



CONGRESSIONAL BUDGET OFFICE  
COST ESTIMATE

October 7, 2004

**H.R. 2699**  
**National Uniformity for Food Act of 2004**

*As ordered reported by the House Committee on Energy and Commerce  
on September 30, 2004*

**SUMMARY**

The National Uniformity for Food Act of 2004 would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to prohibit states or local governments from establishing or continuing in effect requirements that are not identical to specified FDCA provisions concerning the definition of food adulteration or the issuance of warning notifications concerning the safety of food. Regulation of food sanitation would remain primarily a state responsibility.

H.R. 2699 would establish a petition process by which state, local, and national requirements would be set regarding food safety and warning notifications. The bill would allow a state or local government to establish a requirement that would be in conflict with national uniformity standards if the state requirement is needed to prevent imminent hazard to public health. Assuming appropriation of the necessary amounts, CBO estimates that implementing H.R. 2699 would cost \$11 million in 2005 and \$106 million over the 2005-2009 period. Those costs would be incurred by the Food and Drug Administration (FDA). Enacting the bill would not affect direct spending or receipts.

H.R. 2699 would preempt state laws governing the labeling of food products and the issuance of warning notifications. Those preemptions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The costs of complying with those mandates, however, would be minimal and would not exceed the threshold established in UMRA (\$60 million in 2004, adjusted annually for inflation). If states chose to seek exemptions from the federal prohibition, they might incur costs depending on the type of labeling requirement involved and subsequent legal actions. However, those activities, and any costs, would not be associated with complying with the mandate itself.

The bill contains no private-sector mandates as defined in UMRA.

## ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 2699 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars				
	2005	2006	2007	2008	2009
<b>SPENDING SUBJECT TO APPROPRIATION</b>					
FDA Spending Under Current Law <sup>a</sup>					
Estimated Authorization level	1,424	1,460	1,504	1,551	1,599
Estimated Outlays	1,367	1,412	1,465	1,519	1,569
Proposed Changes					
Estimated Authorization Level	12	15	28	32	21
Estimated Outlays	11	15	27	32	22
FDA Spending Under H.R. 2699					
Estimated Authorization Level	1,436	1,475	1,532	1,583	1,620
Estimated Outlays	1,378	1,427	1,492	1,551	1,591

a. Current-law estimates are CBO baseline projections that reflect the 2004 appropriation (\$1,387 million) adjusted for anticipated inflation.

## BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 2699 will be enacted early in fiscal year 2005 and that appropriations will be provided to pay for the additional resources needed by FDA to fulfill the requirements of this legislation. CBO also assumes that such appropriations will be provided near the start of each subsequent fiscal year and that outlays will follow the historical spending patterns for FDA.

The National Uniformity for Food Act of 2004 would amend the Federal Food, Drug, and Cosmetic Act to prohibit states or local governments from establishing or continuing in effect certain requirements involving food safety and warning notifications that are not identical to specified FDCA provisions. State level food warnings may not be issued unless the FDA requires that the warnings be issued for specific foods. Regulation of food sanitation would remain primarily a state responsibility.

The bill would establish a petition process by which notification requirements for state, local, and national food safety and warnings would be established. Under the petition process,

states could solicit an exemption of state or local notification requirements from national uniformity standards. Currently, specific state and local requirements exist that may not be nationally applicable. In addition, state petitions also could request a national uniformity decision.

Further, H.R. 2699 would allow a state to establish a requirement that would otherwise violate proposed FDCA uniformity standards if the requirement is needed to address an imminent adverse health consequence.

Finally, the bill specifically would exempt the following activities from national uniformity: freshness dating, open date labeling, state inspection stamps, unit pricing, religious dietary labeling, organic or natural designation, returnable bottle labeling, statement of geographical origin, and consumer advisories regarding food sanitation for food service establishments.

Based on information from the FDA and a review of states likely to be affected by the bill, CBO estimates that states would submit almost 100 petitions during 2005 and an additional 20 petitions over the 2006-2009 period. That estimate takes into account information that over 30 states currently have laws that would be affected by H.R. 2699, that additional states currently have regulations that would be affected, and that states will likely continue to implement such laws and regulations. CBO estimates that FDA would spend an average of about \$1 million per petition. As a result, we estimate that implementing H.R. 2699 would cost \$106 million over the 2005-2009 period. The majority of the costs of this bill would result from reviewing and issuing final determinations on petitions filed for existing and future food safety and warning notification laws. The remainder of the costs would stem from promulgating regulations to implement the bill.

The bill would impose restrictive limits on the time that FDA would have to review petitions and take final action. CBO assumes that FDA would not be able to fully comply with the time limits imposed under the bill. CBO's estimate of the annual cost of the petition review process reflects such a delay with the number of reviews peaking in 2008 and then declining. The estimate does not include any legal costs to the federal government that may be incurred should states, local governments, or private entities seek to challenge FDA's final rulings on petitions.

## **ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS**

H.R. 2699 would prohibit states from establishing labeling requirements different from federal guidelines in a number of cases, including poisonous substances, color additives, products that could be contaminated with micro-organisms, food and color additives, and animal drugs. The bill also would prohibit states from requiring any warning notifications

concerning food safety that are not identical to federal requirements. These preemptions of state regulatory authority would be intergovernmental mandates as defined in UMRA. However, the costs of complying with those mandates would be minimal and would not exceed the threshold established in UMRA (\$60 million in 2004, adjusted annually for inflation).

Existing state laws that are not identical to federal requirements for the types of labels and warnings addressed by the bill could remain in effect for 180 days after enactment. During those 180 days, a state could petition the FDA for an exemption to the preemption or for the establishment of a national standard, and until the FDA takes final administrative action on the petition, the existing state law would remain in effect. States also could impose requirements that would not be identical to federal requirements to address an imminent health hazard. After issuing such requirements, states would have to file a petition with the FDA within 30 days. If states chose to petition FDA for exemptions from the federal prohibition on differing labeling requirements and warning notifications, they may incur costs depending on the type of requirement involved and subsequent legal actions. However, those activities, and any costs, would not be associated with complying with the mandate itself.

## **ESTIMATED IMPACT ON THE PRIVATE SECTOR**

This bill contains no private-sector mandates as defined in UMRA.

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