels to protect the nation's food supply. Relevant state and local cooperative programs' data reported in the AFDO Survey are listed below.

Inspections (2001) - Total 1,916,191

Dairy Plants	7,562	Retail Food Service	1,178,348
Dairy Farms	159,483	Institutional Food Service	51,290
Subtotal	167,045	Retail Food Stores	516,033
		Subtotal	1,745,671

BSE Feed Inspections **3,475**
 Shellfish Firm Inspection **4,784**

Special Investigations (2001) - Total 86,716

Foodborne Illness Outbreaks	3,075	Farm Pesticide Residues	472
Tracebacks (Not Recalls)	154	Chemical Residues	7,855
Consumer Complaints	46,019	Disasters &/or Emergency Response	2,816
Shellfish Growing Area Class.	20,870	Food Related Animal Health Matters	204

Enforcement Activities (2001) - Total 129,090

Embargo/Seizure	13,910	Criminal Prosecutions	4,048
Stop Sale	31,546	Warning Letters	36,346
Health Advisories	90	Informal Hearings	1,102
Monetary Penalties	9,878	Other	28,537
License/Permit Revocation	74		

Number of Samples Analyzed (2001) - Total 328,065

Food Chemistry	59,991
Microbiology	252,307
Pesticide Residue	15,767

Public Health Impact if State Laws Are Preempted:

General:

- ❖ Four major states have already determined that this bill will invalidate many of their food safety laws and regulations, leaving wide gaps in the nation's food safety chain. FDA does not have the staff, authority or budget to step in to provide the same oversight. Large segments of our consuming population will not be protected by any government oversight.
- ❖ An aging population, new and emerging pathogens, large amounts of imported foods, increasing concern about the security of the food supply and safety of our consumers indicate a need for increased food, milk and shellfish safety, not decreased oversight.
- ❖ Public confidence in the government's ability to ensure a safe milk, shellfish and food supply will be eroded.
- ❖ A significant portion of BSE feed inspections and dairy, seafood and food manufacturing/processing plant inspections are contracted to state agencies and would not be done if the state's laws and rules were invalidated because they were not identical to the federal counterpart.
- ❖ State and local compliance and enforcement procedures will not be able to remove adulterated and contaminated products from commercial sale thereby endangering the consumer.

- ❖ There would be no meaningful role for state and local agencies as timely responders to terrorist threats and imminent health hazards when notification and petitioning to the Secretary is required beforehand.

Milk Safety:

- ❖ The loss of any or all state Grade A milk programs would result in no routine regulatory oversight of milk production and processing facilities including regulatory inspections, pasteurization system efficiency testing, sampling and laboratory analysis of raw and processed products to meet product safety, nutritional and labeling standards.
- ❖ No reciprocity between states for inspections, sampling, etc. currently under NCIMS would be possible to facilitate interstate commerce.
- ❖ Special investigations (recalls, natural disasters, tamperings, foodborne illness outbreaks or terrorist threats) involving Grade A dairy products would be limited to what FDA could do with limited staff and less authority, in some cases.
- ❖ No regulatory monitoring or oversight for animal drug residues in milk could result in increased antibiotic resistance in human pathogens and allergic reactions to β -lactam antibiotics.
- ❖ Lack of pesticide residue testing, well water testing and other analyses could result in adulterated dairy products going to market.
- ❖ Populations targeted to increase consumption of nutritious dairy products (infants, children, pregnant women) may in fact consume unsafe food without regulatory oversight.
- ❖ Without authority to conduct the Grade A milk program, there is a risk of losing the manufactured milk program as well (unless USDA proposed rules to cover Grade A milk as well).

Shellfish Sanitation:

- ❖ The loss of any or all state shellfish programs would result in less safe shellfish harvests, sanitary surveys and classification and decreased or no patrols in shellfish growing areas, enforcement of illegal harvesting in polluted waters, water quality monitoring, laboratory analyses including product identification, tagging operations for tracebacks, processing plant inspections or inspection of shellfish packers and shippers.
- ❖ If some states have no shellfish inspection program, no reciprocity under the NSSP for states to facilitate interstate commerce.
- ❖ Illnesses from typhoid fever, hepatitis A, norovirus, *Vibrio vulnificus* and Paralytic Shellfish Poisoning would likely result with decreased oversight of shellfish growing, processing and distribution. The majority of illnesses associated with shellfish result from problems associated with the harvest of shellfish.
- ❖ *Salmonella typhi* was recently isolated from U.S. shellfish and one recent outbreak of hepatitis A in a Chinese port city with no shellfish safety program resulted in over 250,000 illnesses.

Retail Food Protection:

- ❖ The loss of any or all of the 3000 state and local retail food programs would result in no food service, institutional food service or retail food store inspection, foodborne illness outbreak or other special investigations, food sampling surveillance, emergency response and state standardization of local trainers/inspectors.
- ❖ Highly susceptible populations in institutional facilities would be at increased risk of foodborne illness with less regulatory oversight of their facilities.

- ❖ Food service, retail food store and institutional food service establishments are associated with more than 50% of the identified foodborne outbreaks. Eliminating regulatory oversight programs for this part of the food chain would cause a huge increase in risk for consumers and cases of foodborne illness.
- ❖ Some unique behaviors and unique challenges directly related to foodborne outbreaks that occur at the retail and food service level (300-400% annual staff turnover, lack of education, language and cultural barriers, etc.) would not be overcome with Agency inspection at the manufacturing or processing level.
- ❖ Sixty seven percent (67%) of the foodborne outbreaks whose cause is known are caused by viruses such as norovirus and hepatitis A virus, mostly because of risky behaviors by food employees (lack of or poor hand washing habits; bare hand contact with ready-to-eat foods; ill employees working with food; etc.).

FDA Legal Base for Cooperative Programs:

- ❖ While the Public Health Service Act, in 42 U.S.C. 301 (a), gives FDA authority to cooperate with and assist the states in the shellfish, Grade A milk and retail food programs, the three respective model ordinances/codes (PMO, NSSP and Food Code) have not been made part of the Code of Federal Regulations and would therefore, have to, at least, go through the rule-making process to be enforceable by FDA. This would likely take many years before a final rule could be published that gave FDA authority to conduct the program as the states had done.
- ❖ In the meantime, FDA would be limited to enforcement of contaminated/adulterated and misbranded foods as defined in the Federal FD&C Act in sections 402 and 403, with limited seizure authority and limited staff.

Potential Impact on the Respective Industries:

- ❖ Inspection results would no longer be available concerning all shellfish harvest areas, facilities, products, etc. inspected by the states which provide valuable information to operators about risk factors that cause foodborne illness.
- ❖ Consultative services such as plan reviews, equipment reviews, voluntary HACCP reviews, risk control plans, etc. would not be available to the industry.
- ❖ Inspection and consultation services by knowledgeable individuals familiar with milk, shellfish and food safety requirements will only be available through commercial firms at a much higher cost than regulatory agency fees, such as license/permit fees or inspection fees.

Potential Impact on FDA Infrastructure:

- ❖ If FDA were to assume the regulatory responsibilities of the 3 cooperative milk, shellfish and retail food programs at the same level provided by the state agencies prior to preemption, a vastly expanded infrastructure would be required.
- ❖ Increased staffing needs to replace all state programs would include field investigators, supervisory/management staff, administrative support staff and laboratory technicians.
 - ❖ Milk program estimates – 1470 FTEs
 - ❖ Shellfish program estimates – 500 FTEs
- ❖ Retail Food program estimates – 5,000 FTEs
- ❖ The shellfish program would require boats to patrol and sample growing areas and all programs would require vehicles to transport investigators and samples (or reimburse staff for the use of their own vehicles).

- ❖ # of boats estimated – 264
- ❖ # of motor pool vehicles estimated – 2700 (60% of staff in the field at any one time)
- ❖ Laboratory analyses of milk, shellfish and retail food samples could be accomplished in expanded FDA lab facilities or contracts with private laboratories or remaining state labs. The increased capacity would have to replace the following state laboratories responsible for analyzing more than 328,000 samples annually. Surge capacity in case of outbreaks, disasters or a terrorist threat must be considered.
 - ❖ 65 state Microbiology labs
 - ❖ 52 state Food Chemistry labs
 - ❖ 43 state Pesticide Residue labs
- ❖ Inspection equipment, surveillance sampling and transportation equipment, pasteurizer checks and other technical aids to routine and special investigations would be required, as well as computers, printers and other office supplies.
- ❖ Training for new FDA staff could be accomplished in part through on-line training modules but would require either experienced field staff or a lengthy field orientation.

Budgetary Resources Necessary to Replace Preempted State Programs:

- ❖ Budgetary resources necessary to hire approximately 6,850 new staff (under the worst case scenario where all state/local programs were preempted) could approach \$513 million annually including benefits.
- ❖ The purchase of boats necessary to carry out harvest water sampling, sanitary surveys and patrols would cost an estimated \$10 - 33 million depending on initial cost and annual maintenance and upkeep.
- ❖ Motor pool expenses and purchase or leasing a fleet of cars for transportation of investigators and samples would cost approximately \$4.5 – 5 million per year.
- ❖ Initial expenses for inspection and office equipment could total as high as \$50 million.
- ❖ Buildings and laboratory space would be difficult to estimate without further information.

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