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November 17, 2005

FDA RELEASES FOOD CURRENT GOOD MANUFACTURING PRACTICE MODERNIZATION REPORT

Executive Summary

- On November 2, 2005, FDA issued the “Food CGMP Modernization - A Focus on Food Safety” report.
- The report contains specific recommendations to revise the food CGMPs to:
 - Establish mandatory training and recordkeeping requirements for supervisors, allergens, and personal hygiene.
 - Establish requirements for a written allergen control plan and related recordkeeping.
 - Establish requirements for a written environmental pathogen control plan for *Listeria monocytogenes* and related recordkeeping.
 - Consider applying CGMP requirements to fresh produce.
 - Establish requirements for written cleaning and sanitation procedures and related recordkeeping.
- The report recommended that FDA seek comments on the scope of requirements for training programs and recordkeeping, allergen controls, fresh produce, written sanitation procedures for HACCP and CGMP programs, and the use of time-temperature relationships to control microbial growth.
- Food establishments that manufacture, process, pack, or hold food are well advised to:
 - Evaluate their current practices to ensure compliance with existing food CGMPs; and
 - Consider the effects of the new recommendations on their operations and any changes or suggestions that should be
- In light of FDA’s recent and ongoing activities related to food CGMPs and safety initiatives, FDA will likely publish an Advance Notice of Proposed Rulemaking, possibly in conjunction with a Notice of Proposed Rule, in the next year to solicit more comments on these issues.

Memorandum

On November 2, 2005, the U.S. Food and Drug Administration (FDA or the agency) made available a report about modernizing the agency's current good manufacturing practice (CGMP) regulations for foods. The report, authored by FDA's Food CGMP Modernization Working Group, is titled "Food CGMP Modernization - A Focus on Food Safety."¹ Of primary significance, the report contains the working group's recommendations for updating the food CGMP regulations in 21 C.F.R. Part 110. The recommendations for modernization focus on the following seven major areas:

- Training requirements;
- Food allergen controls;
- *Listeria monocytogenes* controls;
- Written sanitation procedures;
- Application of CGMP regulations to certain agricultural operations;
- Records maintenance and access; and
- Temperature controls.

The working group recommended that FDA seek additional comments on specific issues related to some of these areas, and further noted that modernization of the food CGMP regulations need not be limited only to these seven identified areas. In addition to the recommendations, the report discusses the need for food CGMP modernization, a risk-based approach to food safety regulation, FDA-sponsored CGMP research, and the public response to FDA's request for information about food CGMP modernization.

Part I of this memorandum summarizes the background of the existing CGMPs for foods. Part II describes FDA's recent food CGMP modernization efforts. Part III summarizes the working group's report, including a review of each modernization recommendation. Part IV discusses issues raised by the recommendations that are likely to be of interest to members of the conventional food industry. Part V compares the recommendations to the CGMPs proposed for dietary supplements. Finally, Part VI of this memorandum summarizes FDA's likely next steps concerning CGMPs for foods.

¹ Available at <http://www.cfsan.fda.gov/~dms/cgmps3.html>.

I. Background of Food CGMPs

The general food CGMP regulations are published in 21 C.F.R. Part 110. The purpose of these regulations is to help ensure a safe and sanitary food supply. Accordingly, CGMP regulations serve as a basis for FDA inspections of establishments in which food is manufactured, processed, packed, or held (hereinafter referred to as food establishments or food processors). Failure to comply with CGMPs may render a food adulterated under the Federal Food, Drug, and Cosmetic Act (FDCA or the act) and subject to FDA enforcement action.

Since their inception in 1969 and subsequent revision in 1986, food CGMPs have been used by FDA and industry to protect against unsafe, unsanitary, or otherwise contaminated, food. The regulations were promulgated under adulteration provisions of the FDCA and the agency's authority under section 701(a) (21 U.S.C. § 371(a)) to promulgate regulations for the efficient enforcement of the act. The key adulteration provisions for food CGMPs are sections 402(a)(3) and (a)(4) of the FDCA (21 U.S.C. §§ 342(a)(3) and (a)(4)). Under section 402(a)(3), a food is adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." Section 402(a)(4) provides that a food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." This section does not require a showing that the food actually contains filth or other contaminants. Instead, a finding of adulteration is sufficiently based upon a showing that the food was prepared, packed, or held under conditions whereby it *may* be contaminated or injurious to health.

The food CGMP regulations were last revised in 1986.² Since that time, they have not been substantially amended. They are organized into seven subparts, two of which are reserved, covering general provisions (including personnel), buildings and facilities (including plants, grounds, and sanitary operations and controls), equipment and utensils, production and process controls, and defect action levels. The regulations are general in nature to allow flexibility for food establishments to appropriately tailor the requirements to their unique needs.³

² 51 Fed. Reg. 22458 (June 19, 1986).

³ In addition to the general food CGMPs, there are also specific processing requirements for infant formula (21 C.F.R. Part 106), low acid canned foods (21 C.F.R. Part 113), acidified foods (21 C.F.R. Part 114), and bottled drinking water (21 C.F.R. Part 129). FDA regulations also include specific requirements, including a Hazard Analysis Critical Control Point (HACCP) plan, for juice (21 C.F.R. Part 120) and fish and fishery products (21 C.F.R. Part 123). The requirements of Part 110 apply equally to these specific product categories as well as other processed foods.

II. Recent Food CGMP Modernization Efforts

In July 2002, FDA established the internal Food CGMP Modernization Working Group to evaluate the effectiveness of existing food CGMPs. The group focused its research on the impact of CGMPs on food safety, the effect of revised CGMP regulations on food safety, and the economic consequences of such revisions. Almost two years later, in May 2004, the agency announced its intention to revise and update CGMPs for foods. The agency's first action was a notice of public meetings published in the Federal Register to solicit comments, data, and scientific information about food CGMPs.⁴

In August 2004, FDA also published two separate reports. The first, entitled "Food GMP Modernization Working Group: Report Summarizing Food Recalls, 1999-2003," was made available on August 3, 2004.⁵ The purpose of this report was to inform FDA about the nature of past food recalls. In this study, FDA collected data on food recalls for fiscal years 1999 through 2003 to identify common problems and trends occurring in the food industry. Specifically, the agency sought to identify recalls that occurred due to a CGMP-related problem (i.e., a problem that could have been prevented by CGMP preventive measures). The results of the agency's review showed that of 1,307 food recall actions, 88% occurred because of a GMP-related problem.

The second report, entitled "Good Manufacturing Practices for the 21st Century - Food Processing," was made available on August 9, 2004, and was conducted by Eastern Research Group, Inc. (ERG), under contract to FDA.⁶ The ERG report was based on an extensive literature review and an expert elicitation from a 15-member panel to identify current food safety problems and the range of preventive controls or corrective actions necessary to address them. The literature review showed that microbiological hazards (e.g., pathogenic bacteria, viruses, and parasites) cause most current foodborne illnesses and that these problems can be easily remedied with improved employee training and effective hygienic practices. Chemical safety hazards, described as intentionally added chemicals (e.g. allergens), unintentionally added chemicals (e.g., cleaners and solvents), and natural toxins (e.g., mycotoxins), were also found to contribute to food safety problems. Although problems from chemical hazards varied widely, the most common problems identified were contamination with pesticides, allergens, and natural toxins. Physical hazards (e.g., rocks, metal, glass in food), were described as least likely to affect large numbers of people. Based on the expert elicitation for the ERG study, the top four food safety problems were identified as deficient employee training, contamination of raw materials, poor plant and equipment sanitation, and poor plant design and construction. The expert panel identified a range of preventive controls to address food safety problems, with the most commonly cited controls being training for allergen control and cleaning

⁴ 69 Fed. Reg. 29220 (May 21, 2004). Transcripts of each meeting are available on FDA's website at <http://www.cfsan.fda.gov/~dms/cgmps.html>.

⁵ Available at <http://www.cfsan.fda.gov/~dms/cgmps2.html>.

⁶ Available at <http://www.cfsan.fda.gov/~dms/gmp-toc.html>.

and sanitation procedures; audits and inspections of food processing facilities and raw material suppliers; documentation and recordkeeping of training activities, raw material policies, and cleaning and sanitation procedures, among other things; and evaluation of the effectiveness of training and cleaning procedures.

In September 2005, FDA published a notice in the Federal Register announcing its proposed collection of information to assess the baseline of current food manufacturing practices.⁷ The agency explained that it plans to conduct an Internet survey of registered food processing facilities, in addition to extended case study reviews. This research will seek information relevant to food CGMPs, including employee training, sanitation and personal hygiene, allergen controls, process controls, post-production processing (including fresh produce and ready-to-eat packing practices and post-harvest operations), and recordkeeping. The collected information is intended to be used to assess the impacts of any modernization policies on food processing.

III. Summary of the Food CGMP Modernization Working Group's Report and Recommendations

Based on FDA-sponsored research and public meetings and comments about food CGMP modernization, the working group prepared the "Food CGMP Modernization - A Focus on Food Safety" report. Initially, the report addresses the need for food CGMP modernization and identifies some reasons to consider CGMP modernization. These include the considerable change in the food industry since 1986, increased scientific understanding of foodborne illnesses and how pathogens can be controlled in food processing, and a new appreciation of the significance of food allergens. The report also discusses the importance of a risk-based approach to CGMP modernization to ensure that controls have a significant impact on food safety. The bulk of the report, however, is a summary of the public comments submitted to the agency in response to its notice of public meetings about CGMP modernization. These comments, in addition to the agency's research, clearly serve as the basis for the working group's recommendations, which are the critical component of the report.

The recommendations to update and revise the food CGMP regulations are explained below. For some of these, FDA is advised to seek comments on certain issues relating to the recommendation. Throughout the report, the working group recognized the value of preserving flexibility in the CGMP regulations so that the requirements can be applied to the unique situations of different food establishments. It was intended that these recommendations embody the same degree of flexibility.

⁷ 70 Fed. Reg. 54390 (Sept. 14, 2005).

A. Training Requirements

The recommendations regarding training for food production personnel relate principally to supervisors, allergens, and personal hygiene:

- *Supervisors.* Supervisors responsible for sanitation operations and supervisors responsible for food processes that prevent, control, or eliminate food contamination or adulteration, should be required to have education or experience necessary to ensure compliance with food CGMP regulations.
- *Allergens.* In food processing plants that handle one of the eight major food allergens (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans), food production workers should be required to receive food safety training about (1) the significance of food allergens, (2) proper control of product labeling, and (3) prevention of cross-contamination by food allergens.
- *Hygiene.* All food production workers should be required to receive training about food hygiene and food protection, including employee health and personal hygiene.

In addition, employee training should be required to be presented in a form and manner in which it is easily understood. Significantly, for any employee training related to food safety and CGMPs, food establishments should be required to maintain training records for each employee, including a description of the training program(s) and evidence of successful training completion.

The working group recommended that FDA seek comments about (1) the minimum content and standards for the recommended training areas, (2) whether training programs should be standardized or accredited to ensure minimum standards, and (3) how training programs can be made widely available and affordable, especially for small food processors.

B. Food Allergen Controls

Food establishments that handle any of the eight major food allergens should be required to develop, adopt, and update as necessary, an allergen control plan. Such plan should be required to address the following six key areas of control: (1) training of processing and supervisory personnel, (2) segregation of food allergens during storage and handling, (3) validated cleaning procedures for food contact equipment, (4) prevention of cross contact by food allergens during food processing (e.g., by scheduling production runs, control or rework, or using dedicated production lines), (5) product labeling review, use, and control, and (6) supplier controls for ingredients and labels.

In addition, food establishments should be required to maintain a copy of the allergen control plan at the processing facilities. The plan would be updated when changes to ingredients, products, processing, or labeling occur.

The working group recommended that FDA seek comments about the scope of the requirements for a food allergen control plan and approaches to implementing it in the least burdensome manner, especially for small food processors.

C. *Listeria Monocytogenes* Control

Food processors of ready-to-eat foods that support the growth of *Listeria monocytogenes* should be required to have a written environmental pathogen control plan, including provisions for microbiological monitoring of production and packaging operations. The plan would be used to evaluate the effectiveness of sanitation practices, detect potential microbial harborage sites, and direct corrective actions. In addition to the written plan, food processors should be required to maintain records necessary to evaluate the effectiveness of the plan, identify causes of sanitation failure, and document corrective actions.

D. Written Sanitation Procedures

Food establishments should be required to develop written cleaning and sanitation procedures for all food contact equipment and food contact surfaces. The written procedures would need to define the scope, objective, management responsibility, monitoring, corrective actions, and recordkeeping related to cleaning or sanitation procedures. In addition, establishments should be required to maintain a copy of the written sanitation procedures.

Because the working group does not envision that CGMP requirements for the sanitation procedures would be different from HACCP requirements for sanitation standard operating procedures (SSOPs), food processors that already have SSOPs would satisfy any new requirement for CGMP written sanitation procedures. Based on a comment suggesting that the requirements for SSOPs in HACCP programs be replaced by CGMP requirements, the working group recommended that FDA seek comments about the appropriate application of SSOPs and written sanitation procedures for HACCP and CGMP programs.

E. Application of CGMP Regulations to Certain Agricultural Operations

FDA should consider removing the exclusion in 21 C.F.R. 110.19, which exempts from CGMP requirements any establishment engaged solely in the harvesting, storage, or distribution of raw agricultural commodities.⁸ This recommendation was based on a consideration of the significant increases in foodborne illness outbreaks that have been linked to fresh produce and caused by contamination during production and harvest, processing and packing, or distribution. Some of the specific causes of contamination included poor worker health and hygienic practices, unsanitary conditions such as unclean produce, vermin, and

⁸ “Raw agricultural commodity” is defined in section 201(r) of the act as “any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing” (21 U.S.C. § 321(r)).

inadequate sewage practices, improper sanitation of food processing equipment, cross contamination, and deficient water quality.

The working group recommended that FDA seek comments about the appropriate application of CGMP requirements to the harvesting, packing, storage, and distribution of raw agricultural commodities.

F. Records Maintenance and Access

The working group recommended that food processors should be required to maintain and make available for inspection records related to food CGMPs for the following:

- Employee training programs, including records that describe the training program(s) and document successful training completion for each employee;
- Allergen control plans and records documenting compliance with such plan;
- *Listeria monocytogenes* control plans and records documenting compliance with such plan; and
- Sanitation procedures.

The working group explained that food establishments should maintain certain types of records to document that CGMP controls and systems are being followed, and that such records are necessary for FDA to verify that a food establishment is in compliance with CGMP regulations. This recommendation suggests that FDA will develop detailed criteria for use in evaluating these records.

G. Temperature Controls

The working group recommended that FDA should seek comments about the use of time-temperature relationships, perhaps in the form of microbial growth models, and how such relationships can be used, in regulations or guidance, to ensure proper refrigeration or hot storage. This recommendation was based on the working group's recognition that specific temperature requirements in the CGMP regulations may be problematic due to the capability of pathogens to grow above or below designated temperatures. For example, *Listeria monocytogenes* is capable of growth at temperatures below those required for refrigerated foods.

IV. Issues of Particular Interest

- Records Maintenance and Inspection

If implemented, the working group's recommendations would constitute significant and new records requirements, including establishment, maintenance, and access, for

four major CGMP areas: employee training, allergen controls, *Listeria monocytogenes* controls, and sanitation procedures. Although FDA has previously proposed recordkeeping requirements related to compliance with general food CGMPs, these were never implemented.⁹ The working group justified its recommendations for these requirements on the basis that certain types of records are necessary to document compliance with an establishment's CGMP systems and controls. Moreover, the working group stated that such records are needed during FDA inspections to verify compliance with CGMP regulations.

Requirements for the maintenance and inspection of records are rarely implemented in the regulation of foods. Currently, there are records maintenance and access requirements for low acid canned foods and acidified foods,¹⁰ in addition to HACCP requirements for juice and seafood.¹¹ Further, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA promulgated requirements for food processors, among others, to maintain records to identify the immediate previous sources and immediate subsequent recipients for all food received and released. Under certain circumstances, such records are subject to inspection by the agency. Finally, the agency has proposed significant records requirements for CGMPs for dietary supplements; however, it is not clear the extent to which these requirements will be part of the final rule, which has not yet been published.

The agency's authority to require recordkeeping and inspection for general food CGMPs is questionable. FDA has in the past accepted that the revision of section 704 of the FDCA (21 U.S.C. § 374) to mandate physical access to facilities did not, absent other statutory authority, authorize access to records. This may explain why, where there has not been a clear grant of statutory authority to require the maintenance and inspection of records for foods (e.g., low acid canned foods, acidified foods, and HACCP regulations), FDA has not relied on section 704, but instead cited sections 402(a)(4), 404, and 701(a) of the FDCA. In such instances, FDA argued that these sections constitute sufficient authority for records requirements and relied on a 1978 opinion from the Court of the Appeals for the D.C. Circuit,¹² which is arguably distinguishable from the current regulatory setting and recommendations.

Because the proposed records requirements are only recommendations and not in the form of a proposed rule, the annual burden of these requirements has not been estimated; however, it is reasonable to expect that the time and effort required to create and maintain records will be considerable.

⁹ See 44 Fed. Reg. 33238, 33241-42 (June 8, 1979); 51 Fed. Reg. at 22458-59.

¹⁰ See 21 C.F.R. 108.25(g) and 108.35(h).

¹¹ See 21 C.F.R. 120.12 and 123.9.

¹² *National Confectioners Assoc. v. Califano*, 569 F.2d 690 (D.C. Cir. 1978) (upholding FDA's authority under sections 402(a)(4) and 701(a) of the FDCA to establish specific CGMP requirements, including the maintenance of distribution records of finished products and product coding, for cacao and confectionary products).

- Allergen Control Plan

Although the existing CGMPs include multiple provisions for controlling and preventing contamination in food processing, none of these explicitly mentions controls for major allergens, nor do they require records maintenance or inspection. Accordingly, if implemented, the recommendation for an allergen control plan would constitute new CGMP requirements.

Since the early 1990s, allergen controls and labeling have been an increasingly important concern at FDA; however, the issue was brought to the forefront last year with the passage of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), which amended the FDCA. Under the FALCPA, all foods that are labeled under the FDCA on or after January 1, 2006, and that contain a major food allergen, must either identify in the ingredient declaration the food source from which a major food allergen is derived, or must be labeled with the word “Contains” and the name of the food source from which the allergen is derived, following or adjacent to the ingredient statement. Failure to label allergens in accordance with the FALCPA will render a food misbranded under the FDCA. The FALCPA defined a “major food allergen” as milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans (*see* 21 U.S.C. § 321(qq)(1)).

Among the FALCPA’s provisions is a directive to the Secretary of Health and Human Services to provide a report analyzing, among other things, (1) the ways in which foods, during manufacturing and processing, are unintentionally contaminated with major food allergens, and (2) common industry manufacturing practices and breakdowns by food type. Relevant to the agency’s recent CGMP modernization efforts is the requirement that the report also advise whether CGMPs or other methods can be used to reduce or eliminate cross contact of foods with the major food allergens. In addition, the FALCPA amended the FDCA to require inspections of facilities, consistent with section 704, to ensure (1) compliance with practices to reduce or eliminate cross-contamination by food allergens, and (2) that major food allergens are properly labeled on foods. In light of these provisions, and in addition to the working group’s recommendation for a detailed allergen control plan, it is expected that the agency will act to issue new regulations or guidance to more specifically address allergen controls, safety, and labeling. Presumably, FDA will rely on its new inspectional authority (*see* 21 U.S.C. § 374a), as well as sections 403(a)(4) and 701(a) of the act, to promulgate new requirements for allergens, including requirements for the maintenance and inspection of records. Food processors that handle any of the major allergens would be well advised (1) to evaluate their current practices to ensure proper allergen labeling and effective elimination of allergen cross-contamination, and (2) to consider the effects of the working group’s allergen recommendations on their food establishment and any changes or suggestions that should be communicated to the agency.

- Listeria Monocytogenes Control Plan

The food CGMPs contain requirements to help minimize potential growth for microorganisms and food contamination, including monitoring physical factors such as time, temperature, humidity, water activity in food processing; however, these requirements do not extend to a comprehensive environmental pathogen control plan, to be used to evaluate the

effectiveness of sanitation practices, detect potential microbial harborage sites, and direct corrective actions. The working group's recommendation that food processors of ready-to-eat foods that support the growth of *Listeria monocytogenes* must have a written environmental pathogen control plan, including provisions for microbiological monitoring of production and packaging operations, would establish new requirements under food CGMPs.

Since 2000, FDA has increased its focus on *Listeria monocytogenes*, including joint efforts with the U.S. Department of Agriculture and the Centers for Disease Control (CDC). In fact, on the same day that the working group's food CGMP report was made available, FDA, in conjunction with CDC, also released an update about the current activities related to the agencies' action plan for *Listeria monocytogenes*.¹³ Among several identified objectives, the first one listed was to develop and revise guidance for processors that manufacture or prepare ready-to-eat foods. In light of recent regulatory efforts to address foodborne illness caused by *Listeria monocytogenes*, FDA will certainly consider implementing the working group's recommendation. With the recommendation that the control plan should be commensurate with the risks presented by the processing and packaging environment, food establishments should consider the effect of a required written environmental pathogen control plan for *Listeria monocytogenes* on their processing and packing operations.

- CGMP Application to Raw Agricultural Commodities

Based upon the current exclusion in section 110.19 for establishments engaged in the harvesting, storage, or distribution of raw agricultural commodities, application of food CGMP regulations, in whole or in part, would constitute a brand new approach to CGMP compliance and enforcement for such foods. Although these establishments are not required to follow CGMPs, there is a "good agricultural practices" (GAPs) guidance document available to address food safety issues for raw fruits and vegetables.¹⁴ This guidance document identifies the basic principles of microbial food safety for the growing, harvesting, packing, and transporting of fresh produce. It focuses on the microbial hazards and control of potential hazards for water, manure and municipal biosolids, worker health and hygiene, sanitary facilities, field sanitation, packing facility sanitation, and transportation.

Because GAPs constitute guidance, they are not enforceable by the agency. Given the increased foodborne illness outbreaks linked to contamination during production and harvest, processing and packing, or distribution of fresh produce, it is likely that FDA will, at a minimum, consider changes to the current regulations or guidance to better ensure that these foods are safe and sanitary. Such steps would be in keeping with meeting the first objective of the agency's 2004 action plan for fresh produce, which is to minimize the incidence of foodborne

¹³ Current FDA Activities Related to the *Listeria monocytogenes* Action Plan (Nov. 2, 2005), <http://www.foodsafety.gov/~dms/lmr2pla2.html>.

¹⁴ Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (Oct. 26, 1998), <http://www.cfsan.fda.gov/~dms/prodguide.html>.

illness by preventing contamination of fresh produce with pathogens.¹⁵ Any establishment engaged in the harvesting, storage, or distribution of produce should consider the effectiveness of the GAPs, in addition to the effects of applying the food CGMPs and working group's recommendations, on its operations.

- Mandatory Training Requirements

Current regulations for low acid canned foods, acidified foods, and HACCP programs, require special training or education for personnel and supervisors for those processing operations.¹⁶ The food CGMP regulations, however, contain few requirements for training of personnel or supervisors. In fact, the recommended training requirements represent a clear shift from the current education and training provisions in section 110.10(c) of the CGMP regulations. Based upon the use of "should" instead of "shall," section 110.10(c) is merely advisory in nature and constitutes guidance at best. The regulation states that personnel responsible for identifying sanitation failures or food contamination "should" have an education or background necessary for the production of clean and safe food, and food handlers and supervisors "should" receive appropriate food safety training, including training about personal hygiene and insanitary practices. In 1986, FDA considered mandatory training but, at that time, concluded that the advisory provisions were sufficient to maintain a clean and safe food supply.¹⁷ With regard to training for supervisors, the working group's recommendation that supervisors have the education or experience necessary to ensure compliance with CGMP requirements arguably goes beyond requirements in section 110.10(d), which requires that compliance with food CGMP requirements be assigned to "competent supervisory personnel." Moreover, any provision requiring recordkeeping and inspection for any training program would be a new requirement.

The training recommendation imposes a double burden on a food establishment by requiring food safety training for all food production personnel and the creation and maintenance of records to document that such training has been successfully completed by employees. The annual burden of these requirements has not been estimated; however, it is reasonable to expect that the development and presentation training programs, in addition to the creation and maintenance of training records, will require considerable time and effort from food establishments.

¹⁵ Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption (Oct. 2004), <http://www.cfsan.fda.gov/~dms/prodpla2.html>.

¹⁶ See 21 C.F.R. 113.10, 114.10, 120.13, and 123.10.

¹⁷ 51 Fed. Reg. at 22464.

V. Comparison to Proposed CGMPs for Dietary Supplements

FDA published a proposed rule for dietary supplement CGMPs in March 2003.¹⁸ The agency is expected to publish the final rule in the near future. FDA has repeatedly stated that publication of this final rule is one of its highest priorities. In light of the working group's report and the impending publication of a final rule on dietary supplement CGMPs, it may be useful to consider the differences between the recommendations for conventional food CGMPs and the proposal for dietary supplement CGMPs.

With regard to training requirements, the proposed rule for dietary supplement CGMPs did not specifically address training for supervisors, allergens, or personal health and hygiene; however, it did contain provisions requiring that persons engaged in manufacturing, packing, or holding have the training and experience necessary to perform his or her duties. FDA sought comment on these requirements and also on whether a final rule should require dietary supplement manufacturers to document and keep records regarding each employee's training and what type of information such records should contain.

With regard to written sanitation procedures, the proposed rule contained detailed requirements about sanitation, but did not require written procedures. Instead, FDA invited comments on whether written procedures for maintenance, cleaning, and sanitation should be required in a final rule. The agency also requested comments on whether the final rule should require documentation to demonstrate compliance with such procedures.

For fresh produce, the proposed rule contained a provision analogous to section 110.19 to exclude from CGMP requirements any establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities. FDA recommended that persons that handle raw agricultural commodities use for dietary supplements follow GAPs and then sought comments on whether the final rule should include CGMP requirements for such persons.

Finally, although the proposed rule addressed production and process controls to protect against chemical and microbiological contamination, it did not contain any proposed requirements specifically related to allergens or *Listeria monocytogenes* controls. Based on these differences, dietary supplement manufacturers should expect the final rule to reflect some of the working group's recommendations, particularly as they relate to training requirements and the maintenance and inspection of records.

VI. FDA's Likely Next Steps

Among the agency's top priorities for fiscal year 2005 were food and dietary supplement CGMPs as well as other actions to address allergens, *Listeria monocytogenes*, and fresh produce. Although FDA has not yet published its program priorities for fiscal year 2006, it

¹⁸ 68 Fed. Reg. 12157 (Mar. 13, 2003).

is fully expected that these issues will rank among the top priorities again. Given FDA's separate initiatives already in progress for allergens, *Listeria monocytogenes*, and the safe handling of fresh produce, it is reasonable to expect that they will be the targets of any new requirements in food CGMPs or guidance documents. In light of the working group's advice to FDA to seek additional comments on certain issues related to its recommendations, and the agency's current plans to collect additional information to better assess the baseline of current food manufacturing practices, it is unlikely that FDA will publish a proposed rule for CGMPs in the very near future. In all likelihood, after the agency completes its survey, it will publish an Advance Notice of Proposed Rulemaking, possibly in conjunction with a Notice of Proposed Rule, to solicit additional comments on specific CGMP-related issues.

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