Consumer Federation of America

June 16, 2010

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

Re: Docket No. FDA–2010–N–0195

To Whom It May Concern:

The Consumer Federation of America (CFA) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments for a Risk Profile for Pathogens and Filth in Spices **(Docket No. FDA-2010-N-0195)**.

CFA is a non-profit association of some 280 organizations, with a combined membership of over 50 million Americans. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and anti-hunger and food safety organizations. Since its founding in 1968, CFA has worked to advance the interest of American consumers through research, education and advocacy. CFA's Food Policy Institute was created in 1999 and engages in research, education and advocacy on food and agricultural policy, agricultural biotechnology, food safety and nutrition.

CFA believes that a risk profile can serve as a first step in determining the risk to consumers from pathogens and filth in spices. However, the risk profile must include additional information and data not included in FDA's request for comments. Importantly, a thorough risk profile must first consider the public health impact of contaminated spices. Specific information about foreign manufacturers and the regulatory capacity of foreign governments must also be included. In addition, a risk profile must be considered only a preliminary step in an appropriate regulatory response to the public health risk presented by spices.

The Public Health Impact of Pathogens in Spices Must Be Included in the Risk Profile

As noted in the FDA's request for comments, several recent spice recalls demonstrate the importance of reducing the public health impact from pathogens in spices. In March of this year, 252 people in 44 states and the District of Columbia were infected with *Salmonella* Montevideo after consuming Italian sausage products distributed by Daniele

International, Inc. that were coated in contaminated black and red pepper. The outbreak resulted in a recall of over 1.2 million pounds of ready-to-eat varieties of Italian sausage products.[1] In April 2009, 87 cases of *Salmonella* Rissen infection were confirmed in the Western United States as a result of contaminated white and black pepper from the Union International Food Company.[2] In June and July 2007, 65 persons in 20 states were infected with *Salmonella* Wandsworth after consuming the snack food "Veggie Booty."[3] The FDA determined that a spice imported from China and used in making the snack product was the likely source of the *Salmonella* contamination. These recent recalls are not anomalies; as the Center for Food Safety and Applied Nutrition has found, they are part of an increasing number of recalls of dried spices due to bacterial contamination. In fact, "whereas only two such recalls occurred during the 1990s, 16 recalls were monitored from fiscal year 2000 through the first quarter of 2004."[4]

The FDA's request for comments seeks information to describe "the nature and extent of the public health risk" by identifying the most commonly occurring microbial and filth hazards in spices. While identification of the hazards is important, FDA should go beyond mere identification to explicitly assess the public health impact of each hazard. The FDA is a public health regulatory agency; therefore, the impact on public health should be the agency's primary consideration as it develops risk profiles for pathogens and filth in spices. As such, the description of the public health problem should include a description of the hazard and its public health impact; characteristics of the disease caused by the hazard; epidemiology of the foodborne disease; and the economic impact or burden of the disease on the public. FDA's question regarding the "cost and practicality of currently available and potential future interventions" suggests the agency may consider whether it is unduly burdensome to require spice manufacturers to produce safe spices. While FDA does have to consider the capacity of current production methods and available technologies, the agency's approach should be first and foremost to determine how best to protect the public, to set public-health based standards to that end, and to hold manufacturers accountable for meeting those standards.

The FDA Must Gather Information About Foreign Plants & Processes

CFA agrees that an assessment of risk should include the entire food supply chain, both for domestic as well as foreign spice production and manufacturing. However, it is important to note that the majority of spices consumed in the United States are imported.[5] Spice imports to the United States are comprised of 43 spices from 93 different

[1] News Release, Food Safety and Inspection Service, Rhode Island Firm Recalls Italian Sausage Products Due to Possible *Salmonella* Contamination (Feb. 4, 2010).
[2] FDA, Establishment Inspection Report: U.F. Union International Food Co., Inc. (July 24, 2009).
[3] Centers for Disease Control and Prevention, Salmonella Wandsworth Outbreak Investigation, June - July 2007 (July 18, 2007).
[4] Vibha Vij et. al., *Recalls of Spices Due to Bacterial Contamination Monitored by the U.S. Food and Drug Administration: The Predominance of Salmonellae*, 69 J. of Food Prot. 233 (2006).
[5] Buzzanell, Peter, et. al., *The Spice Market in the United States – Recent Developments and Prospects,* Agriculture Information Bulletin No. AIB709, Economic Research Service, U.S. Department of Agriculture (July 1995).

countries.[6] According to the Economic Research Service, the value of total U.S. spice imports increased from $426 million in 1998 to $597 million in 2007.[7] Consequently, FDA must gather substantial information about the risk factors present in the foreign production and manufacture of spices. In its request for comments, the FDA seeks to address "what is known about differences in production and contamination of imported and domestic spices" and has requested data about specific manufacturing practices. Collecting this information will hopefully provide the FDA with a more informed view of the universe of pathogen controls being used by the spice industry, and can identify areas that need further investigation. Determining the controls used by specific companies and sectors of the industry, and also acquiring information about which companies do not use certain controls and why, could provide the FDA with relevant information about spice manufacturing practices to adequately assess whether specific practices or processes present a greater risk than others. It is of particular importance for FDA to collect substantial detailed information about the manufacturing processes and controls in foreign countries, since FDA currently has little data about spice production and manufacturing abroad.

Further, since FDA is currently unable to effectively regulate foreign manufacturers and importers, the agency should collect adequate information about the regulatory oversight capacity of foreign governments. Such information will help FDA determine whether or not countries can effectively oversee the manufacture of spices to reduce the risk of pathogen contamination. This information, as well as information about the manufacturing practices in foreign countries, will be important to consider in developing a risk profile for spices.

The need to assess the practices, controls, and oversight of foreign plants in particular is made clear by a review of the FDA Import Refusal database, which shows that a significant amount of contaminated product enters the United States each month. Between April and December of 2009, 220 of the 317 import refusals on spices that occurred were due to salmonella or filth. In fact, in April 2009 – the same month that FDA confirmed 87 cases of *Salmonella* Rissen resulting from contaminated white and black pepper – the FDA refused 34 spice imports due to salmonella or filth, including: green cardamom from Guatemala; cumin seeds, ground and cracked cumin, cayenne pepper, hot peppers, and curry powders from Canada; black pepper from Vietnam; oregano from Mexico; chili powder, ground black pepper, ginger powder, and masalas from India; five spices powder from China; and fish curry from Pakistan.[8] In addition, origanum from Mexico was refused as being "poisonous."[9] Notably, several companies are responsible for numerous violations over time. Seventeen shipments from the Original Bulk Packed Spice Company in Canada, for example, were refused import for salmonella on three separate days in April 2009. Well before these recent refusals, 16.6%

[6] Nora Brooks et. al., *Data Feature: Trade Data Show Value, Variety, and Sources of U.S. Food Imports*, 7 Amber Waves 36 (Sept. 2009).
[7] Brooks, Nora et.al., *U.S. Food Import Patterns, 1998-2007,FAU-125*, Economic Research Service, U.S. Department of Agriculture (August 2009).
[8] FDA, Import Refusal Report: Refusal Actions by FDA as Recorded in OASIS for 28-Spices, Flavors, and Salts (Apr. 2009).
[9] FDA, Refusal Details as Recorded in OASIS by FDA for Refusal AF4-0405613-3/1/1/ (Apr. 22, 2009).

of all import refusals due to salmonella from 1998 to 2004 were for spices, flavorings, and salts.[10] Thus, the FDA must gather substantial information about spice production and manufacturing in foreign countries to adequately assess the risk of pathogens and filth in spices.

FDA Must Improve Information Gathering and Data Sharing

In its recent report on the FDA, *Enhancing Food Safety: The Role of the Food and Drug Administration*, the Institute of Medicine found that, "[c]urrently, the FDA has limited analytical expertise and lacks the infrastructure to collect, analyze, interpret, manage, and share data, thus precluding the FDA from using data to support decision making. It is critical that the FDA evaluate its food safety data needs including surveillance, behavioral, economic, food production, and other data based on a risk approach."[11] This echoes similar findings made by the FDA Science Board's Subcommittee on Science and Technology in its 2007 report, *FDA Science and Mission at Risk*, which stated that "the FDA cannot fulfill its mission because its information technology (IT) infrastructure is inadequate." The Subcommittee further stated that "[t]he IT situation at FDA is problematic at best — and at worst it is dangerous."[12] CFA recognizes that the FDA has begun to update its data systems. Still, the FDA must substantially improve its data collection and analysis system in order to properly carry out the necessary elements of a risk-based food safety system, including development and regular updating of risk profiles.

A Risk Profile is Only a Preliminary Step in Addressing Risk

A risk profile is meant to be a preliminary step towards – not a substitute for – a more thorough approach to risk analysis. Codex Alimentarius considers a risk profile as just the second step of "preliminary risk management," which also includes: identification of a food safety problem; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessments; commissioning of the risk assessment; and consideration of the result of the risk assessment.[13] Risk profiles are thus meant as an initial step in the process and should not be used to avoid taking action when necessary. The agency should not use risk profiles as a means of reducing its regulatory and public health responsibilities. The development of a risk profile should always lead the agency to make a determination about the subsequent next step. This should include consideration of the appropriate regulatory response to identified hazards. Specifically, FDA should consider developing performance standards for spices as appropriate to reduce, prevent, or eliminate the risk to the public from filth and pathogenic contamination. Additionally, risk profiles should be continually updated to reflect new information, research, and practices. FDA should develop a process for the regular review of its risk profiles in order to assure continual reassessment of potential hazards and new risks to the public.

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[10] Jean C. Buzby et. al., USDA Economic Research Service, Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports (Sept. 2008).

[11] Institute of Medicine of the National Academies, Report Brief on Enhancing Food Safety: The Role of the Food and Drug Administration (June 2010).

[12] Subcommittee on Science and Technology, FDA, FDA Science and Mission at Risk (Nov. 2007).

[13] Codex Alimentarius, Working Principles for Risk Analysis for Food Safety for Application By Governments (2007).

Thank you for the opportunity to provide comments on this important topic.

Sincerely,

Chris Waldrop
Director, Food Policy Institute