



Department of Health and Human Services
Securing Updated and Necessary Statutory Evaluations Timely
Docket No. HHS-OS-2020-0012
RIN 0991-AC24
Notice of Proposed Rulemaking published Nov. 4, 2020

Dec. 4, 2020

To Whom It May Concern:

The Sustainable Food Policy Alliance (SFPA), whose founding members Danone North America, Mars, Incorporated, Nestlé USA and Unilever United States represent some of the world's best-known food companies, writes to urgently express concerns with the Department of Health and Human Services' recent proposal, "Securing Updated and Necessary Statutory Evaluations Timely," (Docket No. HHS-OS-2020-0012) released on November 4, 2020.

The SFPA respectfully requests at least a 150-day extension of the public comment period for the proposed rule. The current 30 day comment period does not provide enough time to adequately review and consider the several, significant implications of this proposal for the entire food industry. This includes not only major manufacturers, but also our third-party suppliers and partners who are likewise integral to the safety and availability of the U.S. food supply.

In addition to the above requested extension of the public comment period, the SFPA appreciates the opportunity to provide the following general comments. The preamble of this proposed rulemaking states that its purpose is "to enhance the Department's implementation of section 3(a) of the Regulatory Flexibility Act (RFA) 5 U.S.C. 610..." and that "[t]he RFA requires federal agencies to publish in the **Federal Register** 'a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities' in order 'to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant impact of the rules upon a substantial number of small entities.'" The proposed rule defines both the terms "Assess" and "Review". In addition, it references the five factors that Congress directed the agencies to consider when conducting a Review as well as two additional components.

To implement this statute, the most far-reaching change in the proposed rule generally provides that the U.S. Department of Health and Human Services (HHS or Department) regulations "shall expire at the end of either (1) two calendar years after the year that this proposed rule first becomes effective, (2) ten calendar years after the Year of the Regulation's Promulgation, or (3) ten calendar years after the last year in which the Department Assessed and (if Review of the Regulation is required pursuant to paragraph (d)) Reviewed the

Regulation, whichever is latest.” HHS proposes “all of its Regulations (subject to the exceptions listed below) should be Assessed and, if they have a significant economic impact upon a substantial number of small entities, Reviewed.” As put forward in the proposed rule, HHS would assess a regulation every ten years, and if required, review it to avoid expiration or “sunset”. This provision would be fully implemented two years from the effective date of this rule.

Certainly, SFPA supports good regulatory governance achieved in part through the periodic review of regulations. However, the sole measure of an assessment based upon the definition is whether regulations “currently have a significant economic impact upon a substantial number of small entities.” SFPA is concerned that this measure could be overbroad and capture regulations that do not need updating. Measuring impact from a regulation based upon its effect, *not limited in scope to whether it is positive or negative*, is extremely broad.

It is also unclear whether the proposed rule equally prioritizes amending, or updating, regulations, as much as their potential rescission. The Department is given an equal amount of time, up to seven years, to write a new regulation or rescind it. We are concerned about the consequences of imposing a deadline (in as little as two years) for the review and potential revision of hundreds of regulations – a review which would reasonably necessitate a much longer period of time to be done well.

The food industry is heavily regulated, indeed, but these regulations provide our industry with much-needed clarity in compliance expectations, consistency in enforcement, and certainty for our consumers who rely on Federal standards to ensure safe food and accurate labeling. There are certainly examples across the Federal Government of an agency correctly pulling back a proposed rule and restarting its process, and a value in the review of longstanding regulations. However, we oppose any proposal to sunset regulations while this review is ongoing. Our businesses require regulatory certainty and stability if we are to ensure safety and transparency to ultimately succeed in the marketplace. Should a regulation expire under this Proposed Rule (and no regulation replaces it, as envisioned by the Proposed Rule), our industry could be left with no regulations that govern food safety, nutrition labeling, or ingredient safety, to name just a few substantial regulatory schemes that we and all Americans rely on. These regulations ensure public health and safety and enable the consumer confidence that allows our businesses to continue to operate. Not only could this Proposed Rule result in significant chaos for our industry, the Department’s proposal to sunset regulations automatically with the mere passage of time seems to be out of step with the intent of the Administrative Procedure Act and its notice-and-comment rule making requirements.

Finally, but not least, we are concerned that the retrospective reviews in the proposed rule will require significant Food and Drug Administration (FDA) time and resources. Our companies strongly prefer that FDA retain the flexibility to focus on issues that are important to the industry it regulates as well as the American consumers it protects, particularly during a serious pandemic.

The Sustainable Food Policy Alliance recognizes our responsibility to drive positive change for the people who use our products, the people who supply them, and the planet on which we all rely. Given the important role that HHS and its public health agencies play in supporting these goals, we believe this proposal warrants further attention and scrutiny, and we appreciate your attention to this request.

Sincerely,



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