2527 Mill Race Rd., Frederick, MD 21701
Telephone 301.694.0419

www.seasoningmanufacturers.org
alsmeyer@seasoningmanufacturers.org

NSMA
National Seasoning Manufacturers Association

March 3, 2014

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

RE: Docket No. FDA– 2013-N-1204

Submitted via eRulemaking Portal: http://www.regulations.gov

To Whom It May Concern:

The National Seasoning Manufacturers Association (NSMA) appreciates the opportunity to submit comments regarding the Draft Risk Profile: Pathogens and Filth in Spices (DRP) prepared by the Food and Drug Administration (FDA). Founded in 1973, NSMA is a trade association representing the United States seasoning industry. NSMA is composed of member companies that produce food products including but not limited to seasonings, spices, flavorings, vegetable ingredients and derivatives and other food additives. We estimate that more than 90% of the seasonings consumed in the United States are manufactured by NSMA member companies and spices are an essential component in many of these seasonings. Therefore, our members have a compelling interest in this risk profile of spices.

NSMA shares the FDA's commitment to food safety. The highest priority of NSMA and its members is to provide safe and wholesome seasoning products to their customers, which include both the consuming public and other food manufacturers. NSMA is actively engaged in the regulatory process by maintaining routine meetings and dialogue with USDA and FDA and by providing comment to regulatory agencies as needed. NSMA also offers a wide variety of resources to its members including guidance to assist in the manufacturing, handling and processing of safe, wholesome food products. NSMA guidance is often shared with the entire supply chain.

NSMA recognizes that many raw agricultural products carry the risk of harmful microbial contamination and other foodborne hazards. The spice and seasoning industry fully comprehends the microbial risks inherent to raw agricultural products including those risks associated with farming and handling practices at the countries of origin. Consequently, responsible spice manufacturers incorporate processes to eliminate pathogens and other foodborne hazards during the conversion of raw agricultural products into ready-to-use or ready-to-eat foods. Likewise, responsible seasoning manufacturers utilize spices where foodborne hazards have been properly mitigated.

Within the DRP, FDA concluded that, "knowledge and technology are available to significantly reduce the risk of illness from consumption of contaminated spices in the United States." FDA also asserts that it identified failures of the farm-to-table food safety continuum, which potentially lead to the adulteration of "consumed" spice in the U.S. However, the preponderance of the relevant data that FDA offered to support its assertions was not collected throughout the entire farm-to-table continuum associated with spices that were offered for consumption in the U.S. Assessing the risk of foodborne hazards in consumed spices by testing shipments at import is deeply flawed because it cannot be assumed that all shipments at import are consumable food products.

2527 Mill Race Rd., Frederick, MD 21701
Telephone 301.694.0419

www.seasoningmanufacturers.org
alsmeyer@seasoningmanufacturers.org

NSMA
National Seasoning Manufacturers Association

FDA's surveillance data fails to determine the prevalence of foodborne hazards in spices offered as consumable food in the U.S. Risk within the U.S. cannot be inferred using data collected from, "retail settings outside the United States." References to outbreak and contamination data that occurred or was tested in countries other than the U.S. cannot be used to establish a degree of risk to the U.S. consumer. Customary food handling practices, regulatory requirements and consumer perception, have shaped the way by which spices are offered for consumption in any given country. In many of the foreign countries referenced in the DRP, the methods and protocols used for pathogen elimination are prescribed by unique regulations and labeling requirements. Some of the most highly effective treatment methods available to U.S. food producers are rendered illegal or undesirable in many foreign countries. The inconsistencies between U.S. food regulations and foreign food regulations, particularly those concerning pathogen elimination methods, will assuredly influence the frequency and scope of foodborne illnesses that resulted from contaminated spice. Therefore, evaluating U.S. spice consumption risk by extrapolating data from outbreaks and contamination reported by foreign countries is simply conjecture.

The American Spice Trade Association (ASTA) submitted testing data to FDA showing a dramatic reduction in the prevalence of pathogens in spices which had undergone a pathogen reduction treatment when compared to the FDA surveillance data collected at import. In the large data set that ASTA provided, three lots tested positive for *Salmonella* following treatment; two lots were treated with steam and one with Ethylene Oxide. Only one of the 3 lots, a steam treated lot, was identified as having been treated within the U.S. There was no indication of whether any of the lots testing positive were treated with processes that had been validated for pathogen elimination. FDA observed primitive agricultural practices and objectionable customary food handling and processing practices in many of the source countries for spices. Within the U.S. many of the most effective pathogen reduction treatment methods are governed by very strict regulatory requirements. These U.S. restrictions include but are not limited to those products that are lawfully eligible for treatment, gas concentrations, dosage levels and exposure limitations. Perhaps the conformance and adequacy of the pathogen reduction processes and facilities at the source countries deserve more scrutiny.

FDA did not specifically identify the root cause of the recent U.S. outbreaks resulting from the consumption of pathogen-contaminated spices. FDA surmised that inadequate microbial reduction treatment, process failures, multiple violations of Current Good Manufacturing Practices (CGMP) and environmental contamination, may have failed to adequately mitigate pathogenic risks or may have caused the contamination of the spice. Do the FDA's findings related to these outbreaks suggest that spices are high-risk or do the findings suggest that some food manufacturers and suppliers are high-risk? Additional regulations and policies applied to spices cannot mitigate risks when irresponsible food manufacturing firms do not comply with existing regulations and policies or violate basic CGMP's.

FDA's research cites that one death and 457 illnesses have been attributed to the consumption of spices during the continuous 37 year timeframe studied. However, 87 of the illnesses cited resulted from the consumption of contaminated broccoli powder which is not defined as "spice" under 21 CFR 182.10. If it was the intention of the FDA to expand the scope of the risk profile to include dehydrated vegetables that by law cannot be labeled as "spice" then the title of the DRP should be amended to accurately describe the categories of vegetable products included in the study or the FDA should move to amend the legal definition of "spice". FDA determined that the prevalence of contamination in spice shipments reaching the U.S. is substantially higher than contamination found in shipments of other FDA-regulated foods. FDA describes that, "a single contaminated shipment / lot of spice can contain millions to tens of millions of servings." Considering these observations and the very limited number of illnesses occurring in the U.S. attributed to spices during a 37 year timeframe, it seems illogical to suggest that spices are a high risk food product.

2527 Mill Race Rd., Frederick, MD 21701
Telephone 301.694.0419

www.seasoningmanufacturers.org
alsmeyer@seasoningmanufacturers.org

NSMA
National Seasoning Manufacturers Association

Seasonings can be complex combinations of a wide variety of ingredients including: spices, dehydrated vegetables, sweeteners, salts, flours, starches, gums, flavors, seeds, grains, food chemicals and many other ingredient categories. The risk of pathogenic contamination in seasoning ingredients is not limited to spices; many of the other ingredients used in seasonings are dehydrated vegetable matter or processed agricultural products similar to spices and with a similar farm-to-table continuum. However, under current regulations, ingredient suppliers and seasoning manufacturers are constrained from using many of the microbial reduction treatment methods proven to be most effective at mitigating pathogen contamination in spices. NSMA would urge FDA to determine the viability of these treatment methods for as many food ingredients as possible in an effort to broaden their use beyond spices and mitigate the pathogenic risks in similar food ingredients.

Nearly every American foodservice facility and household have spices in their kitchens and on their tables that are used to season each meal. Spices are flavoring constituents in many of the hundreds of billions of pounds of food manufactured and consumed within the U.S. each year. FDA chose to assess the risk to U.S. public health by collecting and analyzing a substantial amount of data that failed to identify or measure risks in consumable spices within the U.S. Why are conclusions offered about the safety of the farm-to-table continuum when only the farm-to-port continuum is surveilled by FDA's testing? In its recent meeting with FDA to discuss the DRP, NSMA asked why testing was not performed on spices and foods incorporating spices collected from the retail setting within the U.S. NSMA was alarmed that some FDA members believed that FDA had no authority to test foods in commerce and consequently, such testing was not included in the DRP studies. NSMA is also concerned that FDA failed to consider the outcomes of the thousands of reconditioning proposals it has received for spices in the preceding decades, as evidence of the efficacy of the treatment methods applied within the U.S. When asked, FDA replied that it had no knowledge of any spice testing positive for pathogenic contamination following an approved reconditioning treatment; and, FDA understood that if a positive test had occurred it would have been informed by the district office. NSMA believes that the mitigation and control options utilized by responsible food manufacturers have proven to be highly effective at removing foodborne hazards and mitigating pathogenic contamination in spices. Moreover, in the opinion of NSMA, the historical record demonstrates that irresponsible food manufacturers present a much higher risk to U.S. public health than the risks associated with any single product category such as spice.

If we can assist the agency with additional information or industry perspective, please do not hesitate to contact us.

Respectfully,

Richard Alsmeyer, Ph.D.
Executive Director
National Seasoning Manufacturers Association