U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

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November 13, 2026

The Honorable Bill Cassidy
Chairman
The Honorable Bernie Sanders
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Brett Guthrie
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration (FDA) entitled "Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods" (RIN: 0910-AI72). We received the rule on October 9, 2026. It was published in the *Federal Register* on October 13, 2026. 91 Fed. Reg. 65040. The effective date of the rule is December 14, 2026, except as to any provisions in the standard of identity (SOI) for dairy products that may be stayed by the filing of proper objections. *See id.* at 65052.

According to FDA, this rule amends the SOI regulations that specify salt (sodium chloride) as a required or optional ingredient to permit the use of salt substitutes in standardized foods, to reduce the sodium content. FDA stated in the rule that within the SOI it is amending, it is also updating the incorporation by reference information to refer to the most recent version of the incorporation by reference materials available at the time of publication and to provide updated contact information for obtaining the incorporation by reference materials. FDA also stated that it is making technical amendments to correct inconsistencies and typographical errors in some SOI regulations.

Enclosed is our assessment of FDA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact me at (202) 512-8156.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Christina Kang
Regulations Coordinator
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"USE OF SALT SUBSTITUTES TO REDUCE THE SODIUM CONTENT
IN STANDARDIZED FOODS"
(RIN: 0910-AI72)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) prepared an analysis of the costs and benefits of this rule. 91 Fed. Reg. 65040, 65053 (Oct. 13, 2026). According to FDA, there are no regulatory costs of the rule as there are no regulatory requirements or regulatory penalties if manufacturers of a standardized food choose not to take advantage of the flexibility to use salt substitutes. *Id.* FDA stated that other costs considered may come from voluntary reformulation and re-labeling costs, as well as potential consumer dissatisfaction with altered product properties. *Id.* Additionally, FDA stated that the benefits of the rule come in the form of increased flexibility for manufacturers and potential public health benefits stemming from decreased sodium consumption. *Id.*

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603–605, 607, and 609

FDA certified that this rule will not have a significant economic impact on a substantial number of small entities. 91 Fed. Reg. at 65053.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

FDA stated that this rule will not result in a mandated expenditure by state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more, adjusted annually for inflation, in any one year. *See* 91 Fed. Reg. at 65053.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

On April 10, 2023, FDA published a proposed rule. 88 Fed. Reg. 21148. FDA stated that they received comments from consumers, consumer groups, trade organizations, manufacturers, public health organizations, public advocacy groups, local government agencies, and other organizations. 91 Fed. Reg. at 65042. FDA responded to comments in the rule. *Id.* at 65043–52.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501–3520

FDA determined that this rule contains no information collection requirements under the Act. 91 Fed. Reg. at 65054.

Statutory authorization for the rule

FDA promulgated this rule pursuant to sections 321, 341, 342, and 371 of title 21, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA stated that this rule is significant under the Order and that it was submitted to the Office of Information and Regulatory Affairs for review. 91 Fed. Reg. at 65052.

Executive Order No. 13132 (Federalism)

FDA stated that the rule does not contain policies that have federalism implications as defined in the Order and therefore a federalism summary impact statement was not required. 91 Fed. Reg. at 95054.