CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

October 1, 1997

H.R. 2469
Food and Nutrition Information Reform Act of 1997

As ordered reported by the House Committee on Commerce
on September 25, 1997

SUMMARY

H.R. 2469 would change parts of the process of regulating food ingredients and claims related to the nutritional content and healthy effects of food, and would provide avenues for approval outside of the petition processes currently required. In addition, it would expedite the issuance of final rules promulgated by the Food and Drug Administration (FDA) in response to petitions and require the completion of action on a pending claim regarding the radiation of red meat.

The bill would result in additional costs to the FDA, but CBO cannot estimate the amount of such costs, which would be subject to appropriation action. Because H.R. 2469 would not affect direct spending or receipts, pay-as-you-go procedures would not apply. The bill contains no intergovernmental mandates, and would impose no costs on state, local, or tribal governments. While it would impose a mandate on the private sector, the costs of carrying out that mandate would be negligible.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

CBO cannot estimate the cost of implementing this bill because we do not have sufficient information to project the cost of provisions regarding food contact substances.

BASIS OF ESTIMATE

For the purposes of this estimate, CBO assumes that all amounts authorized in H.R. 2469 would be appropriated by the start of each fiscal year and that outlays would follow the historical spending patterns of the Food and Drug Administration. The costs of this legislation fall within budget function 550 (Health).

Flexibility for Regulations Regarding Claims. Under H.R. 2469, regulations published by the Secretary regarding claims about the level of a nutrient in a food item or about the relationship of a nutrient to a health-related condition would be effective for a limited time while they were awaiting public review and final regulation. CBO estimates no cost for these provisions because the FDA would not be required to take any additional action.

Petitions for Claims. Under current law, the Secretary is required to act on a petition within a specified amount of time. Under the bill, petitions not acted upon within the time limits would be denied unless an extension were agreed upon between the Secretary and the petitioner. According to the FDA, the Secretary is already meeting these deadlines, so there would be no additional costs as a result of this provision.

In addition, in cases where the Secretary issues a proposed regulation in response to a petition, the bill would require the rulemaking process to be completed within 540 days of the date the petition was received by the Secretary. Any regulation that exceeded this deadline would be considered final. To date, there have been only two regulations that became final rules, and both took longer than 540 days to complete the process. According to the FDA, one and a half additional full-time employees would be necessary to complete the regulations within the deadline and to publish as final rules those regulations not meeting the 540-day deadline. CBO estimates that the additional staff would cost an additional $1 million over the 1998-2002 period.

Health Claims for Food Products and Nutrient Content Claims. The bill would permit claims to be made on food labels concerning the level of a nutrient or its relationship to a health condition without the Secretary's authorization, provided the claim met specific conditions. These conditions include existence of an authoritative statement by the National Academy of Sciences or other qualified scientific entity in support of the claim, notification of the FDA 150 days before the claim is published, and submission of a balanced representation of the scientific literature relating to the claim. A claim would be valid until a regulation issued by the Secretary regarding it became effective or until the Secretary or U.S. district court determined that the requirements of this provision had not been met. Based on information from the FDA, CBO estimates handling the new submission process would cost less than $1 million over the 1998-2002 period.

Irradiation Petition. Within sixty days of enactment, the bill would require FDA to complete all pending petitions regarding the radiation of red meat. Otherwise, the Secretary must report to the House Commerce and Senate Labor and Human Resources Committees the reason why action on any incomplete petition was delayed. According to the FDA, there is only one such petition currently pending and the agency has made completion of the work on this petition a high priority. Given the level of effort already devoted to this project, enactment of this provision would not likely subject the agency to significant additional

costs. If the sixty-day deadline were not met, however, there would be a small cost associated with the additional responsibility of preparing the report.

Food Contact Substances. Currently in most cases, any food contact substance—a substance intended to contact food but not to have any chemical effect on it—may be marketed only after the FDA has promulgated a regulation permitting its use in response to a petition submitted to the agency. The bill would provide for a notification system that is quicker and simpler than the petition process and that would apply only to the substance that was the specific subject of the notification. While the new process would be simpler to administer, it could attract additional applications necessitating additional resources to be devoted to this approval process. However, CBO cannot estimate the magnitude of these costs at this time.

PAY-AS-YOU-GO CONSIDERATIONS: None.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 2469 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act of 1995 and would impose no costs on state, local, or tribal governments.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 2469 would abolish several existing private-sector mandates and impose a new mandate on sellers of colored oleomargarine and margarine. CBO estimates that the direct costs of the new mandate would most likely be less than the costs of the existing private-sector mandates that would be replaced. In addition, the bill would make an existing mandate related to nutrient food claims less burdensome.

Under current law, the sale or offering for sale of colored oleomargarine or margarine, or the possession of those products in a form ready for serving, is prohibited if the products do not meet certain labeling, packaging, weight, and restaurant notification requirements. Section 109 of H.R. 2469 would abolish these requirements and impose a new labeling requirement on sellers of colored oleomargarine or margarine. Because current regulations already require extensive labeling for these products, CBO estimates that the cost of the new labeling requirement would be negligible.

Section 105 of the bill would amend an existing private-sector mandate to be less burdensome. Under current law, nutrient food claims are subject to a labeling requirement. Under the bill, the labeling requirement would apply only if the Secretary makes a

determination that the food contains a nutrient at a level that increases risk of a disease or health-related condition that is diet-related.

ESTIMATE PREPARED BY:

Federal Cost: Cynthia Dudzinski
Impact on State, Local, and Tribal Governments: Leo Lex
Impact on the Private Sector: Anna Cook

ESTIMATE APPROVED BY:

Robert A. Sunshine
Deputy Assistant Director for Budget Analysis