



NFPA

The Food Safety People

September 10, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**NATIONAL
FOOD**

**PROCESSORS
ASSOCIATION**

**Re: Docket No. 2004N-0230; Food; Current Good Manufacturing Practice
Regulations 69 Federal Register 40312; July 2, 2004**

Dear Sir or Madam:

John R. Cady
*President and
Chief Executive Officer*

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

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GENERAL COMMENTS

FDA noted in the announcement of its public meetings on GMP modernization that in the almost 20 years since the GMPs were last revised, the food industry has undergone considerable change that warrants re-looking at the GMPs. NFPA members are dedicated to the production of safe and wholesome food products; we strongly support adherence to Good Manufacturing Practices (GMPs) as outlined in 21 CFR 110. These GMP regulations set forth basic principles of good sanitation/hygiene practices for food processing plants. The GMPs also set Agency expectations for compliance with the Food Drug and Cosmetic Act, in particular Section 402 (a) (4), which indicates a food is adulterated if it is prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or been rendered injurious to health.

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The regulations provide general guidance without mandating prescriptive requirements (with some exceptions). The admittedly subjective terms used in the regulation, such as “adequate facilities,” “where appropriate,” “necessary precautions,” “adequate controls” and the like, provide needed flexibility. This allows application of one set of regulations to the broad US food industry, with its wide variations in company size, products, processing procedures, etc. This flexibility also fosters the use of new technologies as they become available, often without the need to revise regulations. The GMPs have been well accepted by industry and have been very effective in preventing product adulteration.

Because of their effectiveness and flexibility, NFPA believes limited changes are needed to modernize the regulations. However, additional guidance to aid interpretation of the existing regulations with respect to specific areas of concern such as allergen control, environmental monitoring programs, sanitation programs, validation, training, distribution and warehousing should be developed.

FDA raised a number of important questions on how 21 CFR 110 should be revised or otherwise modernized. In support of its position to modernize the GMPs, FDA recently made two reports available on its website:

- Food GMP Modernization Working Group: Report Summarizing Food Recalls, 1999-2003 (August 3, 2004) [“Recall Report”]
- Good Manufacturing Practices (GMPs) for the 21st Century - Food Processing (August 9, 2004) [“GMP Report”]

NFPA considered these reports as it formulated its responses to the questions posed by FDA.

RESPONSES TO FDA QUESTIONS

In general, do the current good manufacturing regulations (part 110) need to be revised or otherwise modernized? If yes, please describe generally the shortcomings of the current regulations.

The GMPs should require appropriate training. NFPA believes that only limited changes may be appropriate or needed to modernize the regulations. In particular, based on information in the two reports noted above, we believe that mandating training requirements in the GMP regulations would enhance GMP implementation (currently training is advisory).

The Recall Report identified 1146 recalls in fiscal years 1999-2003 that occurred because of a GMP-related problem (including labeling problems). In fact, the report states that 65% of these recalls involved labeling problems and 34% involved undeclared allergenic ingredients. Although it is not known to what extent inadequate training played a role in these labeling and

allergen-related recalls, it is likely that training in allergen control that included guidance on proper labeling could reduce such incidents. The Recall Report further identifies ineffective employee training as being associated with 32% of the recalls and failure to follow established SOPs for processing with 26%. Failure to follow existing SOPs is also likely rooted in training. The ineffective use of sanitation principles (involved in 8% of recalls) could also be the result of improper or inadequate training, or perhaps a lack of specific guidance information. Thus, it would appear that appropriate training could reduce the number of recalls.

The GMP Report identified the top ten food safety “problems” as:

- Deficient employee training
- Contamination of raw materials
- Poor plant and equipment sanitation
- Poor plant design and construction
- No preventative maintenance
- Difficult-to-clean equipment
- Post-process contamination at manufacturing plant
- Contamination during processing
- Poor employee hygiene
- Incorrect labeling or packaging

Attachment I provides an assessment of specific regulations that address the top ten food safety problems identified by the GMP Report. Except for training, all of these are requirements specified by “shall” in the regulation; requirements for training are specified by “should.” Moreover, within the report, the top five commonly mentioned preventive controls for these problems list training in seven of the ten (deficient employee training, poor plant and equipment sanitation, difficult-to-clean equipment, post-process contamination at manufacturing plant, contamination during processing, poor employee hygiene, incorrect labeling or packaging). Thus, again the importance of training in addressing food safety and sanitation issues is clearly identified.

We therefore recommend that 21 CFR 110.10 (c) and (d) be modified to read as follows:

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination shall have a background of education or experience, or a combination thereof, to provide a level of expertise necessary for production of clean and safe food. Food handlers and supervisors shall receive appropriate training in proper food handling techniques and food-protection principles and shall be informed of the danger of poor personal hygiene and insanitary practices.

Training programs should be periodically reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and prevent adulteration of food.

(d) *Supervision*. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to appropriately trained supervisory personnel.

Periodic assessments of the effectiveness of training and instruction programs shall be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.

Managers and supervisors of food processes shall have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

Other modernization suggestions:

- The definition of critical control point in the GMPs should be consistent with the National Advisory Committee on Microbiological Criteria for Foods definition:

Critical control point: A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

The term as currently defined goes beyond safety in addressing points where improper control could contribute to filth in the final food or decomposition of the final food. While we understand the need to have controls preventing such adulteration, these should be addressed through control points rather than critical control points, a term which is now clearly associated with HACCP and hence food safety.

- Specific temperature requirements should be deleted.

Under 21 CFR 110.80, Processes and Controls, the section on manufacturing operations requires that food that can support rapid growth of undesirable microorganisms be held “in a manner that prevent the food from becoming adulterated.” The regulations provide specific temperatures that may accomplish this: maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food and maintaining hot foods at 140°F (60°C) or above. Since these regulations have been published, FDA and industry have become concerned about *Listeria monocytogenes* in ready-to-eat foods, and an FDA/FSIS risk assessment has indicated that for foods that support growth of *L. monocytogenes* a temperature of 45°F may not be appropriate, depending on the shelf life of the food. FDA has also developed guidance for retail and food service; the 2001 Food Code recommends a cold-holding temperature of 41°F for “potentially hazardous foods” that support growth of pathogens. The Food Code has also been recently revised to decrease the requirements for hot holding from 140°F to 135°F based on data that suggest this still provides a margin of safety with respect to growth of the organism of concern, *Clostridium perfringens*. Clearly the

codification of specific requirements such as these temperatures does not provide FDA or industry with the flexibility to adjust operations when scientific data support the need; we recommend deleting the specific temperatures in the regulation and incorporating them into a guidance document for temperature control of perishable products.

- The disease control provision in the personnel section should be modified to refer to the CDC list of diseases transmitted through the food supply.

The Centers for Disease Control and Prevention is required to update a list of infectious and communicable diseases transmitted through the food supply each year in accordance with the requirements of Section 103(d) of the Americans With Disabilities Act of 1990 (P.L. 101-336). By referencing this list, the GMPs would remain up to date on any new pathogen capable of transfer through handling of the food supply.

Where 21 CFR 110.10 currently reads:

“(a) *Disease Control*. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food contact surfaces, or food-packing materials becoming contaminated,...

Amend to read:

“(a) *Disease Control*. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, any infectious or communicable disease identified by the Centers for Disease Control and Prevention (CDC) as capable of being transmitted through the food supply, or that has any open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food contact surfaces, or food-packing materials becoming contaminated,...

1. Which practices specified in current part 110 are most effective at preventing each type of food hazard? Which practices are least effective at such prevention?

A number of practices specified in the GMPs make hazards not reasonably likely to occur. Key general GMP requirements that address all hazards are found in 21 CFR 110.80: that all reasonable precautions be taken to ensure that production procedures do not contribute contamination from any source and that all food manufacturing, including packaging and storage be conducted under such conditions and controls as are necessary to minimize the potential for growth of microorganisms, or for the contamination of food. However, the fact that these are such general requirements may reduce their effectiveness without the development of specific guidance on how this should be accomplished.

Biological hazards. Personnel hygiene requirements (21 CFR 110.10) are designed to ensure that pathogen contamination from food handlers is not likely to occur. Pest control requirements (21 CFR 110.35 (c)) are designed to ensure that pathogen contamination from insects, rodents and other pests is not likely to occur. Requirements to clean and sanitize food-contact surfaces (21 CFR 110.35 (d)) are designed to ensure that these surfaces do not contribute to microbial contamination of foods. Key requirements with respect to preventing microbial hazards include requirements 1) that food which can support the rapid growth of microorganisms of public health significance be held in a manner that prevents the food from becoming adulterated and 2) that measures which are taken to destroy or prevent growth of microorganisms (such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or a_w) be adequate (21 CFR 110.80).

Chemical hazards. Requirements for proper storage of toxic cleaning compounds, sanitizing agents and pesticide chemicals are designed to ensure that contamination from these chemicals is unlikely to occur. Compliance with relevant regulations for use of such chemicals is a key practice for preventing chemical hazards; this is a recommendation (“should”) in the GMPs, presumably because FDA cannot mandate compliance with regulations promulgated by other agencies; nevertheless, manufacturers would still have to comply with these regulations.

Physical hazards. Several of the personal hygiene requirements in 21 CFR 110.10 are important in preventing contamination with physical hazards. Requirements that the plant be kept in sufficient repair to prevent food from becoming adulterated (21 CFR 110.35 (a)) and to take effective measures to protect against inclusion of metal or other extraneous material in food (21 CFR 110.80 (b)(8)) are key controls for physical hazards.

2. *In today's food manufacturing environment, what conditions, practices, or other factors are the principal contributors to each type of food hazard?*

Inactivation and controlling growth of pathogens through a variety of practices is key to ensuring that foods do not present a risk from biological hazards. Where such controls exist, not implementing the controls properly (i.e., not following designated procedures) is one of the principal contributors to the presence of biological hazards. Foreign objects (which may or may not have been physical hazards) were involved in only 3% of recalls. The factor that is likely to be the principal contributor to all of these hazards appears to be inadequate or improper training. A second contributor is likely to be a lack of information on what constitutes appropriate practices (which would best be remedied by specific guidance documents).

3. *If the CGMP regulations were revised, which type or types of food hazards could be most readily prevented through CGMP-type controls?*

GMP controls can positively impact biological, chemical, and physical hazards. GMP programs are best at ensuring that potential hazards are “not reasonably likely to occur,” allowing a plant to focus specific controls on significant hazards that are most likely to be a risk to the consumer if they are not controlled. GMP programs best address potential hazards that are not specific to a product and process line, for example, preventing contamination of product with enteric pathogens from food handlers or preventing contamination of products with microorganisms, chemicals or physical hazards from the food processing environment. The CGMPs are focused on addressing these areas. Hazards such as recontamination of a ready-to-eat product are best controlled through specific programs that have GMP components. These would be best addressed through guidance documents that can outline all the components of such a program, including the use of environmental control programs that target the microorganism of concern.

4. *Are there preventive controls, in addition to those set out in part 110, needed to reduce, control, or eliminate each of the three types of food hazards? If yes, please identify the specific hazard and the particular controls, that would reduce, control, or eliminate the hazard.*

Currently, there is no evidence that additional controls are needed to address known hazards. However, as noted above, specific guidance on issues such as allergen control and *L. monocytogenes* recontamination is warranted.

5. *What concepts or underlying principles should guide FDA's adoption of new preventive controls?*

New preventive controls may need to be adopted only if FDA identifies a specific hazard that is not being controlled by current procedures and shows that the preventive control will effectively address it.

6. *How should the effectiveness of preventive controls for each of the three types of hazards be most accurately measured?*

One approach frequently mentioned to determine effectiveness of controls is to track recalls related to the specific hazards. However, this is of limited utility as the types of controls will be product, process and establishment specific and the causes of any problem will be varied. Without knowing the root cause of the problem, it will be difficult to relate it to effectiveness of preventive controls. Moreover, changes in numbers of recalls may be

related to other factors such as an increased regulatory focus. Without appropriate baseline information on the number of recalls, and without information on production volume, inspection activities etc. to put the recall number in context, recalls will be a poor measure of effectiveness.

A better measure would be to assess whether food companies have GMP programs in place, as required by the regulations, and to evaluate their efficacy using the Agency's own criteria for compliance with its inspection-based regulations. These criteria are described below.

FDA Categorization of Inspectional Findings: FDA classifies all inspections under one of three categories:

1. No Action Indicated (NAI): This means that the FDA inspector made no observations during the inspections, as listed on the 483, that were considered to be serious or significant. The firm is clearly in compliance.
2. Voluntary Action Indicated (VAI): This means that the FDA inspector's findings were of moderate significance and that the firm agreed to correct the deficiencies noted. The FDA would plan to check on these at the next inspection. Though the findings were sufficiently important to be brought to the company's attention for action, FDA still considers such firms to be in compliance (or, at least, not "out of compliance").
3. Official Action Indicated (OAI): This means that the FDA inspector found serious deficiencies. If agreed to by the District Office (and sometimes headquarters), the firm would be subject to regulatory action (i.e., warning letter, seizure, or injunction). This means the product would be considered by FDA to be adulterated or misbranded.

Therefore, to "measure success" of preventive controls, FDA could use this same methodology and include a classification with respect to the type of hazard for which actions are indicated. Because only OAI firms are considered to be out of compliance with the regulations, the primary barometer should be how many firms receive this OAI rating following inspection. As time goes by, this number should decrease.

A second barometer could be how many firms move from the middle (VAI) category to the lowest (NAI) category at the next inspection. This would take longer to collect because it would take several years for FDA to conduct enough follow-up inspections of the same firms to develop a meaningful database.

- 7. *In today's food manufacturing environment, what are the principal contributors to the presence of undeclared allergens in food? For example, do labeling errors or cross-contamination contribute? Which preventive controls could help reduce, control, or eliminate the presence of undeclared allergens in food?***

An examination of the food-related recalls in FDA Enforcement Reports for 2004 suggests that about two-thirds were related to unlabelled allergens or sulfites. Most unlabelled allergen problems, and those most likely to result in adverse public health consequences, appear to be due to labeling errors. The current GMPs and other regulations address unlabelled allergens in foods. For example, 21 CFR 101.4 requires all ingredients to be declared on the label, and efforts are underway to ensure consumers are informed of all allergenic food ingredients in understandable language on the label. The presence of inadvertent allergens due to cross-contact is addressed in many parts of the current GMPs: design and construction of equipment and utensils shall preclude adulteration with contaminants; all reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source; all food manufacturing shall be conducted under such conditions and controls as are necessary to minimize the contamination of foods. The problems that have led to the majority of allergen-related recalls are not likely to be solved by revising the GMPs to provide specific controls for allergens. However, guidance on allergen control, developed in conjunction with all stakeholders, could provide information that would assist companies in establishing effective, verifiable programs. Such guidance would outline procedures that companies can use to manage allergens in food processing establishments, including measures to ensure products are appropriately labeled and employees are properly trained to minimize the risk from unlabelled allergens in foods.

- 8. *Are there existing quality systems or standards (such as international standards) that FDA should consider as part of the agency's exploration of food CGMP modernization? Please identify these systems or standards and explain what their consideration might contribute to this effort.***

Any changes to modernize the GMPs should specifically consider the Codex Alimentarius General Principles of Food Hygiene in order to provide additional flexibility for food businesses and increase international harmonization. The Codex General Principles of Food Hygiene lay a foundation for practices essential to ensuring the safety and suitability of food, stating the objectives to be achieved, along with the rationale behind the objectives. This approach, combined with appropriate guidance documents, could provide an effective means of ensuring safe and sanitary food manufacturing, storage and distribution.

9. *There is a broad variation within the food manufacturing and processing industry, including variations in size of establishments, the nature of the food produced, the degree to which the food is processed, and the vulnerability of a particular operation to physical, chemical, or microbial hazards. How, if at all, should the CGMP regulations be revised to take into account such variation? For example, should there be different sets of preventive controls for identifiable segments of the food industry, such as different storage temperature limits?*

The CGMPs are flexible enough to address this broad variation – that is one of the strengths of the current regulation. Different sets of preventive controls in regulations for different segments of industry would be confusing and are unnecessary. However, segment-specific guidance could prove useful. We urge FDA not to include specific requirements for storage temperatures in any revised GMP, as we noted above in the limitations on the current GMPs.

10. *There are a number of measures, procedures, and programs that help to ensure that preventive controls are carried out adequately. These include the following items:*

- *Training programs for managers and/or workers; Audit programs;*
- *Written records, e.g., batch records, sanitation records;*
- *Validation of control measures;*
- *Written sanitation standard operating procedures;*
- *Food label review and control program;*
- *Testing of incoming raw materials, in-process materials, or finished products.*

Which (if any) of these should be required practices for food and manufacturers and why? Which (if any) of these should be recommended practices for food manufacturers and processors and why?

- *Training programs for managers and/or workers*
As noted above, NFPA believes that any revision of the GMPs should require training, as inadequate training appears to be the root cause of failure for many GMP-related problems.
- *Audit programs*
NFPA strongly supports the use of audit programs to verify that companies are operating in compliance with regulatory requirements, are meeting customer specifications, and have appropriate food safety and quality programs in place. In fact, NFPA has established an audit program, NFPA-SAFE (Supplier Audits for Food Excellence), designed to provide a comprehensive assessment of a company's food quality and safety systems to meet the global food industry's audit needs. Audit programs serve as verification activities, either of a company's own programs or those of a supplier or customer. We believe that audit programs should remain as programs

designed by companies to manage their businesses and should not be mandated in GMPs.

- ***Written records, e.g., batch records, sanitation records***
NFPA members are troubled by the implication in FDA's request for comments that the Agency is considering mandatory records inspection provisions. While NFPA members have historically cooperated with FDA during inspections and voluntarily produced records when reasonably requested by the agency, FDA has no statutory authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to *require* companies to allow agency inspection of food company records except under very limited circumstances. FDA itself has maintained this position over many years, and has articulated this view before Congress in numerous instances where the agency sought such authority. In the absence of congressionally-delegated records inspection authority, FDA may not create such authority for itself through the vehicle of GMP regulations, even to ensure compliance with regulations the agency is authorized to mandate. Our arguments to this effect are set out in Attachment II.
- ***Validation of control measures***
Validation is a complex subject. It should be recognized that some areas that fall under the GMPs are not suitable for formal validation procedures, but can be adequately addressed through verification activities (e.g., validation that proper hand washing controls enteric pathogens from food handlers; validation that a specific storage temperature controls pathogen growth). The issue of validation is under consideration by the Codex Committee on Food Hygiene. Once the document has been finalized, it would be appropriate for FDA, working with stakeholders, to develop a guidance document on the role of validation of control measures. The focus should be on the validation of GMP controls for which such validation would be needed to ensure adequacy of the control measure. Since the need for validation will depend on the product, process, and equipment, among other things, there will be a need for flexibility in such guidance.
- ***Written sanitation standard operating procedures***
Many companies have written procedures for a variety of plant activities, including sanitation. Management goes to great lengths to ensure that employees know that abiding by these written procedures is an important part of carrying out their jobs. Although we are not fundamentally opposed to a requirement to have sanitation practices in place, it is not clear that there is a need to mandate written "sanitation standard operating procedures" across the industry. Moreover, we would prefer to use the term "sanitation programs," as sanitation standard operating procedures, or SSOPs, have become associated with HACCP.

We would be interested in any information FDA has to demonstrate that the lack of written sanitation standard operating procedures has contributed to GMP problems. For example, in FDA's Recall Report, 8% of recalls were due to ineffective use of

sanitation principles; however, it is not clear if this was a result of a lack of written sanitation standard operating procedures. Sanitation standard operating procedures were mentioned as controls in the GMP Report for three of the top ten food safety problems (poor plant and equipment sanitation, difficult-to-clean equipment, and post-process contamination at manufacturing plants), but it is not clear that requiring a written program will address the problems. FDA has mandated in its HACCP regulations that seafood and juice processors monitor sanitation standard operating procedures for eight specified areas drawn from the GMPs. We would be interested in an analysis of information with respect to improvements in adhering to GMPs as a result of this requirement. As stated before, NFPA believes strongly in proper training to achieve the desired sanitation results.

- ***Food label review and control program***

Incorrect labeling and packaging was one of the top ten food safety problems in the GMP Report. The Recall Report noted that the root causes of 68% of GMP-related recalls were due to incorrect packaging/labeling. However, there was insufficient data provided to determine that a food label review and control program would address the problem. NFPA believes that companies should have a food label and ingredient control program to ensure accurate ingredient disclosure on products.

- ***Testing of incoming raw materials, in-process materials, or finished products***

The GMP regulation (21 CFR 110.80) states "Chemical, microbial or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination." Thus, there is no need to revise the GMPs to mandate testing.

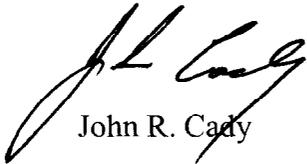
11. Are there preventive controls in addition to those already set out in part 110 for food distributors, wholesalers, and warehousemen that are needed to help ensure the safe and sanitary holding of food? If yes, please identify the controls by hazard and sector of the industry.

NFPA would like to have information documenting problems at the food distributor, wholesaler and warehouse level before determining whether preventive controls in addition to those specified in 21 CFR 110.93 are needed. NFPA members believe that requirements by customers on their suppliers and by manufacturers on distributors, wholesalers and warehousemen generally address this area, but that development of a guidance document would be appropriate.

CONCLUSIONS

In conclusion, the food industry always welcomes the opportunity to improve the safety of the food supply – we recognize our responsibility to produce safe, unadulterated products. We look forward to working with FDA as modernization of GMPs is considered. Any changes, rather than serving as an impediment, should be structured to encourage industry to invest in and implement appropriate food safety practices. Our current thinking is that the GMPs could be improved with minor changes, including the requiring of training programs. NFPA believes that we must ensure that GMPs remain flexible. GMPs should be supplemented with guidance documents for specific products and/or processes in those instances where more detailed information could enhance consumer protection.

Regards,

A handwritten signature in black ink, appearing to read "John R. Cady", written in a cursive style.

John R. Cady