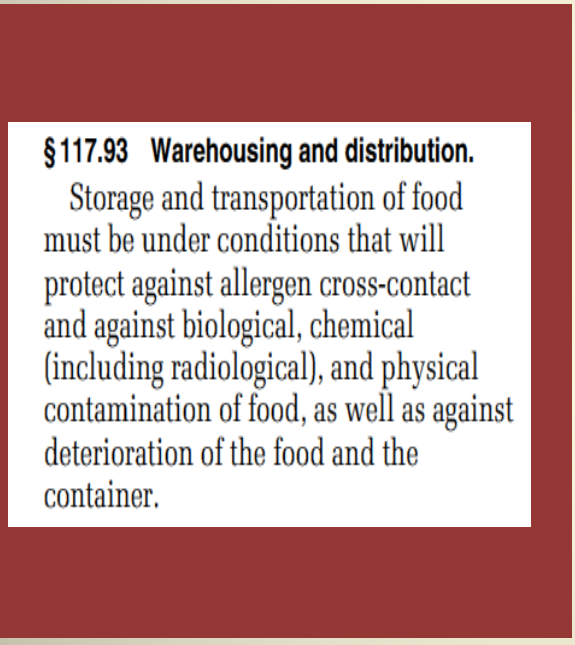
Convenience Distribution ASSOCIATION



§ 117.93 Warehousing and distribution.

Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

Food Safety Modernization Act – Preventive Controls Rule for Human Foods

Are you ready?

By: Anne Barker-Smith
A. Barker-Smith Consulting, LLC

The FDA Food Safety Modernization Act (FSMA) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule is now final and compliance for some businesses begins as early as September 2016.

On September 17, 2015 the FDA published the final *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food* – (in this article referred to as the Preventive Controls for Human Foods Rule). This rule directly covers all firms involved in the manufacturing, packing, or holding human food. This final rule has been two years in the making according to the FDA, "The final rule has elements of both the original and supplemental proposals, in addition to new requirements that are the outgrowth of public input received during the comment period for both proposals". Although the FDA is not comfortable with the acronym, some in the industry have term this process HARPC.

The Preventive Controls Rule for Human Foods has updated the Good Manufacturing Practices (GMP's) regulations for all operations regardless of size or type. Formerly codified in 21 CFR Part 110, the rules have been updated and moved to 21 CFR Part 117. All facilities, regardless of size or operational exemptions, must be in compliance with these rules as they are proven to serve as the back bone of all successful food safety programs. As before, these modernized GMP's cover facility structure/conditions, water suitability and safety, pest management, storage conditions, and other basic operations that ensure that products are not contaminated by their environment. The primary difference is that records are now required as evidence that certain activities have been monitored to ensure control and prove effectiveness.

While the Preventive Controls Rule for Human Food applies to most food processing and food warehousing operations it will not apply to all foods and animal feeds. **The principal exclusions from the Preventive Controls Rule are:**

(i) food that is not regulated by FDA (i.e., food regulated by USDA – meat, poultry and eggs)

(ii) food excluded from Preventive Controls for Human Foods Rule because it is the subject of a similar regulatory scheme (i.e., seafood, juice HACCP)

(iii) or is addressed under another section of FSMA other than Preventive Controls for Human Foods Rule (e.g., fresh unprocessed produce falls under the Produce Safety Rule).

In addition, for certain types of facilities, the FDA has issued exemptions or modifications of the requirements of Preventive Controls for Human Foods Rule, such as some farm activities and very small business. Food warehouses that only sell dry products in "unexposed packaging" must comply with the GMP portion of the rule.

Food warehouses that handle foods in "unexposed packaging" that are temperature controlled for safety (TCS), have modified requirements in that they must meet both GMP and have evidence of temperature controls. In both cases certain records must be maintained.

Facilities that handle exposed products (e.g., storing produce in vented crates, or break cases to sell individual units) of any type must conduct a hazard analysis and evaluate whether there are hazards (biological, chemical or physical hazard could be introduced either accidentally or intentionally) that

would require a preventive control. Facilities of this type must have a written food safety plan. Facilities that import products or sell animal feed (pet food) may have additional requirements in order to be incompliance with additional sections of FSMA.

As a food distributor, unless you are a small or very small business (less than 500 employees, or are selling less than 1 million dollars a year in food), you are required to meet all GMP regulations by September 17, 2016. If you fall under the approved modified requirements (TCS unexposed packaging), you will need to meet the GMP regulations and have at minimum records that show products have not been temperature abused. In this case, FDA permits exception temperature documentation (e.g., alarm reports, non-compliance documents, as long as they provide sufficient time/temperature and disposition and corrective action information). Small or very small businesses have until September 17, 2017 to be full incompliance with covered aspects of the Preventive Controls Rule for Human Food, other sections will have other compliance dates.

Due to the operational nature of most Convenience Store Distributors, you are selling TCS foods in both unexposed and exposed packaging (vented cartons or by breaking master cases). Additionally some facilities may actually be cutting or repacking produce or making deli products for their customers, in these cases this portion of the business regardless of sales or profitability is by definition considered a processor and must be in full compliance with the Preventive Controls Rules for Human Food.

Not exempt…So what do you need?

In a nutshell, each covered facility must conduct a written Hazard Analysis which is used to identify all required preventive controls and establish in writing as necessary a plan to prevent hazards. The food safety plan and associated records must be available upon request by the FDA. *At a minimum the food safety plan must be evaluated* in its entirety every three years, and should be evaluated whenever there is a significant operational or product change or industry issue that may impact the plan.

The written food safety plan must include the following elements:

- **Hazard analysis** [*required by § 117.130(a)(2)*] **:** The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).
- **Preventive controls** [*required by § 117.135(b)*]**:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include:
  - **Process:** Standard Operational Procedures (SOP's) that control warehouse operations and ensure hazards identified in the hazard analysis are not introduced and are controlled while the product is in the firm's control. Examples include but are not limited to receiving, storage and shipping procedures.
  - **Food Allergen:** Big Eight Allergens include: Eggs, Wheat, Milk, Soy, Tree Nuts, Peanuts, Fin-fish, and Crustacean Shellfish. Expected is a plan that controls the potential for cross-contact (accidental introduction or inclusion) with any allergens that are in the facility. In most cases this applies to open packaging, totes used to transport multiple products, or storage where leakage (e.g., dusting or liquid) could contaminate a product. Examples include but are not limited to: Peanut dust from burlap sacks, Milk or Flour spills on lettuce, apples or broccoli.

- **Sanitation Controls:** General sanitation is required under the GMP section of the regulations. In the case of Sanitation Preventive Controls, these are controls that are identified as critical and would result in a food safety failure or breakdown if improperly applied or followed. Examples may include but are not limited to: handwashing and glove use, food contact surfaces, sanitation of scales or containers used to ship open product.
- **Supply-chain Controls** [*required by subpart G*]: You should purchase products from approved vendors who can demonstrate that they are incompliance with all applicable federal food safety laws. Imported products have additional requirements, and your customers may be required to ensure they are buying products from approved vendors and as such may be impacted by substitutions, vendor or other sourcing changes. This was added as a direct result of PCA's 2009 Peanut Recall that resulted in 300 firms being affected by a single contaminated source.
- **Recall plan** [*required by § 117.137(a)*] –the caveat here is this is required if a preventive control has been identified by the hazard analysis. However, please also note that a written RECALL plan is required by the 2002 Bioterrorism Act and is generally accepted as a good business practice. Although Recalls do not prevent food safety issues from occurring, when conducted effectively they reduce the number of illnesses or injuries that would result from adulterated or misbranded products that have enter trade. Additionally under FSMA the FDA can mandate a recall and if you do not or cannot effectively and efficiently participate FDA has the legal authority to conduct one on your behalf and charge you $216 per hour

❖ **Oversight and management of preventive controls.** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.

- **Monitoring** [*required by § 117.145(a)(1)*]**:** These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring the temperature of your coolers & freezers. FDA permits temperature exception records but the instruments still have to be calibrated, so using a calibrated thermometer and recording actual temperature values would be a better monitoring practice especially if temperatures are your preventive control. Additionally, monitoring preventive maintenance activities on coolers, freezers or truck refrigeration units could be a simple record of the date on which the activity took place.
- **Corrective actions and corrections** [*required by §117.150(a)(1)*]**:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during handling or storing food. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records. For example – a correction would be noticing that the cooler which is normally kept between 35-38^{o}F and the unit is not functioning properly - product temperature is being monitored and situation is corrected before product temperature reaches 41^{o}F. A corrective action would be necessary if the unit is broken but the situation is not discovered or fixed before product temperature exceeds 41^{o}F. Product safety may be compromised so the event should undergo a root cause

investigation, where policies, procedures or training or retraining may need alterations or actions.

- **Verification** [*required by §117.165(b)*]**:** These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

  Product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control. In the case of a warehouse facility, this might only be necessary when the hazard analysis indicates it is warranted or the activity has been shown to be at risk by an outbreak.

❖ **It is important to note:** Many activities required by the final rule must be conducted (or overseen) by a *"preventive controls qualified individual"*. A preventive controls qualified individual is a qualified individual 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.

What flow and format must I use?

The new mantra under FSMA is "if you didn't write it down, you didn't do it" conversely, "if you wrote it down –that's the way it happened!" –proper records are your only defense.

If you are operating under a HACCP based food safety program, or have recently passed a 3rd party GMP audit, the documentation that is required, will help you become compliant with the Preventive Controls Rule for Human Foods. Some documentation may need to be updated, altered/adjusted or created. *There is not one format, layout, or look that is recommended or required, but there are key elements that must be included.*

The Food Safety Plan is the sum of the parts, the format of the individual documents or records are not as important as the content. Although not required, an opening statement about the company's operational size, mission, customer base and product mix, is helpful, as it set the stage and helps identify potential risks (population, products, work flow, suppliers etc.). A flow diagram is also not required; however, it is most helpful when conducting the hazard analysis to fully identify steps at which a preventive control should be applied.

Followed by the firm's preventive controls and/or regulatory HACCP CCP's, the hazard analysis by product, followed by the operational policies and procedures that support the food safety plan. **FDA does expect the plan to be facility specific**, and all documents including food safety records should include: the name and address of the firm, an effective date, and a document ID. The ID could be a number, title, or both, that can be used to ensure everyone is using or following the same form, policy,

procedure, or preventive control requirements. Food safety records must identify who took the record, and what day and time the record was taken as well as all actions required to satisfy the purpose of the record.

Regardless of format or style used each policy & procedure should have the what, when, why and who, and how to deal with a failure (corrective action) outlined so that it matches what you want your staff to do, and they can easily follow.

Best Practices expect the inclusion of the following in each document:

- ✓ Purpose (why – are we doing this what are we trying to accomplish or protect)
- ✓ Responsibilities (who does what – positional),
- ✓ Complementary documentation & monitoring records (what records should be taken – what other policies or procedures might apply) –Note: Required monitoring records (forms/temperature records) should be easily identifiable.
- ✓ Process/actions or activities (the what -- actions necessary or expected including established correction steps – how to fix before it is a problem).
- ✓ Corrective Actions (in the event the policy fails or was not caught in time) – what do you do with the product, why did the failure occur, what is the root cause
- ✓ Signature of understanding or adherence by management and the responsible parties.
- ✓ A change record (when, what or why it was changed, who authorized the change) is used to track when and how your plan changes over time.

Please note: The FSCPA Preventive Controls Qualified Individual Course has numerous acceptable formats, all of which are some variation on the Seafood HACCP documentation that is found in the back of the Seafood HACCP Guidance Book – April 2011.

(http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm)

Have questions or need help?

A. Barker-Smith Consulting, LLC

Contact: Anne Barker-Smith, Owner

Email: anne@abarker-smithconsulting.com

Phone: 804-305-2272