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

Re: Food and Drug Administration, HHS
Docket No. FDA-2012-N-0711
77 *Federal Register* 74485 (December 14, 2012)

To Whom It May Concern:

We appreciate the opportunity to submit comments under the "Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of a Docket", 77 *Fed. Reg.* 74485 (December 14, 2012). The notice was issued to obtain comments relative to conducting a risk assessment to establish regulatory thresholds for major food allergens as defined in the Food Allergen Labeling and Consumer Protection Act of 2004.

American Spice Trade Association

The American Spice Trade Association (ASTA) was established in 1907 to provide representation for the American spice trade. Its members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the industrial, food service, and consumer levels. On behalf of its members, ASTA works with federal and state regulators and legislators and assists its members in addressing a variety of technical issues to help members provide an adequate supply of safe and wholesome spices for their industrial, food service and consumer customers.

FDA Role to Protect Public Health and the Food Supply

The FDA plays the critical role in ensuring that our nation's food supply is safe and to help consumers more easily identify ingredients in foods that may cause an allergic reaction as mandated in the Food Allergen labeling and Consumer Protection Act of 2004 (FALCPA).

Food Safety - A Priority

ASTA shares FDA's commitment to safety. The highest priority of ASTA and its members is providing clean, safe spices to their customers: food manufacturers, food service and consumers. In 2011 ASTA published *Clean Safe Spices, Guidance from the American Spice Trade Association* to provide industry with information and tools to mitigate the risk of filth and microbial contamination. Many of these tools can also be effective as it pertains to allergens. This critical resource was recently cited as a reference in the proposed FSMA rule for preventive controls for human food that also addresses allergen controls in implementation of food safety plans.

Allergens Policy Must be Based on Sound Science and Thoughtful Policy

ASTA supports implementation of science-based thresholds for allergens. As FDA indicates in the Federal Register notice, establishment of thresholds would help FDA "determine whether, or what type of, enforcement action is appropriate when specific problems are identified." ASTA agrees with and supports this science based approach. Furthermore, ASTA agrees that the establishment of allergen thresholds would assist FDA with more effective response actions pertaining to unintentional allergen contamination and allow the Agency to better respond to these situations.

While no spices are listed as allergens in the United States, ASTA members would support this science-based policy because of the potential for minimal cross contamination with other crops and in the development of seasoning blends.

It is important to note that spices are used in foods at very low levels. Current zero tolerance thresholds result in over labeling of allergen warnings that reduce consumer choices unnecessarily.

Across the border to our north, Health Canada has determined that gluten below a certain level does not pose a health risk. In The Canadian Food Inspection Agency Food Safety Action Plan Report, 2010-2011 Targeted Surveys for Allergens, it states "a number of factors are considered when determining if a food poses a health risk. The amount of the hazard, in this case gluten, that a person would ingest during a typical meal is a primary consideration. For single ground spices a serving size is relatively small at approximately 0.5 g. (according to Food and Drug Regulations Schedule M References). It was determined, in consultation with Health Canada, that 62 (97%) of the spices with detectable levels of gluten did not pose a risk to sensitive individuals."

ASTA fully supports FDA's decision to explore the establishment of regulatory thresholds to assist the agency in more effectively carrying out its mission as outlined in FALCPA. Establishment of science-based regulatory thresholds for allergens would assist consumers with allergen sensitivities, and provide industry well defined, science-based thresholds. Furthermore, the establishment of regulatory thresholds by FDA would also be helpful to other federal regulatory bodies including the U.S. Department of Agriculture Food Safety Inspection Service that is charged with oversight of meat, poultry, and egg products. USDA FSIS carries out inspections of meat and poultry products and enforcement actions relating to allergens, making sure products are correctly labeled and packaged. Setting a science-based policy on these important issues would benefit government regulators and enforcement authorities.

ASTA and its members are committed to ensuring the safety of spices. We thank you for the opportunity to comment on this notification and respectfully request your consideration during deliberation on the risk assessment for establishing allergen thresholds.

Sincerely,



Cheryl Deem
Executive Director