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September 10, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

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**Re: Docket No. 2004N-0230; Food, Current Good
Manufacturing Practice Regulations**

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) appreciates this opportunity to provide comments as the Food and Drug Administration (FDA) prepares to revisit and modernize the current Good Manufacturing Practice (GMP) regulations for foods. AFFI is the national trade association representing frozen food manufacturers, their marketers, and suppliers. AFFI's 520 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 million. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationally and internationally. As food industry leaders, AFFI's members have a strong interest in the development of sound and effective revisions to the GMPs.

For the past 25 years, GMPs have formed the basis for food safety assurance programs in food manufacturing facilities, and have been very effective. Given the emergence of new food safety concerns and the development of new technologies for addressing these concerns, AFFI supports FDA's efforts to update and revise the food GMPs. In so doing, AFFI urges the agency to build upon and enhance the existing regulations, which should continue to serve as foundational, prerequisite safety controls in food manufacturing.

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As FDA embarks on its effort to revise the food GMPs, AFFI urges the agency to preserve the regulatory flexibility necessary for the diverse food industry. Currently, the GMPs are broad regulations that address the manufacture of a wide range of products in establishments of varying sizes that use many different types of processing technologies. These variations give rise to assorted, and often dissimilar, levels and types of risk. Accordingly, flexibility is crucial. AFFI, therefore, encourages FDA to keep an eye toward the appropriate level of flexibility as it considers the following aspects of food GMPs.

Environmental Controls

AFFI considers environmental controls to be crucial to food safety. Therefore, AFFI suggests that FDA promulgate general regulations, supported by guidance, on self-administered environmental control programs. These regulations and guidance should encourage food manufacturers to do the following:

- Create a baseline sanitation program to identify and sanitize potential harborage sites,
- Develop an environmental testing program to assess effectiveness,
- Evaluate results and conduct a root cause analysis when positive environmental samples are found, and
- Take corrective actions based on root cause analysis.

The level of rigor of such control programs should, of course, be risk-based.

Again, AFFI suggests guidance to supplement the regulations to allow the necessary flexibility to administer programs appropriate for particular circumstances—i.e. different product categories and different pathogen risks. Moreover, AFFI finds it important to encourage testing and corrective action by firms without regulatory penalties. Firms should be persuaded to, not dissuaded from, finding and addressing risks.

Sanitation Practices/Performance Standards

Good sanitation practices are the basis of GMPs. Because we have developed a better understanding of many foodborne diseases over the past quarter century, GMPs should be updated to reflect current best practices within the food industry. Revised GMPs might specify that food manufacturers should develop written “good sanitation practices” that would be self-administered. As discussed elsewhere, environmental controls and allergen controls also should be addressed.

In addition to the revised GMPs, AFFI encourages the agency to consider publishing a guidance document urging firms to incorporate advances in technology and sanitation practices, such as traffic controls to prevent cross-contamination, equipment passivation to address difficult-to-clean areas, equipment design to eliminate potential harborage sites, floor/tool cleaning to address pathogen or bacteria control, the use of dedicated tools for ready-to-eat and raw products, construction zone controls to address environmental cross-contamination, and sanitation effectiveness controls to include addressing biofilms, rotating sanitizers, disassembly of equipment, or the use of steam as a sanitizer. This guidance should be updated as new advances emerge.

Allergens

An effective GMP program should also address allergen control. Because the science regarding allergens and cross-contamination is rapidly developing and changing, FDA should consider general regulations for food companies to develop and implement an allergen control plan, while supplementing any regulation with more detailed guidance regarding food allergens. Agency guidance can be more responsive to emerging science than the often cumbersome rulemaking process. The Food Allergy Issues Alliance, an industry-wide coalition, already has developed guidance for the food industry on controlling allergens, particularly label controls. FDA should consider adopting similar guidance. FDA should also address the issue of “thresholds” for food allergens using the best available science.

Training

AFFI would support a GMP requirement that employees be trained in and adopt appropriate personal hygiene practices and that these practices be monitored. AFFI believes that all employees should be involved in a continuous cycle which includes individual training as well as training that relates to the food safety system as a whole. Employees, of course, should be trained in all aspects of food safety as it relates to their jobs, but, just as importantly, employees should understand how their jobs relate to others in the system.

To update the training aspects of the food GMPs, AFFI suggests that FDA use as guidance the Codex General Principles of Food Hygiene. 1/ This standard recognizes the importance of flexibility, and it encourage each firm to apply general principles in a manner that is most appropriate for its particular circumstances.

Recordkeeping and Records Access

The current GMP regulations impose no recordkeeping obligations on food manufacturers. Because FDA lacks explicit statutory authority to require recordkeeping or records access related to GMPs, the agency should not presume to impose such requirements at this time. Instead, FDA should acknowledge the value that recordkeeping has for a particular firm while administering a comprehensive GMP program.

AFFI, therefore, believes that it may be reasonable for FDA to state its expectation that food companies will maintain the records needed to document adherence to GMPs. This type of recordkeeping already is industry practice. It must be noted, however, that just as companies need flexibility to design GMP programs that fit their circumstances, they need flexibility regarding recordkeeping. Each company may require different types of records to assure itself that it meets GMP standards.

1/ Recommended International Code of Practice, General Principles of Food Hygiene, Section X (Amd. 1999).

AFFI firmly believes, however, that FDA's access to these records should not be routine. AFFI expects that food manufacturers will work cooperatively with FDA to provide records voluntarily when doing so serves a public health interest. FDA, therefore, may request voluntary access to records in response to a specific need.

AFFI strongly believes that the focus of GMP regulations should be on the program itself, and not on the records of the program. Therefore, we suggest that FDA make clear that food products will not be deemed adulterated or misbranded solely based on firm recordkeeping deficiencies. Instead, a GMP program itself and the sanitary conditions under which product has been produced should be found deficient before FDA initiates regulatory action.

Measuring Success

To measure the compliance of food companies with food GMPs, FDA should consider using its existing information-gathering abilities. Specifically, because GMPs are the criteria that constitute the basis for most regulatory inspections, FDA could rely upon its inspection authority. Currently, FDA classifies its inspectional findings into three categories: No Action Indicated (NAI), Voluntary Action Indicated (VAI), and Official Action Indicated (OAI). When an FDA inspector classifies its inspectional findings at a particular firm as OIA, the firm is deemed to be out of compliance with regulations. FDA could track the number of firms receiving an OIA inspection as a barometer of GMP compliance. Similarly, FDA could track the number of firms that move from the VAI category to the NAI category as a secondary indicator of improvements.

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AFFI applauds FDA's commitment to advancing food GMP modernization and appreciates the opportunity to comment on this important process. As FDA considers revisions and updates to the GMPs, AFFI urges the agency to pay particular attention to maintaining the appropriate amount of flexibility, taking into account the diversity of food manufacturers and the risks they face. AFFI would be pleased to discuss with FDA any of the points raised in these comments and it looks forward to working with the agency on this issue.

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Please contact me if AFFI can assist the agency with additional information or perspectives that may be helpful as the agency revisits its regulations governing food GMPs or develops helpful guidance for industry.

Sincerely,

A handwritten signature in black ink that reads "Leslie G. Sarasin". The signature is written in a cursive style with a large initial 'L' and a distinct 'S'.

Leslie G. Sarasin, CAE
President and Chief Executive Officer