CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

July 25, 2000

S. 1155
National Uniformity for Food Act of 2000

As ordered reported by the Senate Committee on Agriculture, Nutrition, and Forestry on June 29, 2000

SUMMARY

The National Uniformity for Food Act of 2000 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 for:

- Labeling special dietary foods and dietary supplements;
- Defining food adulteration, excluding aspects of food sanitation that will remain primarily a state responsibility; and
- Issuing food warning notification concerning the safety of food and its constituents.

S. 1155 would establish a petition process by which state, local, and national food safety and warning notification requirements would be set, and would allow for 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 S. 1155 would cost $9 million in 2001 and $81 million over the 2001-2005 period. Those costs would be incurred by the Food and Drug Administration (FDA).

The bill would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

The National Uniformity for Food Act of 2000 would preempt certain state laws governing food safety 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 ($55 million in 2000, adjusted annually for

inflation). If states chose to seek exemptions from the federal prohibition, they may incur costs dependent on the type of requirement involved and subsequent legal actions. Any such costs, however, would be incurred voluntarily and thus would not be associated with the mandate. The bill contains no new private-sector mandates as defined in UMRA.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 1155 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2000	2001	2002	2003	2004	2005
SPENDING SUBJECT TO APPROPRIATION						
FDA Spending Under Current Law						
Estimated Authorization level [a]	1,049	1,090	1,125	1,161	1,197	1,234
Estimated Outlays	1,038	1,110	1,112	1,142	1,176	1,213
Proposed Changes						
Estimated Authorization Level	0	10	12	21	24	15
Estimated Outlays	0	9	12	20	24	16
FDA Spending Under S. 1155						
Estimated Authorization Level [a]	1,049	1,100	1,137	1,182	1,221	1,249
Estimated Outlays	1,038	1,119	1,124	1,162	1,200	1,229

a. The 2000 level is the amount appropriated for that year. The 2001-2005 levels are baseline projections that reflect annual increases for anticipated inflation.

BASIS OF ESTIMATE

For this estimate, CBO assumes that S. 1155 will be enacted near the start of fiscal year 2001 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 by the start of each fiscal year and that outlays will follow the historical spending patterns for FDA.

The National Uniformity for Food Act of 2000 would amend the Federal Food, Drug, and Cosmetic Act to prohibit states or local governments from establishing or continuing in effect requirements for:

- Labeling special dietary foods and dietary supplements that is not identical to specified FDCA provisions, designed to provide the same type of national uniformity for special dietary food and supplement labeling as now applies to other food labeling;

- Defining food adulteration that is not identical to specified FDCA provisions, excluding aspects of food sanitation which will remain primarily a state responsibility; and

- Issuing warning notifications concerning the food's safety that are not identical to FDCA provisions. State level food warnings may not be issued unless the federal government requires that the warnings be issued for specific foods.

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 could also request a national uniformity decision.

Further, S. 1155 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 about 80 petitions during 2001. CBO estimates that FDA would spend an average of about $1 million per petition. As a result, we estimate that implementing S. 1155 would cost $81 million over the 2001-2005 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 allows for such a delay. 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.

PAY-AS-YOU-GO CONSIDERATIONS: None.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 1155 would prohibit states from establishing food safety requirements different from federal guidelines. 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 ($55 million in 2000, adjusted annually for inflation).

Existing state laws that are not identical to federal requirements for federal food safety and warning notification requirements addressed by the bill could remain in effect for 180 days after enactment. During those 180 days, a state may 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 may also impose requirements that would not be identical to federal requirements in order 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 food safety requirements and warning notifications, they may incur costs depending on the type of requirement involved and subsequent legal actions. Any such costs, however, would be incurred voluntarily and thus would not be associated with the mandate.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

S. 1155 contains no new private-sector mandates as defined in UMRA.

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