



AFFI Statement on the FSMA Preventive Control Provisions

April 20, 2011

Good afternoon. I'm John Allan, the director for regulatory and international affairs for the American Frozen Food Institute – AFFI. On behalf of AFFI's membership, I want to thank you for inviting us to share some general perspectives on Preventive Controls. AFFI's members manufacture and distribute safe, affordable and nutritious frozen foods throughout the United States and globally. Although AFFI's membership comprises many of the largest food companies in the world, the institute prides itself on also representing the interests of small and mid-sized frozen food companies as well.

AFFI has always worked closely with the U.S. Food Drug Administration (FDA), Congress, consumer advocacy groups and allied industry associations on efforts to modernize our nation's food safety system. Over the past three years, AFFI advocated for congressional approval of legislation to modernize America's food safety system in a manner that increases protections for consumers, without imposing ineffective and burdensome regulations on food producers.

Since the passage of the *Food Safety and Modernization Act* (FSMA), AFFI has been and will continue actively engaging our members and assisting them throughout the regulatory implementation process. AFFI also stands ready to collaborate with FDA—providing needed information and sharing our perspectives.

Today I want to focus on AFFI's on-going work related to good manufacturing practices and our industry outreach efforts, and then discuss key points regarding how AFFI believes FDA should move forward with developing regulations and guidance on preventive controls.

On the topic of current good manufacturing practices – CGMPs – I would like to briefly mention the work that the AFFI-led food industry CGMP Coalition has undertaken over the past year. The CGMP Coalition was brought together by AFFI in 2004 and is comprised of over 60 food companies and trade associations.

Its members first came together to respond to, and work with, FDA as it moved forward with the process of modernizing the CGMP regulations. However, early last year, recognizing that existing CGMP regulations had yet to be updated and identifying that the food industry, especially smaller firms, required more robust guidance related to areas such as allergen management, environmental monitoring, sanitation practices and employee training, the CGMP Coalition embarked on an effort to develop a set of principles and recommended practices to help address these needs.

In December of 2010, the CGMP Coalition presented its draft guidance to FDA Center for Food Safety and Applied Nutrition (CFSAN) staff. We had a very productive discussion and are currently in the process of revising the document, based on our conversations, and we hope to be able to share the finished document with the agency very soon.

AFFI has also engaged the broader food industry in a similar coalition-based effort in commenting on FDA's draft guidance for control of *Listeria monocytogenes* in frozen and refrigerated ready-to-eat foods. Furthermore, over the past two years AFFI has organized five Listeria control workshops specifically designed for the frozen food industry. These workshops cover GMPs, sanitary design and sanitation practices and include training on establishing environmental monitoring programs and developing sampling plans.

As FDA finalizes preventive control regulations and guidance as part of implementing FSMA, AFFI would welcome the opportunity to partner with FDA to help conduct additional training.

At this point, I want to discuss AFFI's interests relative to preventive controls, as described within FSMA. Overall, we want to emphasize the need for FDA's regulations and guidance to be science and risk-based, non-prescriptive, and take advantage of the wealth of knowledge and experience the industry possesses. These are all critical to effective and wide-spread implementation by the industry—large and small, domestic and foreign.

AFFI believes that FSMA correctly recognizes that Hazard Analysis and Critical Control Points (HACCP) prerequisite programs and other preventive measures do fall under the umbrella of preventive controls, but they do not necessarily need to be treated as critical control points, as defined under HACCP.

In addition, because of our demonstrated commitment to food safety, AFFI supports the cornerstone provision that food companies must identify hazards that may reasonably occur during food production and implement the most effective controls for mitigating those hazards. Importantly, FSMA provides food processors needed flexibility to address food safety with tailored solutions. Furthermore, when there are changes in formulations or processes, these control systems typically need to evolve and adjust accordingly.

Therefore, AFFI encourages FDA to allow companies to determine how best to control potential hazards. Companies should be able to modify and improve food safety programs and controls, as they see fit, based on the unique conditions within a facility and the food being produced. However, FDA will still need to develop criteria for determining what is, and what is not, an acceptable preventive control program for regulatory purposes. A process may also need to be established for cases where there is disagreement between FDA agents and a company. These criteria should be developed through discussions with industry experts and other interested stakeholders.

Moreover, risk-based regulatory measures are also critical for efficiency, both within the industry and the agency. Since AFFI also represents many companies engaged in the cold chain warehousing and distribution sector, we encourage the agency to utilize its new authority to exempt and/or modify the requirements for such facilities related to performing hazard analyses and developing preventive control plans for certain packaged food items that are not exposed to the environment and clearly not at significant risk of contamination or adulteration.

Another key area of interest for our members relates to environmental and finished product testing. The purpose of an environmental monitoring program is to verify process and CGMP controls in critical food manufacturing areas that have the potential to support survival and/or growth of pathogenic micro-organisms. This is particularly important in monitoring the production of ready-to-eat products.

As you know, a well-designed and executed environmental monitoring program will seek out confirmed or potential pathogen growth niches, harborage sites and transfer points and allow for the proactive correction of deficiencies before product is contaminated. AFFI believes that aggressive environmental monitoring programs, employing a “seek and destroy” –type methodology, should be encouraged through any regulation and guidance developed.

Regarding finished product testing, although useful as one of several ways in which companies can monitor the effectiveness of their food safety programs, AFFI believes that industry and FDA efforts should focus mainly on ensuring that preventive measures are properly designated and effective, rather than utilizing valuable resources to try to detect the rare positive food sample coming off a production line.

In conclusion, we urge the agency to avoid developing prescriptive regulations, and instead focus on setting the overarching goals for preventive control plans and food safety systems, letting food companies take the lead with a risk-based approach rooted in their expertise. AFFI looks forward to working closely with the agency and other stakeholders to help provide input into the establishment of these goals and, importantly, determining how FDA should measure compliance with them.

Thank you again for this opportunity to speak on behalf of the U.S. frozen food industry. I am happy to try to answer any questions you might have.