

FOOD CGMP MODERNIZATION – A FOCUS ON FOOD SAFETY

***Food CGMP Modernization Working Group
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration***

Comments regarding this document may be submitted at any time. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the Docket Number 2004-0230.

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Executive Summary

Beginning in late 2002, the Center for Food Safety and Applied Nutrition formed a Food Current Good Manufacturing Practice (CGMP) Modernization Working Group. The objective of the group was to examine the general food CGMP regulation in 21 CFR Part 110 (hereinafter CGMP regulation) and determine whether the regulation was in need of modernization. Also, the group was specifically tasked to focus on risk-based preventive controls, *i.e.* those that would have the greatest impact on assuring food safety. The working group concluded that there have been changes in both the food industry and in the science of food safety that indicate a need for modernization. In 2003, the working group initiated research programs to identify those areas where GMP-type controls could have the greatest impact on assuring food safety. In 2004, the working group presented its preliminary findings from this research and engaged the public in three public meetings held across the country and through a *Federal Register* notice calling for comments on food CGMP modernization. This report summarizes the public comments and details the working group's key findings.

There was generally strong support for limited revision of the CGMP regulation. Many commenters stressed the need to keep the regulation sufficiently general and flexible to apply broadly to the entire food industry. These commenters noted that the food industry must deal with many different products and processes and varying levels of risk and that the industry must have the flexibility to adjust control measures to the level of risk. Many commenters suggested that a modernized regulation should include a training requirement. There was broad support for mandatory training in the principles of food safety, personal hygiene, plant sanitation, and current good manufacturing practice compliance. There was also broad support for the need to address the problem of undeclared food allergens. Those who commented on the need for food allergen specific controls offered suggestions ranging from a requirement for training to promote food allergen awareness to a requirement for a food allergen control program that would include elements for training, ingredient control, process controls to prevent cross-contact, validated cleaning processes, label controls, and label review.

Agency research as well as comments from the public identified a need for written cleaning and sanitizing procedures, particularly for food contact equipment. For certain high risk products, such as ready-to-eat foods that support the growth of *Listeria monocytogenes*, there is a need for microbiological monitoring of the plant environment in order to verify the adequacy of cleaning and sanitizing procedures and to identify potential environmental sources of product contamination.

Finally, in response to agency questions, several commenters noted that the least successful provisions of the current regulation were those that set forth very specific requirements, such as the specific temperature requirements for cold storage and hot holding of foods.

After considering the research data and public comments, the working group identified seven areas that may present an opportunity to modernize the current regulation. The

working group believes that each of these areas would have a significant impact on ensuring the safety of food and that a modernized regulation would better focus industry and agency resources on food safety risks. The areas that present opportunities for modernization are training, food allergens, *Listeria monocytogenes* control, sanitation procedures, application of certain CGMPs to agricultural operations, records access, and temperature control. Specific modernization opportunities are described below.

1. Require appropriate training for supervisors and workers to ensure that they have the necessary knowledge and expertise in food hygiene, food protection, employee health and personal hygiene to produce safe food products. This training must¹ be delivered in a manner that can be easily understood by the worker. Food processors must maintain a record of this training for each worker.
2. Require food processing establishments that produce foods containing one or more of the eight major food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) to have a food allergen control plan. The plan must address six elements: training of processing and supervisory personnel, segregation of food allergens during storage and handling, validated cleaning procedures for food contact equipment, prevention of cross-contact during processing, product label review and label usage and control, and a supplier control program for ingredients and labels.
3. Require a written environmental pathogen control program for processors of ready-to-eat foods that support the growth of *Listeria monocytogenes*. This control program must be appropriate for the risks presented by the processing and packaging environment and must include microbiological monitoring of the production and packaging environment as appropriate. Processors must maintain the records necessary to judge the effectiveness of the program, to identify the root cause of sanitation failures, and to document corrective actions.
4. Require that food processors develop and maintain written sanitation procedures that define the scope, sanitation objective, management responsibility, monitoring, corrective action, and record keeping associated with the sanitation procedure. At a minimum, sanitation procedures must be developed for all food contact equipment and food contact surfaces.
5. Obtain further comments on removing the exclusion from CGMP compliance in 21 CFR Part 110.19 for establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities.
6. Require that food processors maintain certain critical records and that these records be made available for review and evaluation by FDA investigators. Critical records are those records that a processor (or FDA) would need to review in order to confirm that a firm is operating in compliance with the CGMP

¹ Note that these recommendations use the word “must” to indicate new regulatory options that the working group believes should be mandatory in an amended regulation.

regulation. The need to maintain records is consistent with well known quality system principles, namely that control procedures must be defined, documented, reviewed, and appropriate corrective action taken.

7. Obtain further comments and suggestions on the use of time-temperature relationships, perhaps in the form of microbial growth models, for incorporation into regulations or guidance for proper refrigerated storage or hot holding.

The last modernization opportunity (item 7 above) is based on several comments recommending that the temperature requirements in 21 CFR 110.80(b)(3)(i) and 21 CFR 110.80(b)(3)(iii) should either be deleted or made consistent with the current FDA Food Code. One commenter recommended removing specific temperature requirements from 21 CFR 110.80(b)(3) and instead issuing guidance for temperature control. The working group agrees that specific temperature requirements in this regulation may be problematic, given that pathogens such as *Listeria monocytogenes* are capable of growth at temperatures well below those specified for refrigerated foods.

Introduction

This report summarizes the comments, both written and oral, that were offered to the agency in response to its Federal Register notices² and during three public meetings. The report addresses the major opportunities for modernization of the food CGMPs as suggested by the respondents. Some comments addressed issues that are not relevant to CGMP modernization, *e.g.*, those covered by other existing regulations or regulations under development, and these were excluded from the report. Also, some comments included details and regulatory language that were too lengthy to include in this report. However, the working group made an effort to capture and include the main theme of these comments. Finally, some comments related to minor or technical changes to 21 CFR Part 110 and these are also not discussed.

The regulatory options described in this report represent the working group's initial thinking on major areas for modernization. Modernization of the food CGMP regulation need not be limited to these major areas. For example, as mentioned above, many respondents suggested changes to the definitions in the regulations as well as minor changes and clarification of other provisions of the regulation. The working group envisions that the agency would consider these suggestions for modernization and give stakeholders the opportunity to comment on all proposed changes to the regulation during any rule making process.

The comments by stakeholders indicate that there is broad support for strengthening or including provisions for food safety and GMP training, food allergen control, environmental controls for producers of high-risk ready-to-eat foods, and a requirement for written sanitation procedures. The working group hopes that this report will help focus any further discussion on these issues, particularly as to the best means of implementing these preventive controls in a regulation. In addition to these four areas, there was much useful discussion of other topics affected by the food CGMP regulation, such as the relationship of Hazard Analysis Critical Control Point (HACCP) systems to the CGMPs, the need for specific temperature requirements, and the need for records and agency access to records. The working group appreciates these comments and believes that they are helpful in furthering discussion on these topics in the context of the food CGMP regulations.

The Need for Food CGMP Modernization

The Food and Drug Administration last revised the CGMP regulation for food³ in 1986. The primary purpose of the 1986 revision was to establish new, updated, or more detailed

² 69 *Federal Register* 29220 (May 21, 2004) and 69 *Federal Register* 40312 (July 2, 2004).

³ 21 CFR Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food.

provisions concerning food industry personnel; plants and grounds, sanitary facilities, controls, and operations; equipment and utensils, warehousing, and distribution, and natural or unavoidable defect levels.⁴ FDA designed the revised CGMP regulation to help ensure the safe and sanitary manufacturing, processing, and holding of food for human consumption. Although this regulation has not been updated in many years, it is broad enough to apply to many situations that could not be envisioned at the regulation's inception in 1969. Compliance with CGMP requirements is critically important to the production of safe, wholesome foods. Current good manufacturing practice is at the foundation of other preventive control measures such as HACCP systems. The working group understands the importance of preserving the flexibility of the CGMP regulation, yet believes that it is now time to revisit the regulation and determine appropriate revisions to better ensure a safe and sanitary food supply. Some of the reasons for undertaking this review of the CGMP regulations are listed below.

The food industry has undergone considerable change in the almost 20 years since the food CGMPs were revised. Ready-to-eat foods now represent a larger portion of the American diet. Ready-to-eat fresh produce salads are a popular replacement for salads prepared in the home. Refrigerated foods and heat-and-serve foods are more popular than ever before. Today, consumers are more likely to purchase foods that need little or no preparation or cooking before consumption. This means that if these foods are contaminated with harmful microorganisms, there may not be a consumer preparation step that will reduce or eliminate the hazard. Therefore, greater attention must be paid to the importance of controlling foodborne pathogens during the manufacturing and holding of foods, and for ready-to-eat foods in particular.

Although recent changes in food manufacturing and marketing have been significant, the expansion of our scientific understanding of foodborne illness has been even more significant. In 1986, *Listeria monocytogenes* had only recently been recognized as a foodborne pathogen and very little was known about the importance of controlling this organism in food processing plants. Similarly, the significance of pathogens such as *Escherichia coli* O157:H7, *Campylobacter jejuni*, *Cryptosporidium parvum*, *Cyclospora cayatanensis*, and *Norovirus* were not as well understood in 1986 as they are today. In addition to these new pathogens, familiar pathogens such as *Salmonella* continue to present a challenge. Modern good manufacturing practices can play a role in reducing the risk of these pathogens.

In 1986, the problem of food allergens was not appreciated to the extent that it is today. In a recent report, H.A. Sampson writes that "Recent epidemiologic studies suggest that nearly 4% of Americans are afflicted with food allergies, a prevalence much higher than appreciated in the past."⁵ An analysis of food recalls reported to the FDA between 1999 and 2003 showed that 34% of food recalls involved undeclared allergenic ingredients (e.g., milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, or soybeans).⁶ The

⁴ 51 *Federal Register* 22458 (June 19, 1986)

⁵ Sampson, H.A. 2004. Update on Food Allergy. *J. Allergy Clin. Immunol.* 113(5):805-819.

⁶ Food and Drug Administration. 2004. Food GMP Modernization Working Group: Report Summarizing Food Recalls, 1999-2003. <http://www.cfsan.fda.gov/~dms/cgmpps2.html>

prevention of cross-contact of food products with a food allergen and the prevention of errors in product labeling depend on current good manufacturing practice at the food processing establishment. The working group believes that many of these recalls could have been avoided through the use of CGMP preventive controls.

A Risk-Based Approach to CGMP Modernization

A risk-based approach to food safety regulation is one where regulatory requirements are matched to food safety outcomes. Ideally, risk-based regulations should give regulated establishments maximum flexibility to adapt the required controls to their unique situation. The changes proposed by the working group are intended to preserve the flexibility of the current regulation while requiring the implementation of controls that will significantly enhance food safety.

The CGMP regulation in Part 110 is necessarily general in nature, so as to be broadly applicable to all food processing establishments and to allow for flexibility in its implementation, yet it is absolutely critical to the assurance of a safe food supply. The working group believes that the CGMP regulation should be modernized to strengthen its focus on those current good manufacturing practices that will have the greatest impact on food safety. Through research and public comment, the working group has identified current good manufacturing practice requirements that can effectively reduce the risk of foodborne illness and better support process-specific food safety control programs such as HACCP. The working group believes that these requirements can be implemented in a regulation that targets the food products and processes where they will be most effective.

The current regulation does not require that food establishment employees be trained in the principles of food safety and good manufacturing practices. Yet, proper training in these areas can have a significant impact on food allergen awareness and control, on proper equipment sanitation, on cleanliness and sanitation, and on compliance with temperature control requirements.

The current regulation does not require written cleaning and sanitation procedures for food contact equipment. Cleaning and sanitation of food contact equipment is critical to preventing ready-to-eat (RTE) foods from being systematically contaminated by harmful bacteria that might become established on unclean equipment surfaces. Harmful bacteria such as *Salmonella* and *L. monocytogenes* are known to contaminate RTE foods through unsanitary equipment surfaces. Also, written cleaning and sanitation procedures facilitate the proper training and supervision of employees responsible for these tasks.

During the past 20 years, our experience with *L. monocytogenes* has taught us that the production of certain high risk foods, in particular ready-to-eat foods that support the growth of *Listeria*, requires additional care. This bacterium is especially difficult to control in the plant environment, and it is necessary to microbiologically monitor the food processing plant environment as both an assessment of the ongoing effectiveness of

cleaning and sanitation operations and to identify harborage for this organism in the plant environment. For example, microbiological monitoring could include testing for *Listeria* on food contact surfaces and potential harborage areas on or near the food processing line. It is particularly important to conduct such environmental monitoring in food processing establishments that produce ready-to-eat foods as certain of these foods may allow the organism to grow to high numbers before the food is consumed. The CGMP regulation does not specifically require microbiological monitoring of the plant environment in establishments that manufacture high risk foods.

The current regulation does not specifically address the risk of food allergens or require food allergen control programs by food processing establishments that use food allergens in their products. The control of undeclared food allergens can involve several different tasks, such as employee training, product formulation control, raw material control, label review and control, rework control, and the proper cleaning of production lines between processing allergen and non-allergen containing products. Clearly, food processing establishments that produce foods containing allergens need to have appropriate control programs, yet they should have the flexibility to adapt those programs to their unique circumstances.

Food safety hazards such as those described above are best controlled through proper implementation of good manufacturing practices. By amending 21 CFR Part 110 to modernize good manufacturing practices, the agency could focus the attention of food processors on measures that have been proven to significantly reduce the risk of foodborne illness. An amended regulation would also allow the agency to better focus its regulatory efforts on ensuring compliance with controls that have a significant food safety impact.

FDA Sponsored CGMP Research

Under contract to FDA, Eastern Research Group, Inc. (ERG) conducted an extensive literature review and an expert elicitation of current food safety problems and the range of preventive controls needed to address them. The expert elicitation identified the most significant food safety problems, foods at high risk for these problems, and other major areas of concern. The independent experts identified “deficient employee training,” “contamination of raw materials,” “poor plant and equipment sanitation,” and “poor plant design and construction” as the top four food safety problems faced by food manufacturers today. Results from the expert elicitation indicated that the needs of small and medium-sized food processors likely differ from larger processors, with smaller facilities generating higher risk scores than large facilities across all food safety problems and sectors considered.

The food safety experts who participated in the study recommended a range of preventive controls that could address most of the food safety problems faced by food manufacturers today. They did not, however, differentiate these preventive control recommendations by

facility size despite the higher risk rankings of smaller facilities. The most frequently mentioned preventive controls with broad applicability across sectors and food safety problems included:

Training – Ongoing and targeted training on issues ranging from allergen control, cleaning and sanitation procedures, incoming ingredient receipt protocol, and monitoring for employees, management, as well as suppliers.

Audits – Periodic audits and inspections of facility and raw material suppliers either in-house or by third-party firms.

Documentation – Documentation of training activities, raw material handling policies and activities, cleaning and sanitation, receiving records, and use of sign-off logs.

Validation/Evaluation – Evaluation of training effectiveness and establishment of accountability, and validation of cleaning through testing (*e.g.*, swabs, organoleptic evaluations, and bioluminescence tests).

Post-study follow-up discussions with four of the experts also generated additional recommendations. Although most experts agreed that food CGMPs could be improved, opinions on how this should be done varied widely. Some experts indicated that CGMPs were lacking in some areas, whereas others noted that the food CGMPs should remain as written and that other approaches should be taken to encourage greater compliance. These recommendations included:

- Revision of food CGMPs in key areas, such as training
- Addition of new requirements, including components of HACCP, allergen control, and recordkeeping
- Issuance of a guidance document that would clarify the modernized CGMPs and
- Institution of positive incentive programs, such as reduced inspections for select facilities that meet certain requirements.

Finally, ERG's literature review and comparative analysis of other CGMPs (*i.e.*, for pharmaceutical/biologic products and medical devices) and quality system programs revealed that the majority of preventive control recommendations echo the principles of these other CGMPs regulations and quality systems. All the programs reviewed, including the International Organization for Standardization (ISO) 9001: 2000, American Society for Quality (ASQ) Q9004-3-1993 (Quality Management and Quality System Elements – Guidelines for Processed Materials), pharmaceutical CGMPs, and medical device CGMPs, have similar key provisions on training, audits, documentation, and evaluation/validation. ERG's report is available through FDA's web site at <http://www.cfsan.fda.gov/~dms/gmp-toc.html>.

The Public Response to FDA's Call for Information on CGMP Modernization

On May 21, 2004 and July 2, 2004, the agency published a Federal Register Notice⁷ announcing its desire to reexamine the CGMP regulation and asking the public to respond to questions about this regulation. Many commenters did not respond directly to the questions, choosing instead to comment on specific areas of concern. Where possible, these comments have been associated with the questions asked in the *Federal Register* notices. These questions and a brief summary of key elements of the public responses are listed below:

Questions Posed by the Agency

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.

Comments from the public meetings and from written submissions were overwhelmingly supportive of the need to modernize the food CGMP regulation, although there were differences in the extent of the needed changes. Many commenters stressed that the regulation was sufficiently general and flexible in nature to apply broadly to the entire food industry and that this utility must be retained in any revised regulation. Many commenters noted that the CGMP regulation had served its purpose well and that only limited changes are needed. One commenter stressed that the modernization effort should remain focused on basic sanitation and related controls, and that flexibility was critical to dealing with the wide variation in the degree of risk associated with different manufacturing processes. Another commenter suggested that the agency "...adopt a risk-based assessment approach for food GMPs..." that "...would encourage manufactures to identify potential risk-based control points...and to establish limits to monitor and control these risks." Another commenter wrote that the agency "...should identify only those targeted and particular areas where the food CGMPs could be enhanced, within their existing framework." One commenter encouraged the agency to work with the industry to conduct an evaluation of current food industry practices in order to establish a baseline. Finally, many commenters stressed the need for additional guidance from the agency where specific segments of the industry would benefit from more detailed information on how to implement the regulations.

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?*

One commenter cited 21 CFR 110.80, Processes and Controls, as a key provision of the regulation that addresses all hazards, but that could be made more effective by developing specific guidance on how to implement these requirements. Specifically, this commenter suggested that the requirement that "all reasonable precautions be taken to ensure that production procedures do not contribute contamination from any

⁷ *Federal Register* 69:29220. May 21, 2004. and *Federal Register* 69:40312. July 2, 2004

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...” is so general in nature that specific guidance is needed in order to make the requirement more effective. Other provisions cited as being most effective are 21 CFR 110.10, personnel hygiene requirements; 21 CFR 110.35(a), general maintenance; 21 CFR 110.35(b), storage of toxic materials; 21 CFR 110.35(c), pest control; 21 CFR 110.35(d), sanitation of food contact surfaces; and 21 CFR 110.80(b)(8), protect against the inclusion of metal or other extraneous material in food. Other commenters generally endorsed these same types of controls for biological, chemical and physical hazards without citing specific sections of the regulations.

One commenter stated that “...the area(s) where the CGMPs are least effective are where they are too prescriptive, such as the specific temperature requirement in 21 CFR 110.80 to maintain refrigerated foods at 45°F (7.2°C) or below and maintaining hot foods at 140°F (60°C) or above.” This commenter suggested that the refrigeration temperature is handled differently in the Pasteurized Milk Ordinance and the Food Code, causing affected products to be subject to differing standards. This was echoed by several other commenters. One commenter wrote that “...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...”

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

One commenter stated that “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.” This commenter went on to say that a failure to implement the controls properly is one of the principle contributors to biological hazards.

Another commenter stated that “...failure to follow the current GMP’s and consistently assuring execution of adequate programs and procedures are the foremost contributors. This is further evidence of the importance of proper training for all personnel”

Many commenters stated that a lack of training or improper training was a contributing factor to the failure to control food safety hazards. One commenter wrote that “One of the biggest contributors to administering a sound CGMP program is the challenge presented in training a diverse work force.”

One commenter wrote that another contributor to food safety hazards was “...a lack of information on what constitutes appropriate practices...”.

Another commenter wrote that “...post pasteurization contamination, environmental pathogens and allergen control” were the most challenging factors to manage.

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

One commenter stated that the CGMP regulation was best suited to controlling “potential hazards that are not specific to a particular product and process line, for example ...preventing contamination of products with microorganisms, chemicals or physical hazards from the food processing environment.”

One commenter wrote that “GMP’s can manage hazards...but GMPs cannot control hazards....GMPs are best suited for managing chemical and physical hazards and have some effect on microbiological hazard.”

Several commenters wrote that food allergen hazards should be prevented through CGMP-type controls:

One commenter recommended the revision of the CGMP regulation to include controls to “...help reduce, control, or eliminate the presence of undeclared allergens in food...”

Another commenter wrote that the “...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.”

Another commenter wrote that “...the FDA should revise the GMPs to include specific steps to prevent the inadvertent contamination of packaged foods with the major allergens.”

One commenter wrote that “It is not clear that any hazards can be totally prevented by CGMP controls, but CGMPs can help reduce the likelihood of hazards occurring....post-processing contamination by pathogens could be reduced through implementation of an environmental control program.”

Yet another commenter wrote that “We would suggest added examples behind each hazard (e.g., chemical – (e.g. allergens)).”

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 by hazard the controls needed.*

One commenter stated that there was no evidence that additional controls are needed to address known hazards; however, specific guidance on allergen control and *L. monocytogenes* is warranted.

Another commenter wrote that “We believe that reduction and control are covered at a high level within the cGMP’s. The specific values required are plant, product and process dependent. Due to the complexity, we believe that it would be impractical for the cGMP’s to spell this out.”

Another commenter wrote that “...major examples of where the current food CGMP regulations could be enhanced would be in the areas of: allergen control; environmental control; sanitation programs; and training.”

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

One commenter stated that “new preventive controls may need to be adopted only if FDA identifies specific hazards that are not being controlled by current procedures and shows that the preventive control will effectively address it.”

Many commenters suggested that new preventive controls should be science-based and risk-based, and flexible and broadly applicable.

Another commenter wrote that “...cGMPs should remain [as] performance standards, setting agency expectations and providing general guidance on how to meet them without mandating prescriptive requirements to comply. Preventative controls must be based on risk assessments.”

Another commenter wrote that “FDA should keep the existing CGMP regulations as the foundation, and enhance those regulations only in targeted ways.” This commenter also wrote that the enhancements should “...retain the flexibility needed to apply the regulations to their particular circumstances...” and that “...technical issues should be addressed in guidance documents that can more easily evolve through time...”

One commenter wrote that “FDA should also gather from the food processing industry ‘best practices’ and analyze those prior to advancing any changes in the current GMPs.”

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

Several commenters suggested that the agency’s own inspectional results, *i.e.*, No Action Indicated (NAI), Voluntary Action Indicated (VAI), and Official Action Indicated (OAI), could serve as a measure of the effectiveness of preventative controls. One commenter suggested that the agency should focus on the number of

firms that fall into the third (OAI) category and should use the number of firms that improve from a VAI classification to a NAI classification as a measure of success.

One commenter suggested that the agency develop "...a universal GMP inspection checklist for FDA field investigators and standardized GMP training in order to obtain more consistent interpretation of the food GMP regulations. Once this has been accomplished, then a tracking and measurement system can be developed ...".

7. *In today's food manufacturing environment, what are the principal contributors to contamination of food by allergens (declared and undeclared)? What preventive controls can help reduce/control/eliminate the problems with these allergens?*

One commenter wrote: "...we have found errors in package ingredient declaration, carton handling practices and assuring proper match of formula to specific cartons to be the most common reason for the presence of undeclared allergens. Appropriate control by packaging vendors and our internal handling practices is critical in reducing the occurrence of these events."

Another commenter wrote that "...labeling errors account for a substantial majority of food allergen problems, and that cross-contamination during manufacturing account for a much lesser number. Addressing both of these issues could be improved by including an explicit requirement in the CGMPs for an allergen control program within the manufacturing facility." Several other commenters also listed labeling errors as a leading cause of undeclared allergens.

Another commenter wrote that "The principal contributors to the presence of undeclared allergens in food are: 1) cross-contamination (shared equipment), 2) lack of employee training, and 3) rework." This commenter also wrote that the following preventive controls are needed: "...1) revision of current GMPs to include guidelines regarding rework and shared equipment, 2) guidance on the need for employee training regarding food allergies, and 3) guidance on the use of precautionary ('may contain') statements." This commenter concluded by writing that "It is imperative that any revisions made to address food allergens must be mandatory (*i.e.*, 'shall') as opposed to optional (*i.e.*, 'should')."

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.*

One commenter wrote that it believes that "...FDA's own food CGMP regulations should remain the basis for any modernization effort..." This commenter also wrote that "...FDA should consider the Codex Alimentarius Code of Practice for Food

Hygiene as a model for setting standards at the ‘general principles’ level...” This view was echoed by several other commenters.

One commenter wrote that the Codex Code of Hygienic Practice for Milk and Milk Products adopted in 2004 also provides a good example of “...how to incorporate new flexibility into the existing food GMPs.”

Several commenters at the public meetings also endorsed the value of the Codex document as a resource for food CGMP modernization.

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?*

Several commenters stated that the CGMP regulation should remain applicable to all types and sizes of facilities. Although this may make it more difficult to interpret the regulation in the context of different processes and facilities, the flexibility of this approach outweighs this burden.

One commenter wrote that it “...recognize[s] that it is reasonable to provide more time to small businesses to implement [regulations]...as many small companies simply do not have the resources...to adopt and implement regulations in a short period of time.”

Another commenter wrote that “We do not believe that safe food should be dependent on the size of the processing facility. Food GMPs should apply equally to all parts of the food processing industry...”

10. *There are a number of preventive controls, as well as programs that help to ensure that preventive controls are carried out adequately. These include the following:*
- a. Training programs for managers and/or workers.*
 - b. Audit programs*
 - c. Written records, e.g., batch records, sanitation records*
 - d. Validation of control measures*
 - e. Written sanitation SOPs*
 - f. Food label review and control program*
 - g. Testing of in-coming raw materials, in-process materials, or finished products*

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

One commenter wrote that all of these measures, procedures and programs, "...in the appropriate form, are critical to manufacturing a food product." And that "...it should be left up to the plant and food industry to control and implement these based on the risk."

Another commenter wrote that "It is likely that mandatory use of such an approach [*referring to risk-based control points*] more broadly in food manufacturing could significantly reduce hazards in all three of the areas – physical, chemical and biological – identified by FDA."

Another commenter wrote that the most valuable enhancements to the CGMP regulations would be to "...add general requirements for allergen control, environmental control, sanitation programs and training." This commenter also wrote that it would "...support limited and carefully circumscribed regulations governing records."

11. Are there preventative 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.

One commenter wrote: "We would encourage FDA to expand the section 110.93 Warehouse and distribution. We believe shipping vehicles deserve separate statements identifying the need for evaluation of overall condition to assure it is suitable for use...to prevent the food from becoming adulterated."

Another commenter wrote that "The current food CGMPs when applied are adequate and effective in this regard."

Many commenters chose either not to answer the questions posed by the agency in the Federal Register notice or to provide additional comments not directly related to a specific question. These comments are summarized below.

General Comments

One commenter stated that "...the regulations should be more specific in the statement of the hazards in connection with the regulation or recommendations. For example, under the section on personnel, controls for physical, chemical and biological hazards are intermingled. Inspection staff prefer to evaluate compliance with rules in broad categories

such as personnel, building and facilities, equipment... we recommend that within each of the categories, the regulations be arranged to group control requirements or recommendations for like hazards together.”

One commenter stated that “...revised GMP regulations should require companies to develop written internal quality assurance/quality control programs that clearly state management's approach to fulfilling its food safety functions. Structural independence between the quality assurance and production departments of an establishment is essential. For example, it should be unacceptable for the QC personnel to be hired or fired by a production supervisor.”

Definitions

Many commenters addressed the issue of which definitions should be included in the CGMP regulations. One commenter suggested that definitions for “batter,” “Blanching,” “Microorganisms,” Quality Control Operation,” and “Should” should be removed from the regulation.

One commenter suggested that the following terms be added to the list of definitions: “Adulterated,” “Approved,” Critical Control Point,” Food Employee,” HACCP Plan,” “Hazard,” “Person in Charge,” “pH,” “Potentially Hazardous Food,” “Ready-to-Eat Food,” “Regulatory Authority,” “Risk,” “Sanitize,” “Scheduled Process,” “Standard Sanitation Operating Procedures (SSOPs).”

Another commenter suggested adding the terms “Hazard Analysis” and “Allergen”.

Another commenter suggested “Removing critical control point terminology from the revised GMPs...”

Another commenter suggested adding definitions for “critical limit” and “food safety hazard”.

In many cases, commenters proposed specific definitions for these terms.

Several commenters suggested that the definition for “Critical Control Point” be made consistent with the definition proposed by the National Advisory Committee on Microbiological Criteria for Foods.

Lubricants

One commenter provided detailed recommendations on the use of food grade lubricants. This commenter suggested that “Food grade lubricants should be used in food and beverage manufacturing plants from the time that raw materials arrive until after final packaging to improve food safety.” This commenter suggested that a research study

shows that "...60 percent of U.S. food and beverage manufacturers are still using non-food grade oils and greases when making food or beverage products..." The commenter cited twelve specific incidents of contamination of foods with non-food grade lubricants between 1979 and 2002. Of these, four incidents involved FDA-regulated foods.

Lot Size

One commenter stated that "One of the key factors exacerbating our large multi-state outbreaks is the super-sized batches developed at large processing facilities. FDA must encourage processors to create small batch sizes and to sanitize equipment between batches. This single measure will dramatically reduce cross-contamination....to the greatest extent possible, foods from a single farm, orchard or seafood harvest should be packaged together and not mixed with those of other farms. They should then be shipped to as few retail facilities as possible. Doing so would reduce the size of outbreaks, the number of illnesses, and the difficulty of trace-back."

Another commenter wrote "...a proposal for reduced lot size volumes for all foods as a solution to reduce recall sizes and improve traceability is flawed. Limitations in lot sizes will result in limitations in production runs and increase the number of product change-overs. It has been documented in the dairy industry that potential food hazard conditions are magnified and their likelihood of occurrence is increased during product change-overs. Minimizing lot size for many food industries would significantly increase the potential for product mishandling, mislabeling, and increased micro contamination during change-over activities."

Raw Agricultural Commodities

One commenter, citing 21 CFR 110.19 Exclusions, encouraged FDA to issue some minimum guidance on raw agricultural commodities.

Another commenter wrote that "...the rule was last updated in 1986. Since that time, the entire food industry, including the produce industry, has undergone widespread change. The nation's food safety regulations must reflect those changes and adapt with the shifting food environment.... any revision of the CGMP regulations should maintain the exemption for raw agricultural commodities. The produce industry is complex with a diverse supply chain taking fresh fruits and vegetables from production to consumption. The current GMPs are wholly appropriate for food manufacturers, including some segments of the produce industry such as fresh-cut operations." This commenter suggested that good agricultural practices and guidance were more appropriate ways of addressing the food safety risks associated with raw agricultural products.

Finished Product Testing

One commenter stated “Raw or undercooked produce products that are chopped or mixed, such as salsa, Cole slaw, guacamole and salad mixes should be subjected to final microbial product testing, as should raw or undercooked dairy and seafood products.”

Allergen Controls

One commenter, citing 21 CFR 110.20(b)(2) Plant and Grounds, recommended the phrase “or cross contact with foods containing allergens” be inserted after the statement “Permit the proper precautions to reduce the potential for contamination of food.”

One commenter, citing 21 CFR 110.40(d), recommended adding the phrase “and also prevent cross contact with unlabeled allergenic material” to the end of the current text.

One commenter, citing 21 CFR 110.80(a)(5), recommended adding a phrase at the end which says “and be used in a manner that does not create an allergen cross contact situation.”

One commenter, citing 21 CFR 110.80(b)(5), recommended adding the phrase “and allergen cross contact” to the end of the current text.

One commenter, citing 21 CFR 110.80(b)(7), recommended adding a phrase “and cross contact of allergens when necessary” to the end of the current text.

One commenter noted that “The current regulations contain a number of provisions that relate to preventing contamination in the food processing environment, but there is no explicit mention of food allergens.” This commenter recommended that the agency amend the CGMP regulation to require food processors to develop and adopt allergen control practices within their facilities, yet keep the regulatory requirement flexible so that manufacturers can adapt control practices to their unique requirements.

One commenter wrote that “The primary elements of an allergen control plan would include: identification of ingredients containing food allergen(s); management of these ingredients (*e.g.*, physical segregation); process controls; verified cleaning processes; label controls and label review; and employee training.” This commenter also wrote that their organization “...strongly encourages FDA to develop *de minimis* levels and ultimately thresholds for individual allergens, based on the best available science.”

Another commenter wrote that the following preventive controls are needed: “...1) revision of current GMPs to include guidelines regarding rework and shared equipment, 2) guidance on the need for employee training regarding food allergies, and 3) guidance on the use of precautionary (‘may contain’) statements.” This commenter concluded by writing that “It is imperative that any revisions made to address food allergens must be mandatory (*i.e.*, ‘shall’) as opposed to optional (*i.e.*, ‘should’).”

Another commenter recommended that 21 CFR 110.80 "...be revised to include a separate section requiring an allergen control program for those processing plants that handle any of the eight common allergens. The allergen control plan should address the following: Training of processing and supervisory personnel; Separation of allergenic ingredients during storage and processing; Cleaning and Sanitation of processing equipment; Scheduling of production runs to enhance physical separation and time separation; Reworking ingredients and finished products; Product label review; and Supplier control program for ingredients and packaging."

This commenter also wrote that the evaluation of a plant's allergen control program by FDA investigators "...must be performance based..." and "...not be based on review of plant processing records or the written allergen control program, unless voluntarily supplied by the food processor."

Manufacturing Operations

One commenter, citing 21 CFR 110.80(b)(4), recommended adding the terms "preservation systems" and "modified atmosphere packaging" to the list of measures that are taken to destroy or prevent the growth of undesirable microorganisms.

One commenter, citing 21 CFR 110.80(b)(8), recommended adding "X-ray" to the list of measures that may be used to protect against the inclusion of metal or other extraneous material in food.

Regarding 21 CFR 110.80, one commenter wrote "The flexibility in this Section is an overall strength of the regulation. We believe this strength could be enhanced by requiring the application of a scheduled process for the manufacture of certain 'potentially hazardous foods.' The determination of what foods would require a scheduled process would be determined by the regulatory authority and based on illnesses associated with the products, how the products are packaged (reduced oxygen packaging), or other recognized concern." This commenter went on to state that "We further believe a requirement for food facilities to establish a written recall procedure should be included in this Section."

Warehousing and Distribution

One commenter recommended that more "focus and guidance" be given to transportation vehicles. The commenter listed issues including "...condition, cleanliness, previous loadings, LTL issues with co-mingling, and hauling of questionable previous loads..". The commenter suggested the use of general language to specifically target the sanitary condition of transport vehicles.

One commenter suggested that 21 CFR 110.93 be rewritten. This commenter suggested regulatory wording that included sections on food storage and food transportation with detailed provisions for each that are too lengthy to quote in this report. These provisions included requirements for construction and maintenance of facilities to exclude pests, adequate lighting, proper refrigerated and frozen storage, chemical storage and labeling, hand washing, wastewater disposal, pesticide use, storage conditions for shell eggs and molluscan shellfish, stock rotation, distressed food salvage, hygienic standards for food transportation vehicles, and temperature monitoring for vehicles that transport potentially hazardous foods.

Another commenter wrote that its organization "...does not support the revision of the food GMPs to address transportation issues since this is already addressed ...through a number of existing regulations. In addition, transportation issues are not a significant problem, based on the Eastern Research Group (ERG) data and causes of recalls."

Another commenter stated "...vehicles used for the transfer of animals, animal meats or animal byproducts, should be prohibited from transporting produce or produce products.... On refrigerated vehicles carrying foods, records of temperature variations should be automated."

Written Sanitation Practices

One commenter wrote that "The current regulations have a number of provisions covering different aspects of food sanitation, but there is no explicit requirement or reference suggesting that each facility develop a detailed written set of practices or procedures for how the facility will comply with the GMP sanitation requirements." This commenter recommended that the following text be included in a modernized regulation:

Each manufacturer, regardless of size or products produced, should document practices that it will employ to ensure adherence to these requirements. In addition, each manufacturer should review and update these practices to reflect developments in technology. Employees should be trained to comply with the specific manufacturer's practices as well as these requirements.

Another commenter wrote that they would "... support a clarification in the food CGMP regulations to expressly require food manufacturers to develop and adopt written programs outlining 'good sanitation practices' they intend to follow in their manufacturing facilities. This provision should be general in nature to allow companies the flexibility to adapt such programs to their circumstances."

Another commenter wrote that they were "... 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."

Another commenter wrote that “Food plants that manufacture or handle high-risk foods should be required to meet a higher standard. For plants whose products are identified as high-risk for *Listeria monocytogenes*.... a formalized action plan to effectively control or minimize the potential for this pathogen contaminating finished product should be developed and implemented by them.”

Another commenter wrote that “... a standard sanitation operating procedure should be required...” This commenter went on to recommend that the regulation should have language added that describes nine requirements for effective SSOPs. These requirements generally define the scope, management responsibility, monitoring, corrective action, and record keeping associated with the SSOPs.

One commenter stated that revision of the current regulation should attempt to strengthen the current requirements by “Requiring specific daily sanitation regimens that incorporate features such as monitoring, corrective action and record keeping.... Statistics from the seafood HACCP program...have shown that this type of requirement has helped with compliance. For example, the seafood HACCP regulation... In 1998 [the first year of inspections], the percent of firms that had adequate sanitation controls, including GMPs, sanitation, and record keeping was 21 percent. While in 2003...it was 54 percent, an over 100 percent improvement in five years.”

One commenter stated that “The big question that I think comes up in good manufacturing practices now after we've seen the seafood HACCP regulations and the juice HACCP regulations is what do you do with SSOPs? Should they be incorporated into the GMPs? I think that we should really consider possibly removing those from those two HACCP regulations and putting the SSOP requirement into the GMPs so that you'll have a good definition across the board throughout the nation, and what the components are of each category.”

One commenter wrote “...the revised CGMPs should provide that food establishments that produce or handle high-risk foods, such as those at risk for *Listeria monocytogenes* (*i.e.*, soft cheese, pasteurized and unpasteurized milk products, seafood products, and prepared salads), be required to meet stiffer standards. Facilities making such products should be required to have written plans addressing *L. monocytogenes* and to test their environments and final products for the presence of the pathogen.”

Environmental Monitoring

One commenter noted that “One of the most significant advances in food processing controls since the original promulgation of the food GMP regulations is the development of environmental monitoring programs which include appropriate microbial testing. These programs help processors evaluate the effectiveness of sanitation programs and guide the development of improved sanitation programs.” This commenter recommended that the following text be included in a modernized regulation:

Each manufacturer should monitor the production and processing environment, including microbial testing as appropriate, to evaluate the effectiveness of its sanitation practices, detect potential microbial harborage sites, and guide corrective actions.

Several commenters wrote expressing the need for environmental controls. One commenter wrote that it "...would support enhancing the food CGMP's by providing for an environmental control program based on the following general principles:

- a. Baseline sanitation program to identify and sanitize potential harborage sites;
- b. Environmental testing program to assess effectiveness;
- c. Evaluation of results and root cause analysis when positive environmental samples are found; and
- d. Corrective actions taken based on root cause analysis."

This commenter went on to caution that any such regulatory change "would need to provide the flexibility for individual food companies to administer the program as appropriate to their particular circumstances...." including applying the program to different food categories based on risk and choosing the most appropriate test and organism to address the risks. They also wrote that the regulations needed to be structured in a way that encouraged testing and corrective action by firms without fear of regulatory repercussions and that specific elements of a control program should be "...placed in a guidance document that would supplement the regulations."

Another commenter wrote that their organization "... supports the revision of 110.35 so plants 'should' have a 'written environmental control program for post-processing/packaging areas in plants processing RTE foods.' The details of this written program need to be left to the food processor since each environmental monitoring program must be designed to meet the individual characteristics of a manufacturer's RTE processing facility."

Maintenance of Records and Access to records

One commenter wrote that "FDA's legal authority to mandate records retention or seek access to them is very limited..." but that "...manufacturers should be expected to maintain records as necessary to achieve and monitor their basic adherence to GMPs." This commenter noted that "Manufacturers typically maintain records necessary to monitor their effectiveness in achieving compliance with the GMP requirements and the current regulations could reasonably be interpreted implicitly to require recordkeeping." However, the commenter recommended that the following text be included in a modernized regulation:

"Each manufacturer should maintain such records as are necessary to achieve and self-monitor adherence to these requirements."

Another commenter opposed any attempt by the agency to include a mandatory records inspection provision in a modernized food CGMP regulation. The commenter wrote that “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.”

Another commenter wrote that “It is reasonable for FDA to expect food companies to maintain records needed to document adherence to CGMPs. This is current industry practice. Company management needs those records to assure itself that its GMP program is being followed...Although it is reasonable for FDA to proscribe (*sic*) what types of records the agency believes should be maintained by food companies, the companies themselves need the flexibility to decide how those records are kept and in what form...”. This commenter went on to state that “The product would not become or be considered adulterated or misbranded due to any recordkeeping deficiencies *per se*....In this way, the remedial focus of the CGMP regulations should be on the adequacy of the CGMP program itself, not on the records alone.”

Another commenter wrote that it does “...not support expanding processing records access through modifications to the food GMPs. It is certainly understood that food companies are expected to maintain records to document their own adherence to GMPs; however, the statute does not authorize access to these same records by FDA investigators.”

One commenter stated that “...Manufacturing operations should be required not only to manufacture their products--and I'm quoting from 110 now—‘under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food’ but also to document these controls. You have strong standards in the existing GMPs. What's missing is the recordkeeping component.”

HACCP and CGMP Regulations

Many commenters referred to the need for controls using language that is common to HACCP programs (*e.g.*, “establish critical limits,” and “risk-based assessment approach”).

Comments from public meetings and written responses overwhelmingly endorsed the value of HACCP programs and stressed that CGMPs were prerequisites of a HACCP program and that HACCP should remain a voluntary program for most sectors of the food industry.

One commenter wrote that “We believe that mandating HACCP across all sectors would dilute its effectiveness.” Another commenter wrote that “...the agency should ensure that regulations remain flexible and broad and separate from any HACCP-type controls.” This commenter went on to write that they “...do not support the inclusion of HACCP-type controls in the CGMP regulations.”

A commenter wrote that it "...believe[s] that the opportunity to revise and update the food GMPs should not be used as an indirect path toward hybridizing GMPs into HACCP-like regulations. GMPs have been a recognized part of the federal food safety regulations for many years prior to any mandatory HACCP program. They should continue to stand separate from HACCP." This commenter also wrote that in order to "...prevent confusion between GMPs and HACCP, the GMPs should not utilize HACCP terms, *i.e.* sanitary standard operating procedures (SSOPs), critical control points, critical limits, deviations, corrective actions, verification and validation, since they have very specific meanings"

Another commenter wrote that "...GMPs should require HACCP-like procedures for the identification of hazards and interventions to control those hazards."

"Shall" vs. "Should"

Several commenters wrote or stated that 21 CFR 110 was a regulation and that the word "should" be replaced with the word "shall".

One commenter wrote "As 21 CFR Part 110 is a regulation and not a guideline, we believe any requirements within this document must be mandated in the context of 'shall' and not 'should.' This, in our opinion, would have a much greater impact on strengthening the regulation and creating uniformity between state and federal regulatory agencies."

Training

Many commenters addressed the value of training as a means of enhancing the value of all aspects of the food CGMP regulations. One commenter stated that "...training ...is essential to making all the other control elements effective." Another commenter, in discussing the findings of the report "Food GMP Modernization Working Group: Report Summarizing Food Recalls, 1999-2003,"⁸ noted that "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...could reduce such incidents." This commenter also noted that a "...failure to follow existing SOPs is also likely rooted in training." This commenter recommended 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 and 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

⁸ Food and Drug Administration. 2004. Food GMP Modernization Working Group: Report Summarizing Food Recalls, 1999-2003. <http://www.cfsan.fda.gov/~dms/cgmps2.html>

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.

One commenter wrote that “A culture of compliance is most effective when based on and incorporated within a competitive atmosphere. Food safety specifications required from the top down through the supply chain are far more stringent and effective than regulatory requirements. FDA needs to use its resources to leverage this culture across the industry.” This commenter recommended that the agency “Adopt the Codex ‘Recommended International Code of Practice: General Principles of Food Hygiene’ Section X – Training.” This commenter also wrote that the agency should “Allow processors to establish their own programs without mandating specific approaches.”

Another commenter wrote that “FDA should require food safety competency and food safety training for select personnel in food plants, particularly where high-risk foods are handled or where food plants are unable to gain compliance.”

Another commenter wrote that 21 CFR 110.10(c) *Education and Training* “...must be mandated. Remove ‘should’ and replace with ‘shall’ in 2 areas for education and training. This commenter went on to make specific recommendations for 21 CFR 110.10(d):

Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the regulatory authority knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements of this regulation. The person in charge shall demonstrate knowledge by:

(a) Complying with this Code by having no critical violations during the current inspection;

- (b) Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; or
- (c) Responding correctly to the inspector's questions as they relate to the specific food operation....

The commenter then outlined 14 specific areas of food safety knowledge.

Another commenter referenced the findings of the report "Food GMP Modernization Working Group: Report Summarizing Food Recalls, 1999-2003"⁹ and wrote that "Of the top ten food safety problems identified....all are specified by 'shall' in the GMP regulation, except for training which is a 'should.' Further, the top five commonly mentioned preventive controls for these problems list training in seven of the ten...the importance of training in addressing food safety and sanitation issues is clearly identified." This commenter recommended that 21 CFR 110.10 (c) have the "should" references replaced with "shall" and the term "competency" replaced with "knowledge" "...since 'competency' begs the need to challenge and evaluate, whereas 'knowledge' is a simple matter of 'knowing' or 'not knowing.'"

One commenter stated that "The section of education and training of employees only includes the dangers of poor personal hygiene and improper food handling techniques. It should also include education and training in all aspects of hazard control including allergen control."

Temperature Requirements

One commenter wrote that specific temperature requirements should be deleted from the current regulation. Under 21 CFR 110.80 (b)(3), the current regulation requires that "food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held "in a manner that prevents the food from becoming adulterated...". The regulation states that this "may be accomplished by any effective means, including: (i) Maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved...." and "(iii) Maintaining hot foods at 140°F (60°C) or above." The commenter noted that since these regulations were published, "...the 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*."

⁹ Food and Drug Administration. 2004. Food GMP Modernization Working Group: Report Summarizing Food Recalls, 1999-2003. <http://www.cfsan.fda.gov/~dms/cgmmps2.html>

This commenter went on to state that "...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..." The commenter suggested that specific temperature requirements be incorporated into a guidance document for temperature control of perishable foods.

Another commenter wrote that "...the specific temperature requirements (Part 110.80(b)(3)(i)...and Part 110.80(b)(3)(iii)) do not allow for the application of new scientific information, adjustment for emerging pathogens, or new toxicological information....It would be preferable for the GMPs to be more flexible and contain general statements about temperature control, such as 'adequate' or 'scientifically supported' for control of common pathogens."

Another commenter wrote to support "...lowering cold holding temperatures for potentially hazardous foods to 41°F to be consistent with the FDA Food Code and State requirements."

Another commenter wrote "We believe the temperature requirements for refrigerated foods and foods held hot should be harmonized with the Retail Food Code (*i.e.*, refrigerated @ 41 degrees F and held hot @ 135 degrees F)."

Validation of Preventive Controls

One commenter wrote that "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)." This commenter went on to point out that the Codex Committee on Food Hygiene is considering the issue of validation and that once the committee finalizes its document, the agency should work with stakeholders to develop a guidance document to address validation of control measures. This commenter also wrote that "The focus should be on the validation of GMP controls for which such validation would be needed to ensure adequacy of the control measure."

Another commenter wrote that it does "...not support the addition of equipment cleaning validation to the existing food GMPs since validation is a term linked to HACCP and implies extensive and thorough scientific studies, when effective equipment cleaning and sanitizing can be easily demonstrated through chemical supplier experience as well as pre-startup monitoring by the processing plant."

Employee Health

One commenter wrote that 21 CFR 110.10(a) should be renamed from “Disease Control” to “Employee Health” and made to “...be more in tune with the 2001 FDA Model Food Code as it relates to food employees including listing the big 4 (Hepatitis A virus, *Salmonella typhi*, *Shigella*, and Shiga toxin producing *E. coli*). The section should also include a list of symptoms associated with foodborne illness, (Diarrhea, Fever, Vomiting, Jaundice, or Sore Throat with fever in addition to the lesions and open wounds already addressed by this section. This section should also apply to current employees as well as job applicants to whom a conditional offer of employment has been offered. Some thought should be given to including high-risk activities that might lead to secondary infection. Exclusion and restriction needs to be defined along with specific steps necessary for a restricted/excluded employee to resume duties. An employee must be required to report symptoms or illness to the Person in Charge immediately and the Person in Charge must be required to notify the regulatory authority that a food employee is diagnosed with one of the four mentioned illnesses.”

Another commenter wrote “...the section addressing the health of personnel is highly relevant today....These provisions should be strengthened with additional enforcement controls. Daily assessment of employee health, cleanliness, and hand washing is a critical responsibility of management and should be accompanied by multi-lingual training ...”

Cleanliness

One commenter wrote recommending several changes to 21 CFR 110.10. Specifically, the commenter recommended that:

21 CFR 110.10(b)(1) “...should indicate that no street clothing would be allowed unless protective outer garments are worn.”

21 CFR 110.10(b)(4) have the following text added to the regulation: “While preparing food, food employees shall not wear jewelry on their arms and hand. This does not apply to jewelry on the hand which is covered and protected.”

21 CFR 110.10(b)(5) have the following text added” “The gloves shall be of an impermeable material unless covered by a durable tight fitting disposable glove made of impermeable materials.” The commenter also wrote that “This section should also include a statement related to minimizing bare hand contact with Ready to Eat foods. Fingernails should also be addressed in this section.”

Plant and Grounds

One commenter wrote that “This section is written in fairly general terms, which we believe is good. We also think it’s good to address outdoor operations because so many wineries have outdoor fermentation tanks. The language should be expanded so that it is not limited to fermentation tanks. Many operations have their first step (receiving) outside and a slightly broader term could address these other outdoor activities. The language in 110.20(3) should be rewritten as follows:

The plant and facilities shall take the proper precautions to protect food in outdoor storage or processes such as receiving, initial product washing or bulk fermentation tanks.

Sanitary Operations

One commenter suggested the revision of 21 CFR 110.35 *Sanitary Operations*. The suggestions are too extensive to restate here, but could be categorized as clarification of these regulations. However, the commenter did recommend the inclusion of a requirement for documenting compliance with 21 CFR 110.35(b)(1) (sanitary operations, including cleaning and sanitizing substances, toxic materials, pest control sanitation of food-contact surfaces, and storage of cleaned equipment and utensils) and retaining this documentation for a period of two years.

Filtration

One commenter wrote that 21 CFR 110.20 should be modified to address air quality and filtration. This commenter suggested the following regulatory language:

110.20(b)(8) Air filtration systems, including prefilters and particulate matter air filters, shall be used when appropriate on air supplies to production areas and on tank vents holding a food product or ingredient. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants.

110.40(h) Filters and separation systems for liquids shall be provided when appropriate for adequate control over microorganisms, particulates and other hazardous or undesirable physical, chemical or microbiological contaminants. As close as possible prior to actual use, the integrity of bacterially retentive final filters used at critical control points shall be verified through routine testing by a pressure hold test or a diffusive air forward flow test.

110.80(b) Measures such as filtration shall be used to physically remove hazardous or undesirable microorganisms when appropriate.

Imported foods

One commenter wrote “The primary purpose for revising the current food GMPs is to improve public health for the U.S. consumer. Since the effectiveness of the current food GMPs has been proven over time, we encourage FDA to commit more resources toward food GMP application to foreign food production and processing plants.”

Agency Access to Records

As detailed above, several commenters wrote about the agency’s access to manufacturing records. These commenters expressed the view that the agency has limited authority to require specific types of records and to gain access to those records. The working group believes that manufacturers must keep certain types of processing records to ensure that important processing procedures, such as those that ensure food safety, are being carried out properly. Without adequate records, a manufacturer cannot determine whether or not a given lot of product was properly processed or that required tests were performed. Similarly, the working group believes that the agency would need to be able to review certain types of records in order to verify that a food establishment is in compliance with the regulations.

The working group appreciates the need to minimize the types of records that food processing establishments must maintain. However, compliance with some of the proposed amendments to the regulations could not be determined by investigational observation alone. For example, an investigator could not adequately determine whether an establishment has an adequate allergen control plan without inspecting that plan and ensuring that the provisions of that plan are effectively implemented. Similarly, an investigator could not adequately determine whether employee training requirements are being met without actually examining the content of the training program and records of employee training.

The agency has a long history of effective records-based inspection in the food industry. The cornerstone of the low acid canned food regulations (21 CFR Part 113) is the requirement to maintain records of those processes that assure the safety of the product (21 CFR 113.100). Agency investigators routinely inspect these records to verify compliance with the regulations. This program has been highly successful and has contributed to the outstanding safety record enjoyed by the low acid canned foods industry. The working group believes that this program has been successful in part for two reasons: 1) record-keeping requirements are limited to those processing steps that are important to ensuring food safety and 2) the requirements with respect to what

information the records must contain are well understood by the regulated industry and by regulators. In light of this history, the working group believes that requiring certain types of records to be made available for inspection by investigators would help ensure food safety by facilitating verification of compliance with the regulations.

Opportunities for Modernization of 21 CFR Part 110

Nearly every individual or organization that offered comments on food CGMP modernization mentioned the importance of 21 CFR Part 110 in ensuring food safety and the importance of maintaining the flexibility and broad application of the current regulation. The working group also recognizes the importance of these regulations and the need to preserve flexibility where possible. The food CGMP regulation is a valuable prerequisite that supports other food safety and quality programs such as HACCP and processor or product specific quality control programs. Also, the CGMPs are important to state and local regulators and provide support for their regulatory programs. The working group believes that the regulation ought to be made more risk-based by strengthening the focus on those current good manufacturing practices that will have the greatest impact on food safety. In recommending the modernization of the food CGMPs, the working group recognizes the importance of preserving the flexibility and broad applicability of the regulations. The working group recognizes that these regulations would be most effective if they can be applied to the unique requirements of each type of food processor regulated by the agency. The working group also recognizes the often competing need to make the regulations sufficiently explicit so as to ensure that their intent and meaning are clearly understood.

Note that these recommendations use the word “must” to indicate new regulatory provisions that the working group believes should be mandatory in an amended regulation. It is expected that the codified language would use the term “shall” for these proposed requirements. For certain modernization opportunities, the working group recommends that the agency request further comments on specific issues. These issues and the requested comments are listed under the heading for each modernization opportunity, where applicable.

Training Requirements

Many commenters stressed the importance of a requirement for training food production workers in the principles of food safety and the food CGMP regulations. The working group agrees that training plays a major role in achieving compliance with all aspects of 21 CFR Part 110. The working group also agrees that the training program should be flexible enough that it can be tailored to the needs of the individual processor or industry segment.

The working group believes that the CGMP regulation should be amended to require those personnel responsible for supervising sanitation operations, and those that supervise

food processes that prevent, control, or eliminate food contamination or adulteration to have the education or experience or a combination of these that provides the knowledge and expertise needed to ensure compliance with these regulations and to produce a safe food product. For workers in food processing plants that use one of the eight major food allergens, all food safety training would be required to include material on the significance of food allergens, proper control of product labeling and the prevention of cross contact by food allergens.

The working group believes that the CGMP regulation should be modified to require all food production workers to have appropriate training in the principles of food hygiene and food protection, and to include the importance of employee health and personal hygiene.

Furthermore, the working group believes that this training must be delivered in a form that is readily understandable to all personnel. The training must be delivered in a manner that can be easily understood by the trainee. Food processors would be required to maintain a record of this training for each trainee.

The working group recommends that the agency request comments and suggestions on the minimum content and standards that should be incorporated into the proposed training programs. The working group recognizes the importance of flexibility so that the training can be tailored to meet the needs of specific industry segments, but also believes that certain core principles of food safety, equipment sanitation, and regulatory compliance must be included in the training for all food workers and supervisors. The agency should also request comments and suggestions on whether this training should be standardized or accredited in some way to ensure that the training meets a minimum standard or is otherwise acceptable.

The working group is aware that small food processors may not have the resources to develop their own training programs. To accommodate these small producers, training should be made available through a variety of outlets such as trade associations, universities, state extension programs, Internet-based training, and private providers. The working group recommends that the agency request comments and suggestions on how such training can be made both widely available and affordable.

Food Allergen Controls

Many commenters favored some form of required allergen control program. The working group believes that 21 CFR Part 110 should be amended to require food processors that handle any of the eight common allergens to develop and adopt allergen control practices within their facilities. The working group believes that this control program must address six areas of control:

- Training of processing and supervisory personnel
- Segregation of food allergens during storage and handling

- Validated cleaning procedures for food contact equipment
- Prevention of cross contact during processing through measures such as:
 - scheduling of production runs;
 - control or rework; and
 - use of dedicated production lines
- Product label review and label usage and control; and
- Supplier control program for ingredients and labels

The working group believes that food processors must maintain a copy of the allergen control plan at the processing facility and update the plan as necessary whenever required by changes in ingredients, products, processes or labeling. The working group appreciates the need to keep this regulatory requirement flexible so that manufacturers can adapt control practices to their unique requirements. The working group recommends that agency request comments and suggestions on the scope of this requirement and ways that it might be implemented in the least burdensome manner, especially for small processors.

Listeria monocytogenes Control

The working group agrees with the many commenters who noted the importance of environmental monitoring programs, especially in those processing plants that produce ready-to-eat foods that support the growth of *Listeria monocytogenes*. The working group believes that 21 CFR Part 110 should be modified to require a written environmental pathogen control program for food processors that produce ready-to-eat foods that support the growth of *Listeria monocytogenes*. The purpose of the environmental control program is to evaluate the effectiveness of sanitation practices, detect potential microbial harborage sites, and guide corrective actions. This control program must be commensurate with the risks presented by the processing and packaging environment and must include microbiological monitoring of the production and packaging environment as appropriate. The working group believes that processors must maintain appropriate records as necessary to judge the effectiveness of the program, to identify the root cause of sanitation failures, and to document corrective actions.

Written Sanitation Procedures

Written sanitation procedures are an important means of training sanitation workers and for ensuring the continuing effectiveness of plant sanitation operations. The working group believes that 21 CFR Part 110 should be modified to require that food processors develop and maintain written cleaning and sanitation procedures that define the scope, cleaning or sanitation objective, management responsibility, monitoring, corrective action, and record keeping associated with the cleaning or sanitation procedure. At a minimum, cleaning and sanitation procedures must be developed for all food contact equipment and food contact surfaces.

Several commenters were concerned about the terminology used to refer to written sanitation procedures. These commenters noted that the term “Sanitation Standard Operating Procedure (SSOP)” has become associated with HACCP and they were concerned that the use of this term would confuse GMP programs with HACCP programs. The working group is aware that many food processors have voluntarily implemented HACCP plans and SSOPs. The working group does not believe that it is necessary to have separate terminology for CGMP and HACCP programs. In fact, the phrase “sanitation standard operating procedure” was in common use before it was incorporated into HACCP regulations for establishments regulated by the U.S. Department of Agriculture’s Food Safety Inspection Service. If processors already have SSOPs that would satisfy a new requirement in 21 CFR Part 110 for written sanitation procedures, the working group sees no reason why these processors could not continue to refer to these procedures as SSOPs. Furthermore, the HACCP requirements for SSOPs are no different from the GMP requirements for the written sanitation procedures proposed here. In recognition of the dual use of SSOPs, one commenter suggested that the requirement for SSOPs be removed from HACCP requirements and made a CGMP requirement. The working group recommends that the agency request further comments and suggestions on the appropriate application of SSOPs/written sanitation procedures and their relationship to HACCP and CGMP programs.

Application of CGMP Regulations to Certain Agricultural Operations

21 CFR Part 110.19(a) excludes “establishments engaged solely in the harvesting, storage, or distribution of one or more ‘raw agricultural commodities,’ as defined in section 201(r) of the Food, Drug and Cosmetic Act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public” from compliance with the regulations in Part 110. Part 110.19(b) states “FDA, however, will issue special regulations if it is necessary to cover these excluded operations.”

One of the reasons for considering a modernization of the CGMP regulations is the significant increase in our understanding of foodborne illness. With respect to fresh produce, the Centers for Disease Control and Prevention (CDC) have reported that “...the mean number of reported outbreaks associated with fruits and vegetables more than doubled from the period 1973 to 1987 (4.3 per year) to the period 1988 to 1991 (9.75 per year). The mean number of persons affected by reported produce-associated outbreaks more than doubled (242 per year in the first period compared with 614 per year in the second period).”¹⁰

Recent investigations of outbreaks linked to fresh produce have identified contamination during production and harvest, initial processing and packing, distribution, and final

¹⁰ Tauxe, R., Kruse, H., Hedberg, C., Potter, M., Madden, J., and Wachsmuth, K. 1997. Microbial Hazards and Emerging Issues Associated with Produce A Preliminary Report to the National Advisory Committee on Microbiologic Criteria for Foods. J. Food Protect. 60(11)-1400-1408.

processing as the likely source of product contamination.¹¹ FDA's recent outbreak investigations provide more detailed insight into the types of CGMP deficiencies that may be contributing to the contamination of fresh produce. Since 1998, FDA has conducted 36 farm and packing house investigations at both domestic and non-domestic facilities. Although most of these investigations were conducted months after the outbreak, and the farm or packing houses were often not producing the implicated crop at the time, the farms and packing houses were producing other crops at the investigators visited these facilities. Investigators were able to observe conditions that could contribute to produce product contamination and to review records related to farm or packing house processes and practices. The results of these investigations showed that worker health and hygienic practices were contributory factors in 23 of 30 outbreaks. Unsanitary conditions were found in 10 of the facilities investigated. The produce was not clean in six investigations, vermin were observed in four investigations, and the packing shed was not enclosed at five of the facilities. Failing to properly deal with sewage was observed in 15 of the 30 investigations. No portable toilets for field or packing shed employees were noted in six investigations. When portable toilets were present, they were not properly serviced in nine investigations. Improper sanitation of food processing equipment was observed in 14 of 36 investigations. Cross contamination was observed in 11 investigations, and other issues included a failure to clean and sanitize utensils or the use of utensils that could not be effectively cleaned and sanitized. Water quality was an issue in 13 of 30 farm or packing house investigations. Improper or inadequate chlorination was the most common water problem and was observed in 12 investigations. The use of water storage tanks that were not clean or that did not protect the water from contamination was also a common observation. Also, investigators observed cross connections between potable water and a source of contamination in eight investigations.

The agency has aggressively sought to promote good agricultural practices (GAPs) as a means of reducing the risk of foodborne illness from fresh produce. In 1998, the agency published its *Guidance to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* as a means of informing raw agricultural product producers, packers and processors of important food safety controls. In light of the recent investigational findings described above, the working group recommends that the agency consider removing the exclusion from CGMP compliance in 21 CFR Part 110.19 for establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities. The working group recommends that the agency request further comments on the appropriate application of CGMP controls to raw agricultural product harvesting, packing, storage and distribution.

Records Maintenance and Access

Several commenters expressed the view that the agency has limited authority to require specific types of records and to gain access to those records. However, the working group believes that manufacturers must keep certain types of processing records to document

¹¹ Tauxe, R. E. 1997. Emerging Foodborne Diseases: An evolving Public Health Challenge. *Emerging Infect. Dis.* 3(4):425-434.

that controls and systems that ensure food safety are being carried out properly, and that the agency needs to be able to review these records in order to verify that a food establishment is in compliance with the regulations.

The working group believes that 21 CFR Part 110 should be amended to require that establishments maintain and make available for inspection the following types of records:

- Employee training programs related to food safety and CGMPs. Such records would include a description of the training program(s) and evidence of successful completion of the training for each affected employee.
- Allergen control plans and records documenting compliance with the provisions of that plan.
- *Listeria monocytogenes* control plans and records documenting compliance with the provisions of that plan.
- Written sanitation procedures

The working group envisions that the agency would develop detailed criteria for investigators to use in evaluating these records.

Temperature Controls

Several commenters wrote that the temperature requirements in 21 CFR 110.80(b)(3)(i) and 21 CFR 110.80(b)(3)(iii) should either be deleted or made consistent with Food Code 2001.¹² The working group agrees that specific temperature requirements in this regulation may be problematic, given that pathogens such as *Listeria monocytogenes* are capable of growth at temperatures well below those specified for refrigerated foods. The working group appreciates that the interaction of time and temperature is a critical factor for limiting the growth of pathogens. One commenter recommended removing specific temperature requirements from 21 CFR 110.80(b)(3) and instead issuing guidance for temperature control. The working group recommends that the agency request further comments and suggestions on the use of time-temperature relationships, perhaps in the form of microbial growth models, and how these can be incorporated into regulations or guidance to ensure proper refrigerated storage or hot holding.

¹² U.S. Food and Drug Administration. Food Code 2001. Washington, DC 20204