CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

February 27, 2006

H.R. 4167
National Uniformity for Food Act of 2005

As ordered reported by the House Committee on Energy and Commerce on December 15, 2005

SUMMARY

The National Uniformity for Food Act of 2005 would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to prohibit states or local governments from establishing or continuing in effect requirements imposed on food that are not identical to federal requirements under specified FDCA provisions concerning the definition of food adulteration or the issuance of warning notifications concerning the safety of food.

H.R. 4167 would establish a petition process by which states could request exemption for selected food safety and notification requirements that do not meet the national uniformity requirements instituted under the bill. States may also petition that a national standard determination be made by the Food and Drug Administration (FDA) regarding the specific requirement. Under certain circumstances, the bill would allow a state to establish a requirement that would be in conflict with national uniformity standards if it is needed to prevent imminent hazard to public health. Assuming appropriation of the necessary amounts, CBO estimates that implementing H.R. 4167 would cost less than $500,000 in 2006 and about $100 million over the 2006-2011 period. Those costs would be incurred by FDA. Enacting the bill would not affect direct spending or receipts.

H.R. 4167 would preempt certain state laws governing food safety, 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 ($64 million in 2006, adjusted annually for inflation). If states chose to seek exemptions from the federal prohibition, they might 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.

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

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of H.R. 4167 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2006	2007	2008	2009	2010	2011
SPENDING SUBJECT TO APPROPRIATION						
FDA Spending Under Current Law[a]						
Estimated Authorization level	1,495	1,548	1,597	1,647	1,698	1,751
Estimated Outlays	1,460	1,516	1,568	1,603	1,667	1,725
Proposed Changes						
Estimated Authorization Level	*	9	23	35	25	10
Estimated Outlays	*	7	21	34	26	12
FDA Spending Under H.R. 4167						
Estimated Authorization Level	1,495	1,557	1,620	1,682	1,723	1,761
Estimated Outlays	1,460	1,523	1,589	1,637	1,693	1,737

* = less than $500,000.

a. The 2006 level is the amount appropriated for that year for the Food and Drug Administration (FDA). Current-law estimates for 2007 through 2011 reflect the 2006 amount adjusted for anticipated inflation.

BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 4167 will be enacted before the end of fiscal year 2006, that the necessary amounts will be provided each year, and that spending will follow historical spending patterns for FDA.

The National Uniformity for Food Act of 2005 would amend the FDCA 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 federal requirements under specified FDCA provisions. For example, state level warnings may not be issued unless the FDA requires that the warnings be issued for specific foods.

The bill would create a petition process through which states could solicit an exemption of specific state or local requirements regarding food safety and warning notifications 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. 4167 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.

The scope of the state and local regulations that would be affected by the legislation is ambiguous. For example, it is unclear whether certain provisions of the legislation would preempt only state and local requirements dealing with food labeling or whether the preemption would apply more broadly to other food safety requirements. Moreover, it is unclear whether a state or local requirement would be preempted in the absence of a specific federal requirement. CBO assumes that states would respond to such ambiguity by submitting petitions that might be affected by a broad interpretation of the current language. For the purpose of our estimate, however, CBO assumes that the regulation of food sanitation would remain primarily a state responsibility.

Based on information from FDA and a review of state requirements most likely to be affected by the bill, CBO assumes that states would submit roughly 200 petitions to FDA early in 2007 and an additional 40 petitions over the 2008-2011 period. That estimate takes into account information that all states currently have laws or regulations that likely would be affected by H.R. 4167 and that states probably will continue to implement such laws and regulations.

CBO estimates that FDA would spend roughly $400,000 per petition, on average, for costs associated with the petition process during the first five years following enactment of the bill. We estimate that implementing H.R. 4167 would cost about $100 million over the 2006-2011 period, assuming appropriation of the necessary funds. 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 primarily from FDA's cost to promulgate regulations and its legal expenses related to petitions subject to ongoing litigation.

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 2009 and then declining. The estimate does not include any legal costs to the Department of Justice 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. 4167 would preempt certain state laws governing food safety and labeling requirements different from federal requirements in a number of cases, including poisonous substances, 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 ($64 million in 2006, adjusted annually for inflation).

Existing state laws that are not identical to certain federal food safety requirements and the types of labels and warnings addressed by the bill could remain in effect for 180 days after enactment. During that time, 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 new private-sector mandates as defined in UMRA.

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