U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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November 17, 2023

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

The Honorable Cathy McMorris Rodgers
Chair
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: Revocation of Uses of Partially Hydrogenated Oils in 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) titled "Revocation of Uses of Partially Hydrogenated Oils in Foods" (RIN: 0910-AI15). We received the rule on October 31, 2023. It was published in the *Federal Register* as a direct final rule on August 9, 2023. 88 Fed. Reg. 53764. The stated effective date is December 22, 2023.

According to FDA, it is amending its regulations that provide for the use of partially hydrogenated oils (PHOs) in food in light of its determination that PHOs are no longer generally recognized as safe (GRAS). FDA stated that the rule removes PHOs as an optional ingredient in the standards of identity for peanut butter and canned tuna. FDA also stated that it is revising its regulations affirming food substances as GRAS pertaining to menhaden oil and rapeseed oil to no longer include partially hydrogenated forms of these oils and deletes the regulation affirming hydrogenated fish oil as GRAS as an indirect food substance. FDA stated further that they are also revoking prior sanctions (*i.e.,* pre-1958 authorization of certain uses) for the use of PHOs in margarine, shortening, and bread, rolls, and buns based on its conclusion that these uses of PHOs may be injurious to health. Finally, FDA stated that it is issuing these amendments directly as a final rule because they are noncontroversial given the public health risks associated with PHOs and the increasing use of PHO alternatives, and it anticipates no significant adverse comments because PHOs were declared no longer GRAS for any use in human food in 2015.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). This direct final rule was published in the *Federal*

Register on August 9, 2023. 88 Fed. Reg. 53764. But the House of Representatives and the Senate did not receive the rule until November 2, 2023. Email from Regulatory Policy Analyst, FDA to Senior Staff Attorney, GAO, Subject: *RE: [EXTERNAL] RE: Congressional Review of Regulations Report - RIN 0910–AI15 Partially Hydrogenated Oils DFR (CFSAN 2021-465)* (Nov. 6, 2023). The stated effective date of the rule is December 22, 2023. Thus, based on the date of receipt by Congress, the final rule does not have the required 60-day delay in its effective date.

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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Daniel Jedzinak
Regulations Policy and Management Staff
Food and Drug Administration

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
TITLED
"REVOCATION OF USES OF PARTIALLY HYDROGENATED OILS IN FOODS"
(RIN: 0910-AI15)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) stated that it estimated the costs of removing foods containing partially hydrogenated oils (PHOs) from the market that accrue from product reformulation, relabeling products, changing food recipes, finding substitute ingredients, and changes in functional and sensory product properties, such as taste, texture, and shelf life. According to FDA, the benefits of this final rule accrue from reduction of coronary heart diseases. FDA stated that the annualized primary cost estimate of the final rule is $24.5 million with a lower bound estimate of $20.8 million and an upper bound estimate of $29.7 million, discounted at 7 percent over a 20-year period. FDA also stated that the annualized benefits of the final rule discounted at 7 percent over a 20-year period is $61.5 million for the primary estimate with a lower bound of $20.1 million and an upper bound of $120.7 million.

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

FDA determined that the final rule will have a significant economic impact on a substantial number of small entities because the rule may require some small business entities to undertake costly reformulations. FDA stated that it developed a more comprehensive economic analysis of the impacts of the final rule in a separate document.

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

FDA determined that this final rule would not result in an expenditure in any year that meets or exceeds $177 million ($100 million, adjusted for inflation).

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO's major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: "the Act does not apply to this rule because it does not increase direct spending; the Act does not apply to this rule because it meets one of the Act's exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act's requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the

OMB Director as required by section 263(a) or (b) of the Act" in their submissions of rules to GAO under the Congressional Review Act. OMB, *Memorandum for the Heads of Executive Departments and Agencies,* Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11–12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

FDA did not discuss the Administrative Pay-As-You-Go Act of 2023 in this final rule.

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

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

According to FDA, this final rule is appropriate for direct final rulemaking because it includes only noncontroversial amendments, and it anticipates that it will not receive significant adverse comments. FDA stated that if it receives any significant adverse comments, it intends to withdraw the final rule before its effective date by publication of a notice in the *Federal Register*. FDA also stated that it has published a companion proposed rule proposing to amend its regulations and revoke prior-sanctioned uses of PHOs to conform with the current state of scientific knowledge regarding the public health risks of PHOs. 88 Fed. Reg. 53827 (Aug. 9, 2023). FDA explained that the companion proposed rule provides a procedural framework within which the rule may be finalized if the direct final rule is withdrawn because of any significant adverse comments. FDA also noted that any comments received in response to the companion proposed rule will be considered as comments regarding the direct final rule.

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

FDA determined that this final rule contains no information collection requirements under PRA.

Statutory authorization for the rule

FDA promulgated this final rule pursuant to sections 321, 341, 342, 343, 348, 371, 379e of title 21, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

According to FDA, the Office of Information and Regulatory Affairs has determined that this final rule is not a significant regulatory action as defined by the Order, as amended.

Executive Order No. 13132 (Federalism)

FDA determined that the rule does not contain policies that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA stated that it has concluded that the rule does not contain policies that have federalism implications as defined in the Order and, consequently, a federalism summary impact statement is not required.