WHITE PAPER

Understanding GMPs in Food Processing

REMCO PRODUCTS

The basics.

In many industries, there are procedures and standards that are followed to assure a quality product. These are often referred to as Good Manufacturing Practices, or GMPs.

In food processing, GMPs are usually referred to as practices and procedures performed by a food processor which can affect the safety of the food product. GMPs may refer to the people, equipment, process and the environment in the production process. (1)

The Food and Drug Administration (FDA) enforces certain GMPs that are applied to food, human and animal drugs, biologics, devices, processed tissues and most recently dietary supplements. (2)

GMPs were actually developed with the advent of US regulation of the pharmaceutical industry. Early in the 20th century, there were few regulations governing the purity, consistency and efficacy of drugs, which resulted in errors and complications, some with tragic consequences. Congress passed the Federal Food, Drug and Cosmetic Act in 1938, for the first time requiring companies to prove their products were safe. Then in the 1970s, GMP requirements were put in place for pharmaceuticals as well as medical devices to assure these products would meet the stringent quality standards.(3) Now GMPs are recognized and used in food processing as the foundation for the preparation, packaging and distribution of safe food throughout the world.

HACCP defined.

GMPs are sometimes prefixed with the letter "C" meaning "Current Good Manufacturing Practices." When referred in food processing, CGMPs and GMPs are generally considered the same.

CGMPs in food processing.

Current food Good Manufacturing Practices (CGMPs) are published in Title 21 of the Code of Federal Regulations, Part 110 (21 CFR 110). These CGMPs describe the methods, equipment, facilities, and controls for producing processed food. As the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of regulatory control over the safety of the nation's food supply. CGMPs also serve as one basis for FDA inspections.(4)

The FDA outlines current CGMPs for food processing in five written subparts: (5)

1. **General Provisions (Subpart A)** — The first section defines terminology used in describing CGMPs. It also delineates plant and employee responsibilities with regard to personal hygiene. Food safety education is addressed as well as the need for supervisory personnel to ensure compliance.

2. **Building and Facilities (Subpart B)** — In this section, CGMPs are outlined for the maintenance of the grounds, including litter control, waste removal and treatment, and grounds maintenance and drainage. Plants should be designed and built to reduce the potential for contamination. Sanitary operations, facilities and controls are also outlined.

3. **Equipment (Subpart C)** — This section provides requirements and expectations for the design, construction and maintenance of equipment and utensils to ensure sanitary conditions. It also includes an automatic control for regulating temperature or an alarm system to alert employes to significant change in temperature. Other requirements are general and intended to prevent contamination from any source.

4. **Process and Controls (Subpart E)** — This section of CGMPs addresses general sanitation and controls necessary to ensure that food is suitable for human consumption. It addresses the monitoring of physical factors (critical control points or CCPs), such as time, temperature, humidity, pH, flow rate, and acidification. Warehouse and distribution requirements are also included, requiring finished foods to be stored and distributed under conditions that protect against physical, chemical and microbial contamination. The container must also be protected from deterioration. This section also outlines very general requirements for warehousing and distribution.

5. **Defect Action Levels (Subpart G)** — The last part of the food CGMPs allows the FDA to define maximum defect action levels (DALs) for a defect that is natural or unavoidable even when foods are produced under CGMPs (as covered in the sections above). These defects are not hazardous to health at low levels and include rodent filth, insects or mold. Those exceeding maximum DALs will be considered in violation.

FSMA and CGMPs.

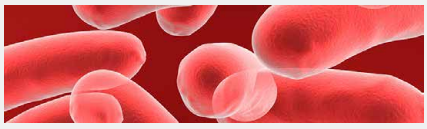
The Food Safety and Modernization Act (FSMA) of 2011 contains new provisions in Section 103 requiring hazard analysis and risk-based preventive controls. The provisions would require facilities to maintain a written food safety plan that would identify hazards, specify the steps that would put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results, and specify what actions would be taken to correct the problems that arise.[6]

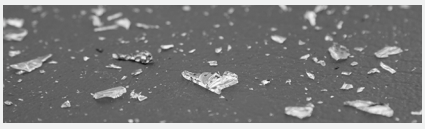
What constitutes a hazard?

Biological hazards — The Centers for Disease Control (CDC) lists four levels of biohazards. Level One: Bacteria and other microorganisms that are transmitted from one person to another via contact or through the air, e.g., Escherichia Coli and Bacilius subtilis. Level Two: Viruses and more severe bacteria, e.g., measles, influenza, and salmonella poisoning. Level Three: Strains and species of viruses that are more harmful to humans and could lead to death, e.g., Typhus and West Nile virus. Level Four: The most severe known and are often fatal, e.g., Ebola virus and Marburg virus. [7]

Physical hazards — Any extraneous object or foreign matter in a food item which may cause illness or injury to a person consuming the product. These foreign objects include, but are not limited to bone or bone chips, metal flakes or fragments, injection needles, BB's or shotgun pellets, pieces of product packaging, stones, glass or wood fragments, insects or other filth, personal items, or any other foreign material not normally found in food products. Sources for such contaminants include raw materials, badly maintained facilities and equipment, improper production procedures and poor employee practices. [8]

Chemical hazards — There are two primary categories of chemical hazards: prohibited substances and unavoidable poisonous or deleterious substances. None of the prohibited substances should be in food ingredients or supplies. The FDA has tolerance levels for unavoidable chemical hazards such as pesticides, herbicides, growth hormones and antibiotics, additives and processing aids, lubricants, paints, cleaners and sanitizers.[9] Allergens are also considered with chemical hazards. The top eight food allergens include milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans. [10]





Did you know...

The proposed FSMA rule on preventive controls for human food would apply to food facilities that manufacture, process, pack or hold human food. Facilities would to be required to register with the FDA and would be regularly inspected by either the FDA or a state or local government entity.

While the FSMA proposed rule comment period has still not passed, it has set the stage for food processors to be proactive in developing preventive controls in the four areas as outlined by the FDA:

1. **Process controls** — steps, actions and checkpoints to assure the integrity of the food manufacturing process.
2. **Food allergen controls** — to help reduce the risk of cross-contamination of food processes with known food allergens.
3. **Sanitation controls** — those steps or actions taken before, during or after food production that help prevent contamination of the food process.
4. **A recall plan** — a plan of action for the removal or correction of a marketed product that is in violation of food safety requirements.

FSMA would also modify the existing CGMP regulations to provide clarification that requirements intended to control against contamination of food also require protection against cross-contact of food by allergens.[11] Other language in the regulation would be modernized for clarification, and some outdated requirements would be updated or deleted.

Every food processor must follow CGMPs.

Existing CGMPs published in 21 CFR 110 are required for all facilities. If modified by FSMA, the new CGMP requirements would still apply to facilities exempt from the hazard analysis and risk-based preventive control requirements.

Four Focus Areas of the Food Safety Modernization Act

The FDA lists its Exemptions and Modified Requirements for Preventive Controls for Human Food as follows: [12]

Type of Facility or Operation	Hazard Analysis and Risk Based Preventive Control Requirements	Current Good Manufacturing Practices (CGMP)
Certain low-risk manufacturing/processing activities, packing or holding activities that are conducted by small or very small businesses on farms for specific foods. Examples including making jams and jellies, honey, and maple syrup.	Exempt	Must comply
Foods subject to the low-acid canned food (LACF) regulation. The exemption for facilities producing low-acid canned food applies only to those microbiological hazards addressed by the LACF regulation.	Exempt	Must comply
Foods subject to HACCP regulations (seafood and juice)	Exempt	Must comply
Dietary supplements	Exempt	Must comply with dietary supplement CGMPs
Alcoholic beverages at certain alcohol-related facilities, and certain prepackaged food sold in limited quantities along with alcoholic beverages at the same facilities.	Exempt	Must comply
A facility that has food sales averaging less than $500,000 per year during the last three years. In addition, sales to qualified end users must exceed sales to others. A qualified end-user is either a consumer (in any location), or a restaurant or retail food establishment purchasing the food for sale directly to consumers that is located in the same State or not more than 275 miles away	Modified Preventive Control Requirements Apply: Facility must certify that it is a “qualified facility” and that it is implementing and monitoring preventive controls or complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.	Must comply
A very small business. Three options are being proposed to define a very small business: less than $250,000, less than $500,000, and less than $1,000,000 in total annual sales of food, adjusted for inflation.	Modified Preventive Control Requirements Apply: Facility must certify that it is a “qualified facility” and that it is implementing and monitoring preventive controls or complying with applicable non-Federal food safety law (which triggers a labeling requirement). Also must maintain records to support certifications.	Must comply
Activities within the definition of “farm”	Exempt	Exempt
Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment	If refrigeration is not required for safety, the facility is exempt If refrigeration is required for safety, modified preventive control requirements apply: Requirements concerning temperature controls, including monitoring, verification and records.	Must comply
Facilities such as grain elevators that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing	Exempt (provided they are solely engaged in such storage)	Exempt
Facilities, such as warehouses, that store raw agricultural commodities that are fruits and vegetables intended for further distribution or processing.	Must comply	Exempt

(Note: This chart does not contain all of the information necessary to determine the proposed requirements for compliance in a particular circumstance. Consult the proposed rule for specific requirements.)

Conclusion.

For food processors, assuring food safety should go beyond compliance with government regulations. Quality food producers should consider continually looking for ways to improve their processes for the protection of all those who consume their products. In the meantime, CGMPs and the proposed FSMA rule regarding food safety plans will continue to guide the food industry. The comment period for the FSMA Proposed Rule for Preventive Controls for Human Food Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Human Food ends on November 15, 2013.[13]

References:

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(10) FDA, http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm079311.htm

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