



January 18, 2021

President-Elect Joseph R. Biden, Jr.  
Biden-Harris Transition Team  
1401 Constitution Avenue NW  
Washington, DC 20230

Re: Securing Updated and Necessary Statutory Evaluations Timely Final Rule

Dear President-Elect Biden:

The Sustainable Food Policy Alliance (SFPA), whose founding members include Danone North America, Mars, Incorporated, Nestlé USA and Unilever United States, is writing to express our deep concern with, and implore the incoming Presidential administration to use any and all administrative authority to postpone the effective date of and rescind the Department of Health and Human Services' (HHS or Department) recent Final Rule, "Securing Updated and Necessary Statutory Evaluations Timely," (Docket No. HHS-OS-2020-0012), RIN 0991-AC24, (SUNSET Final Rule) both filed for public inspection on January 15<sup>th</sup> and scheduled for publication on January 19<sup>th</sup> in the Federal Register.

SFPA submitted public comments on December 4, 2020 to share our concerns with the Department's proposal at the time, and we are aware of the key differences between the SUNSET Proposed and Final Rules. However, merely extending the implementation date from two to five years after the effective date of the Final Rule and exempting certain food regulations does not address the concerns we raised. We greatly appreciate your attention and review of this matter.

We believe that food industry regulations provide our industry with important 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 the sunset of regulations while this review is ongoing and are concerned of the uncertainty this could create for the regulation of the food industry.

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

Final Rule (and no regulation replaces it, as envisioned by the Final Rule), our industry could be left with significant and concerning gaps in the regulations that govern food safety, nutrition labeling, or ingredient safety, to name just a few substantial regulatory schemes that all Americans rely on for their food supply. These regulations ensure public health and safety and enable the consumer confidence that allows our businesses to continue to operate. Not only could this Final Rule result in significant chaos for our industry, the Department's sunset of 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.

The general purpose of the Final Rule in question is to "enhance the Department's implementation of section 3(a) of the Regulatory Flexibility Act (RFA) 5 U.S.C. 610..." and that it "will lead to the amendment or rescission, where appropriate, of Department regulations that have a significant economic impact upon a substantial number of small entities." To implement this statute, the most far-reaching change in the Final Rule generally provides that the HHS regulations "shall expire at the end of either (1) five calendar years after the year that this Final Rule first becomes effective, (2) ten calendar years after the Year of the Section's Promulgation, or (3) ten calendar years after the last year in which the Department Assessed and, if required, Reviewed the Section, whichever is latest." HHS would assess a regulation every ten years, and if required, review it to avoid expiration or "sunset".

As noted in our previous public comments, 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 Final Rule equally prioritizes amending, or updating, regulations, as much as their potential rescission. The Department is given an equal amount of time, up to five years, to amend a regulation or rescind it. We are concerned about the consequences of imposing a deadline 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.

Finally, but not least, we are concerned that the retrospective reviews in the Final 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 the SUNSET Final Rule's effective date should be delayed and the Final Rule rescinded, and we appreciate your attention to this request.

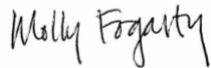
Sincerely,



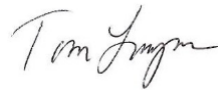
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