



North American Millers' Association

1400 Crystal Drive • Suite 650 • Arlington, VA 22202
202-484-2200 • Fax 202-488-7416 • www.namamillers.org

Submitted electronically via regulations.gov

December 4, 2020

The Honorable Alex Azar
Secretary of Health and Human Services
c/o James Lawrence
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201
Docket HHS-OS-2020-0012 / RIN 0991-AC24

**Re: Securing Updated and Necessary Statutory Evaluations Timely (Nov. 4, 2020),
Docket No. HHS-OS- 2020-0012.**

Dear Mr Secretary,

The North American Millers' Association (NAMA) appreciates the opportunity to provide comments on the Department of Health and Human Services' ("HHS" or "the Department") Proposed Rule "Securing Updated and Necessary Statutory Evaluations Timely" (hereinafter "Proposed Rule"). ^{1/} NAMA represents millers of wheat, corn, oats, and rye across the continental United States, Puerto Rico, and Canada. Our members take raw grain and, through grinding and crushing, create flour and other products that are used to make favorite foods, such as bread, cereals, pasta, cookies, cakes, and snack foods. As such, our members will undoubtedly be affected by the Proposed Rule and are uniquely positioned to offer valuable feedback to HHS about the impact of existing U.S. Food and Drug Administration (FDA) regulations on businesses of varying sizes and our potential perspective regarding the Proposed Rule.

NAMA supports regulatory reform and values opportunities to review and modernize regulations to ensure they are no more burdensome than necessary, especially for small businesses. We applaud HHS's efforts to take another look at the regulatory review process and consider ways to improve it. However, we have significant concerns about the expansive and accelerated approach taken in the Proposed Rule. In general, NAMA is concerned that the suggested approach would require intense work from FDA that would not only take critical agency resources and experience away from managing the COVID-19 pandemic and routine agency activities, but also would not allow for the kind of targeted and reasoned regulatory reform that is necessary and appropriate.

^{1/} 85 Fed. Reg. 70096 – 70124 (Nov. 4, 2020).

Further, we are concerned that there is a genuine potential that the Proposed Rule could lead to the inadvertent sunseting of regulations that have been in place for many years and are essential to maintaining consumer confidence in our nation's food supply, as well as a level playing field within the industry. FDA regulations of interest to the milling industry pertaining to the Food Safety Modernization Act (FSMA), nutrition labeling, claims, ingredient labeling, and food standards of identity to name a few would require FDA to analyze and justify. Abandoning these rules of law has the potential to lead to confusion and disruption within the food supply chain and damage consumer confidence.

Due to the short comment period our preliminary review of the Proposed Rule raises the following issues with the Department's proposed approach:

1. The Proposed Rule should provide greater clarity as to how the sunset exceptions will function;
2. The Proposed Rule does not sufficiently outline how agencies will consider the factors for and how the Review process for regulations will be conducted;
3. The timeline for Review in the Proposed Rule is unrealistic and could lead to inadvertent sunseting of regulations which would cause unnecessary chaos and harm to the industry and consumers alike;
4. The proposed public review website shifts responsibility from the Department to the public, is unduly burdensome, and does not guarantee the necessary regulations will be reviewed in a timely manner;
5. The Proposed Rule would disproportionately impact the food industry because many companies are small businesses; and,
6. The use of machine learning in regulatory reform is a novel approach and affected members of the public have been afforded no opportunity to comment on the methodology.

Effective regulatory reform is important to our industry and to all our members. The food industry in particular, which is comprised of so many small business members, supports the need for a measured approach to regulatory reform. Nonetheless, in light of the concerns outlined above and the short comment period, HHS should issue a subsequent Proposed Rule to address the issues we raise, so that we can provide meaningful comment on the Department's proposal. Should the agency have any further questions regarding our comments or if any additional information may be helpful, feel free to contact Dale Nellor, NAMA's Vice President of Government and Technical Affairs at 202-484-2185 or dnellor@namamillers.org.

Sincerely,



Jane DeMarchi
President
North American Millers' Association