August 13, 2019

Mr. Frank Yiannas
Deputy Commissioner for Food Policy & Response
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dr. Susan Mayne,
Director, Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740-3835

Re: Illinois HB 2123 Sesame Labeling Law

Dear Deputy Commissioner Yiannas and Dr. Mayne:

The Grocery Manufacturers Association (GMA) advocates for smart regulatory frameworks that maintain affordability, promote choice and build consumer trust in the products they use every day. We believe that smart regulations result in uniform structures, empower consumers to make informed decisions and are grounded in risk-based science. When a patchwork of regulatory policies exists, it contributes to consumer confusion and adds unnecessary stress to the supply chain resulting in higher prices.

To this end, GMA generally supports the creation of uniform national standards and the regulatory primacy held by long-standing federal authorities, including the U.S. Food and Drug Administration (FDA or agency). Conversely, state and local government mandates that are inconsistent with national standards create confusion for consumers and jeopardize their ability to access clear and reliable product information.

A recently enacted State of Illinois law now requires that manufacturers label sesame in food products.[1] As described in greater detail below, GMA believes this law is expressly preempted and should be barred under the doctrine of primary jurisdiction.

[1] Illinois H.B. 2123, July 26, 2019.

Food allergies are a serious public health issue and consumers deserve a uniform framework that communicates clear and reliable information consistently across the country, regardless of the state in which the product is purchased. We urge the FDA to engage with the State of Illinois to confirm the FDA's sole and preeminent responsibility for the labeling of major food allergens.

**Background on Illinois Sesame Labeling Law**

On July 26, 2019, Illinois HB 2123 amended Section 11 of the Illinois Food, Drug and Cosmetic Act to state that a food is misbranded, "[i]f it contains sesame, is offered for sale in package form but not for immediate consumption, and the label does not include sesame."[2] The amendment was effective upon becoming law. Though there is little legislative history on the amendment and the law itself does not reference the term "allergen," we know from public statements and social media posts by Illinois State Representative Jonathan Carroll who sponsored the bill that the law is intended to require the labeling of sesame as a major allergen. He stated on Twitter regarding the legislation, "I'm very excited to help set the nation['s] standard for food allergy safety here in Illinois."[3]

**The Illinois Law is Preempted**

Illinois HB 2123 is expressly preempted because Illinois has established a requirement for the labeling of allergens that is not identical to the FDA requirement. Specifically, the Illinois law on sesame labeling differs from FDA requirements in the following critical respects:

- FDA has not defined sesame as a major food allergen;
- The Food, Drug and Cosmetics Act law does not require the term "sesame" to appear in the ingredient statement or the allergen information statement; it only requires the term to appear on the label; and
- The Illinois law applies to all sesame derivatives and is not limited to sesame derivatives that contain protein or exempt highly refined oils from its scope.

As you are aware, the Federal Food, Drug, and Cosmetic Act (FFDCA) expressly preempts state and local requirements that differ from the allergen labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).[4] The FFDCA provides that "no State or political subdivision of a state may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce – any requirement for the labeling of food of the type required by section … 343(w), or 343(x) … of this title that is not identical to the requirement of such section."[5] Section 343(w) deems a food misbranded unless the major food allergens are declared by common names in the ingredient statement or an allergen information

[2] The full text of the law is available here: http://www.ilga.gov/legislation/publicacts/fulltext.asp?name=101-0129&GA=101&SessionId=108&DocTypeId=HB&DocNum=2123&GAID=15&Session.
[3] Rep. Jonathan Carroll (@repjcarroll), Twitter (July 27, 2019, 12:19pm), available at https://twitter.com/repjcarroll/status/1155199044848951298. *See also*, "I want to thank Governor Pritzker for signing HB2123 into law today. **It requires allergy labeling for sesame in prepackaged foods**," (emphasis added) July 26, 2019, 2:18pm, available at https://twitter.com/repjcarroll/status/1154863504358293504.
[4] FFDCA 403A(a)(3); 21 USC 343-1(a)(2).
[5] 21 U.S.C. 343-1(a)(2).

statement. Section 343(x) authorizes FDA to issue regulations requiring disclosure of non-major food allergens such as sesame.

FDA has not issued any regulations requiring disclosure for foods containing sesame, but in 2018, the agency did open a docket to collect data and information on whether sesame should be defined as a major food allergen.[6]

The Illinois Food, Drug and Cosmetic Act does not require the term "sesame" to appear in the ingredient statement or the allergen information statement. The Illinois Food, Drug and Cosmetic Act contains many provisions that are identical to the FFDCA. Noticeably absent from the Illinois law, however, is the FFDCA provision that deems a food misbranded for failing to disclose the presence of the major food allergen by using commonly understood names in either the ingredient statement or an allergen information statement. The Illinois law simply requires "sesame" to appear on the label but does not specify where the word sesame must appear. It does not, for example, require sesame to appear in the statement of identity, in the ingredient statement or in an allergen information statement.

Further, Illinois HB 2123, however, requires foods that contain sesame derivatives to label the food as containing sesame – even those that may be excluded from FALCPA labeling requirements. The Illinois legislator who sponsored the bill has a daughter with a sesame allergy and has stated publicly that FDA does not require sesame to be labeled on foods "and it's becoming a problem." He also stated he sponsored the legislation to "protect kids like his daughter."[7]

**FDA Should Exercise Primary Jurisdiction**

In addition to being expressly preempted, the Illinois law should be barred under the doctrine of primary jurisdiction. While this doctrine traditionally enables a court to stay litigation if it finds that a case involves technical or policy questions that an administrative agency such as the FDA should resolve, the doctrine may be aptly applied in this instance as well.

In October 2018, FDA issued a notice seeking comment on whether it should amend its regulations to include sesame in the list of major food allergens.[8] Our understanding is that the FDA is in the process of determining whether sesame should be defined as a major food allergen and be labeled as other major food allergens as required by FALCPA.

The State of Illinois should, at a minimum, delay the effective date of the legislation in order to allow FDA to complete its rulemaking and make its determination. Allergen labeling is both an area within the FDA's expertise and a topic currently being addressed by the agency. The expert advice of the FDA in this area will help ensure uniformity in administration of the comprehensive regulatory regime established by the FFDCA and, importantly, empower consumers to make informed decisions.

* * * * *

[6] 83 *Fed. Reg*. 54594 (Oct. 30, 2018).
[7] https://www.nprillinois.org/post/illinois-lawmaker-wants-clearer-labeling-sesame#stream/0
[8] 83 *Fed. Reg.* 54594 (Oct. 30, 2018).

Illinois HB 2123 creates confusion in an area where the FDA has sole and preeminent responsibility and is actively examining whether sesame should be labeled as a major food allergen. GMA urges the FDA to engage with the State of Illinois on this issue for the benefit of consumers and our industry.

Thank you for your time and attention to this matter. Please let me know if I can be of further assistance.

Sincerely,

Dr. Betsy Booren
Senior Vice President, Regulatory and Technical Affairs
Grocery Manufacturers Association