Preventive Controls Rules: Human Food and Animal Food

PC.1 What are the major requirements under the final preventive controls rules?

They can be found in two fact sheets:

- Preventive Controls for Human Food At-A-Glance Fact Sheet
- Preventive Controls for Animal Food At-A-Glance Fact Sheet

PC.2 Product testing and environmental monitoring are in the final rules. When would companies need to apply these activities?

The preventive controls final rules require that a facility verify that hazards are being controlled and take corrective action to prevent contamination; and product testing and environmental monitoring are examples of steps a firm may take. A facility's decision to conduct product testing, and to establish the frequency of such testing, will reflect a risk-based approach consistent with its hazard analysis. Consequently, the FDA expects that facilities that produce foods that have frequently been associated with outbreaks of foodborne illness or pathogen contamination, or produce ready-to-eat foods for which an effective preventive control cannot be implemented, would establish product testing programs more often than facilities that do not produce such foods.

Similarly, a facility that identifies an environmental pathogen as a hazard requiring a preventive control, for example, sanitation controls, would conduct environmental monitoring. Such a facility would decide what, if any, role product testing would play as a verification activity or as part of a corrective action as a result of positive findings from environmental monitoring, based on the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system.

PC.3 The rule requires food facilities to have a written food safety plan that includes a hazard analysis and preventive controls. How often must that plan be reanalyzed?

At least once every three years. The facility must also review portions of the food safety plan under certain circumstances, such as when a preventive control is found to be ineffective.

PC.4 My company has three separate food facilities. Are we required to have three distinct facility-specific food safety plans even though we produce the exact same food product at all three facilities?

The overall framework is directed to a facility. Thus, the preventive controls for human food rule establishes a requirement for every facility to have its own written food safety plan. Even if a corporation makes or holds similar products at separate facilities, it is unlikely that the separate facilities have exactly the same equipment and layout. Procedural instructions must be tailored to the equipment being used, and the layout of a facility including processing lines, technologies, and raw materials utilized as they will affect the approach to applying preventive controls such as allergen controls.

PC.5 What is a preventive controls qualified individual?

This is a new term in the final rule. A preventive controls qualified individual is someone who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system. The written food safety plan required of food facilities must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals. And the preventive controls qualified

individual is charged with overseeing the validation that preventive controls are capable of controlling identified hazards and the records review.

PC.6 Do I need to employ a preventive controls qualified individual (PCQI)?

The preventive controls for human food rule creates new requirements for covered domestic and foreign facilities producing human food to develop and implement a food safety plan based on hazard analysis and risk-based preventive controls. In general, the rule applies to facilities that have to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). However, there are a number of exemptions and modified requirements that may apply (see 21 CFR 117.5 for exemptions that may apply to your facility).

If no exemptions apply to you, then you are required to have a PCQI develop and implement your facility's food safety plan. A PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

PC.7 How does a PCQI demonstrate that he or she is qualified to serve as a PCQI?

The preventive controls for human food final rule specifies that a PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

However, the rule does not require any specific certifications, including certification by the Food Safety Preventive Controls Alliance (FSPCA). An individual may voluntarily choose to attend the PCQI training provided through the FSPCA, but this is not mandatory. In general, FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the rule, irrespective of documented training and experience.

PC.8 I have many food safety certifications (HACCP, GFSI, SQF, BRC, etc). Do I still need to take the PCQI training from the FSPCA?

The preventive controls for human food rule specifies that a PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

There are some differences in the requirements of the CGMP & PC rule compared to the requirements of HACCP regulations and other preventive-based food safety programs such that the training provided by the International HACCP Alliance/GFSI/SQF/BRC etc or other institutions might not be equivalent. Such an individual may need additional training specific to the CGMP & PC rule. However, the CGMP & PC rule does not require any specific certifications, including certification by the FSPCA. In general, FDA will assess the adequacy of a facility's food safety plan rather than an

individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the rule, irrespective of documented training and experience.

PC.9 I have worked as a food safety manager for a very long time. Do I need to take PCQI training, or does my job experience satisfy the requirements to be a PCQI?

The preventive controls for human food final rule specifies that a PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum.

In general, FDA will assess the adequacy of a facility's food safety plan rather than an individual's documented qualifications. Deficiencies in the food safety plan indicate that a PCQI may need additional training specific to the rule, irrespective of documented training and experience.

PC.10 Can I use one PCQI for all my facilities, or must I have one PCQI for each facility?

The preventive controls for human food final rule does not prohibit a company from utilizing the services of a single PCQI for multiple locations. Additionally, there are no restrictions on the proximity of the locations that are under the direction of any PCQI. Note, however, that each facility must have a PCQI prepare or oversee the preparation of a food safety plan specific to that facility in accordance with 21 CFR 117.126(a)(2).

PC.11 What is a qualified facility?

A "qualified facility" is (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) either:

- A "very small business," a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee), or
- A facility to which both of the following conditions apply: During the 3-year period preceding the applicable calendar year,
  (1) the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
  (2) the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

(See 21 CFR section 117.3 for definitions of "qualified facility," "very small business," and "qualified end-user")

PC.12 What are the requirements applicable to a qualified facility?

A qualified facility is exempt from subparts C (Requirements for Hazard Analysis and Risk-Based Preventive Controls) and G (Requirements for a Supply-Chain Program) of the preventive controls for human food rule. However, a qualified facility is subject to modified requirements. It must submit two attestations to FDA: (1) an attestation that it is a qualified facility and (2) either an attestation that it has identified potential hazards, is implementing preventive controls to address the hazards, and is

monitoring performance of the preventive controls or an attestation that the facility is in compliance with non-federal food safety laws and regulations. Further, a consumer notification requirement may be applicable, depending on which attestation a qualified facility provides.

The compliance date for a business meeting the definition of a "qualified facility" (including a "very small business") is September 17, 2018. However, there is an earlier compliance date of January 1, 2016 for a facility to maintain (but not submit) financial records to support its status as a qualified facility.

The rule also establishes two additional compliance dates applicable to qualified facilities. First, it establishes December 17, 2018 as the compliance date for (1) the initial submission of the attestation by a facility that it is a qualified facility and (2) the attestation by a qualified facility about its food safety practices or that it is in compliance with non-federal food safety law. Second, it establishes January 1, 2020, as the compliance date for the consumer notification requirement. The consumer notification requirement applies to a qualified facility that submits an attestation that it is in compliance with applicable non-federal food safety law and requires such a facility to notify consumers as to the name and complete business address of the facility where the food was manufactured or processed.

PC.13 What records must be kept by a qualified facility regarding its attestations?

A qualified facility must maintain those records relied on to support the attestations (see 21 CFR section 117.201(f)).

PC.14 What form is used for qualified facility attestations?

Form FDA 3942a (for Human Food) is an attestation form for a food facility meeting the definition of a "Qualified facility." A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year. The attestations required must be:

- Submitted to FDA initially:
  - By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food before September 17, 2018;
  - Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food after September 17, 2018; or
  - By July 31 of the applicable calendar year, when the status of a facility changes from "not a qualified facility" to "qualified facility" based on the annual determination; and
- Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.
- When the status of a facility changes from "qualified facility" to "not a qualified facility" based on the annual determination, the facility must notify FDA of that change in status using Form 3942a by July 31 of the applicable calendar year.

More information about the qualified facility attestation form can be found at: http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/qualifiedfacilityattestation/default.htm

PC.15 In determining whether my business meets the definition of a "very small business," what is the meant by the "applicable calendar year"?

The applicable calendar year is the year after the three calendar years used to determine whether a facility is a very small business. The most recent applicable calendar year is the current year. For example, on June 3, 2024, 2024 is the most recent applicable calendar year and is the applicable calendar year when the three calendar years used to determine whether a facility is a very small business are 2021-2023. The exception is when three calendar years of records are not available, such as when a facility begins business after the compliance date for very small businesses. In such situations, the applicable calendar year refers to the year during which the calculation is made but is not preceded by 3 calendar years used to determine whether a facility is a very small business.

PC.16 Does the final rule include provisions to appeal the withdrawal of a qualified facility exemption?

Yes. The final rule provides procedures for a facility to appeal the withdrawal order and request an informal hearing. And there is a procedure for reinstating an exemption that was withdrawn.

PC. 17 How are the preventive controls rules different from the Hazard Analysis and Critical Control Points (HACCP) system?

The Hazard Analysis and Critical Control Points systems that many FDA-regulated manufacturers have in place are the foundation of the preventive controls regulations. Although there are similarities between the FSMA preventive controls requirements and the HACCP system, not every provision is identical. For example, in HACCP systems, controls are applied at critical control points (CCPs), whereas preventive controls include controls at CCPs or controls other than those at CCPs that are appropriate for food safety.

PC.18 What are the manufacturing/processing activities allowed under the farm definition?

Drying/dehydrating raw agricultural commodities that creates a distinct commodity, such as producing raisins and prunes from grapes and plums, and packaging and labeling such commodities, without additional manufacturing/processing are allowed under the farm definition. Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing, are other examples of manufacturing/processing activities that can be conducted under the farm definition.

PC.19 What does this final rule specifically require human food facilities to do when providing a by-product for use as animal food?

Processors already implementing human food safety requirements, such as brewers, would not need to implement additional preventive controls or Current Good Manufacturing Practice (CGMP) regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except to prevent physical and chemical contamination when holding and distributing the by-product. This regulation applies to human food facilities that both donate or sell a by-product for use in animal food. Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.

Further processing a by-product for use as animal food (e.g., drying, pelleting, heat-treatment) would require compliance with CGMPs to ensure the animal food’s safety and to make sure that the processing does not introduce hazards to the animal food. The company can choose to follow either the human food or animal food CGMPs when further processing the by-product. In addition, unless they are a qualified facility or otherwise exempt from subpart C (hazard analysis and preventive controls) the facility would need to assess its processing and determine whether there are any

hazards that would require a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring a preventive control would document such a determination in its hazard analysis but would not need to establish preventive controls.

PC.20 Do the preventive controls requirements apply to human food by-products for use in animal food that are dried, frozen or slightly modified specifically to facilitate storage and transportation?

As written, the CGMP and hazard analysis and risk-based preventive control requirements of the Preventive Controls for Animal Food rule apply to manufacturing/processing activities, including those performed to facilitate storage and transportation, unless an exemption applies. In draft guidance #239 Human Food By-Products for Use as Animal Food, we identified several manufacturing/processing activities for which there would only be limited CGMP requirements related to holding and distribution, including passive dewatering, as well as holding by-products at a particular temperature to facilitate transportation (e.g., keeping something in liquid or solid state).

Several sectors of the food industry have expressed concern about having to meet preventive controls requirements for certain other activities performed on their human food by-product and have asked that FDA consider streamlining the requirements for other activities that are also commonly performed to facilitate the storage and transportation of their by-products, including commingling ingredients, evaporating, chopping, mechanical mixing, pressing, trimming and washing.

The agency takes these concerns seriously and understands the practical value of these activities in preparing human food by-products for storage and transportation. As we implement FSMA requirements, we recognize the need to balance how these requirements impact current industry practices and the need to protect human and animal health. We are committed to working with industry to address these concerns, and are considering approaches that balance practical and public health considerations.

As we consider these approaches, the industry should be aware that in August 2017, we announced that we would not be conducting routine regulatory inspections of compliance with the animal food preventive controls requirements until the fall of 2018. This delay in routine regulatory inspections includes inspection of human food by-products that are further processed and required to comply with the animal food preventive control requirements.

PC.21 Are facilities (such as pilot plants or test kitchens) that manufacture/process, pack, or hold food for research and development (R&D), consumer testing, or as food samples subject to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule?

In general, a foreign or domestic facility that manufactures, processes, packs, or holds human food for consumption in the United States and that has to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act is subject to the requirements related to preventive controls (primarily located in subpart C and subpart G) of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117; 80 Fed. Reg. 55908) (CGMP & PC rule), unless subject to an exemption (see 21 CFR § 117.5 for exemptions). Note that an establishment may also be subject to the Current Good Manufacturing Practice (CGMP) requirements in subpart B; those requirements are not dependent on whether a facility is required to register.

If a research and development (R&D)/pilot plant or test kitchen is a facility required to register (see 21 CFR § 1.225 , it will be subject to the requirements of the CGMP & PC rule, unless an exemption applies (see 21 CFR § 117.5 for exemptions).

Food used in R&D or as product samples is "food" for purposes of the food facility registration requirements of section 415 of the FD&C Act (see 21 CFR Part 1, subpart H). Accordingly, a facility that manufactures/processes, packs, or holds food used in R&D or as product samples is required to register with FDA. However, if the food is not for consumption in the United States by humans or animals, the facility is not required to register (see FDA's Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition) - Revised, Answer to Question C.2.11: "Are facilities that manufacture/process, pack, or hold food used in research and development or as food samples required to register with FDA?")

If an R&D/pilot plant is not required to register with FDA, it not subject to the requirements of subpart C(Hazard Analysis and Risk-Based Preventive Controls) and subpart G (Supply-Chain Program) of the CGMP & PC rule. However, the R&D/pilot plant could still be subject to the requirements of subpart B (Current Good Manufacturing Practice (CGMP)) of the CGMP & PC rule.

PC.22 What are "Unexposed packaged foods"? Do unexposed packaged foods have to be in final packaged form ready for consumer purchase, or can they be ingredients that will be used in further processing to manufacture finished foods?

"Unexposed packaged food" means packaged food that is not exposed to the environment (see 21 CFR § 117.3). A food does not have to be packaged for a retail consumer (e.g., boxes of crackers or packages of chips) to be an unexposed packaged food. For example, an ingredient that will be used as a direct additive in food may be packaged in such a way that it meets the definition of "unexposed packaged food." Unexposed packaged food is protected from outside bacteria by its packaging. See also the discussion in Response 170regarding produce packed in "vented crates," which is not "unexposed packaged food." (See Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule, Response 170; 80 Fed. Reg. 55908 at 55970 (CGMP & PC Rule)).

PC.23 If a facility is solely engaged in the storage of unexposed packaged food, is it exempt from the requirements for preventive controls?

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117; 80 Fed. Reg. 55908) (CGMP & PC rule) creates requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food. In general, if a facility manufactures, processes, packs, or holds food for human consumption in the United States and has to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (see 21 CFR Part 1, subpart H), the facility is subject to the preventive controls requirements in the CGMP & PC rule, unless subject to an exemption. Note that an establishment may also be subject to the Current Good Manufacturing Practice (CGMP) requirements in subpart B; those requirements are not dependent on whether a facility is required to register.

Subparts C (Requirements for Hazard Analysis and Risk-Based Preventive Controls) and G (Requirements for a Supply-Chain Program) of CGMP & PC rule do not apply to a facility **solely** engaged in the storage of unexposed packaged food (see 21 CFR § 117.7(a)).

To qualify for the exemption, the facility storing the unexposed packaged food must be **solely** engaged in the storage of unexposed packaged food. For example, the exemption in § 117.7 would not apply to a facility that stores but also processes food (see CGMP & PC rule, Response 212; 80 Fed. Reg. 55908 at 55985). Also note that unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in 21 CFR § 117.206.

PC.24 Is a facility that is solely engaged in the storage of unexposed packaged food exempt from the requirements for preventive controls if some of the unexposed packaged food that is stored requires time/temperature control prevent or minimize pathogen growth?

A facility solely engaged in the storage of unexposed packaged food, including unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens **is subject to the modified requirements in** 21 CFR § 117.206 for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (see 21 CFR § 117.7(b)). Thus, the modified requirements apply to the food that requires the time/temperature control.

PC.25 What exemptions from preventive controls are included in the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule?

In general, a foreign or domestic facility that manufactures, processes, packs, or holds food for consumption in the United States and has to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (see 21 CFR Part 1, subpart H) is subject to the requirements related to preventive controls (primarily located in subparts C and G) of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117; 80 Fed. Reg. 55908) (CGMP & PC rule), unless subject to an exemption. Note that an establishment may also be subject to the Current Good Manufacturing Practice (CGMP) requirements in subpart B; those requirements are not dependent on whether a facility is required to register. Also, the CGMP requirements may apply to facilities or food exempt from preventive controls (see 21 CFR 117.5(k) for exemptions from CGMPs).

The CGMP & PC rule contains the following exemptions or modified requirements related to preventive controls:

Exemptions:

- Activities subject to seafood HACCP (21 CFR Part 123) at a facility in compliance with seafood HACCP (21 CFR 117.5(b))
- Activities subject to juice HACCP (21 CFR Part 120) at a facility in compliance with juice HACCP (21 CFR 117.5(c))
- Activities subject to 21 CFR Part 113 (low acid canned foods) at a facility in compliance with part 113 (21 CFR 117.5(d)). This exemption is limited to microbiological hazards that are regulated under part 113.
- Manufacturing, processing, packaging, or holding a dietary supplement that is in compliance with certain requirements (21 CFR 117.5(e))
- Activities of a facility subject to the produce safety regulation in 21 CFR Part 112 (21 CFR 117.5(f))
- Certain low-risk on-farm activities on certain foods conducted by small or very small businesses (21 CFR 117.5(g) and (h)).
- Alcoholic beverages and prepackaged food at certain facilities that manufacture, process, pack, or hold alcoholic beverages (21 CFR 117.5(i))
- Facilities solely engaged in the storage or raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing (21 CFR 117.5(j))

Modified Requirements:

- Qualified facilities (21 CFR 117.5(a))
- Facilities solely engaged in the storage of unexposed packaged food (21 CFR 117.7). There are modified requirements applicable to these facilities for unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (21 CFR § 117.206).