

October 17, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

(Submitted electronically: www.regulations.gov)

Re: Docket No. FDA-2014-D-0055. Voluntary Sodium Reduction Goals: Target Mean and Recommended Maximum Concentrations for Sodium in Commercially Processed, Packaged and Prepared Foods. 81 Fed. Reg. 35363 (June 2, 3536-35367)

Dear Sir or Madam:

The American Butter Institute (ABI) is an Arlington, VA-based trade association for manufacturers, processors, marketers, and distributors of butter and butter products. Originally established as the National Association of Creamery Butter Manufacturers in 1908, ABI's mission is to promote and protect the interest and welfare of the butter industry. There are currently 25 active member companies that market approximately 90% of all the butter manufactured in the U.S.

ABI evaluated Category #14 "Butter" and has concluded that this category should be removed from FDA's guidance for sodium reduction goals for the following reasons:

- Unsalted butter is already available for consumers as an option. At least 50% of the foodservice butter market is comprised of unsalted butter; about 40% of all butter manufactured is unsalted.
- Sodium plays a functional role in butter, and reduction in sodium in salted butter will result in a shorter shelf-life and greater microbial spoilage and development of off-flavors (e.g., rancid) over time. Unsalted butter has a shelf-life of 120-180 days, salted butter has a shelf-life of 200-240 days.
- Sodium in butter also plays a role in food safety. Any reductions in sodium should only be made after validation of the modified formulation through microbial challenge studies, including consideration of consumer behavior (i.e., leaving butter on a counter to soften).
- Reductions in sodium content are constrained by the fact that salt- or sodium-substitutes are not permitted in the standard of identity. Per its standard, "butter" must be made exclusively from milk and/or cream, and only salt or coloring are permitted as optional ingredients. Unlike

other dairy standards of identity, which were established through regulation by the FDA, the standard of identity for butter was established by statute¹. Amending the optional ingredients permitted in butter is outside the authority of the agency and would require Congressional action.

Should FDA not agree to remove this category from the sodium reduction guidance, we suggest this category be re-named to “Salted Butter” and the description modified to specifically exclude unsalted butter. It is clear from the histogram plot of the category that unsalted varieties were not included in the survey by FDA and were not included in calculating the baseline mean. This would be consistent with FDA’s statement that the guidance does not focus on foods that contain only naturally-occurring sodium.

Thank you for the opportunity to share our perspectives. Please contact us if you have additional questions.

Sincerely,



Clay Detlefsen
Senior Vice President, Environmental and Regulatory Affairs & Staff Counsel

¹Butter Act 21 USC 321a.