SECTION ONE

CURRENT FOOD GOOD MANUFACTURING PRACTICES

Current food good manufacturing practices (GMPs) are published in Title 21 of the Code of Federal Regulations, Part 110 (21 CFR 110). GMPs 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. GMPs also serve as one basis for FDA inspections.

The current GMPs are the result of an extended rulemaking process that spanned decades. The following section (Section 1.1) describes when, why, and how the food GMPs were developed and some of the obstacles that were overcome. Table 1-1 summarizes the major events that led to the development of GMPs as they are today. Section 1.2 provides a detailed discussion of the requirements in each of the five subparts of the GMP regulation, and concludes with a table (Table 1-2) outlining the main requirements.

1.1 The Development of Food GMPs

Food safety has been regulated since the mid-1800s and was mostly the responsibility of local and state regulators. However, the Pure Food and Drugs Act, passed by Congress in 1906, marked the first major federal consumer protection law with respect to food processing. The 1906 law prevented interstate and foreign commerce in misbranded or adulterated foods, drinks, or drugs. The intent of the Act was to prevent poisoning and consumer fraud. As more food products were manufactured in subsequent years, however, poor-quality food products and deceptive packaging continued to be produced due to loopholes in the law. Consumers were often unaware of what they were buying until products were opened. Therefore, in 1933, the FDA decided to overhaul the 1906 Act.

In 1938, after a battle about USDA jurisdictions with respect to the Act's enforcement, the Food Drug, and Cosmetic Act (FDCA) replaced the 1906 Act. The FDCA provided the necessary identity and quality standards to protect consumers from fraud. The FDCA provides the regulatory basis for today's food GMPs. Two sections of the FDCA are directly related to conditions in a facility where food has been manufactured.

- Section 402 (a)(3) specifies that food has been manufactured under such conditions that it is unfit for consumption.
- Section 402 (a)(4) considers that food may be adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.

These provisions are unlike other parts of Section 402, in that they relate to the conditions of a facility where food is produced or stored. Thus, instead of having to prove that the food is adulterated, insanitary conditions are considered sufficient to show that the food might have become adulterated.

Given the FDCA's vagueness in establishing violations and thus, the difficulty of enforcing it, FDA began working on draft GMP regulations by the mid-1960s (although others had made the suggestion to do so as early as 1948). The objective of the GMP regulations was to describe general rules for maintaining sanitary conditions that must be followed by all food processing facilities to ensure that the statutory requirements of Section 402(a)(3) and (4) were met. After much industry involvement, including much debate about FDA's authority to adopt rules to carry out the provisions of the FDCA, the GMP regulations for food processing facilities were finally proposed in 1968 (see Table 1-1).

Three broad categories of interrelated issues arose during the development of the GMPs (Dunkelberger, 1995):

- Concern that the regulations were unduly stringent and especially burdensome for small food companies without necessarily improving the quality or safety of foods.
- Contention that the GMP regulations must prescribe conditions that "reasonably" relate to insanitary conditions that may contaminate food and render it injurious to health.
- Assertions that the regulations did not have the force of law.

These first two issues were resolved mostly through the use of more general terms, such as "adequate," "sufficient," and "suitable," rather than hard-line standards. FDA also used "shall" when the agency felt compliance was necessary and "should" when practices in the rule were less obviously related to the statutory requirements of the Act. The third issue became inconsequential when it was proved that FDA did have the statutory authority to promulgate the GMP regulations. The GMP regulations were finalized in April of 1969 and published as Part 128 of the Code of Federal Regulations (CFR). In 1977, Part 128 was recodified and published as Part 110 of the CFR.

The final GMP regulations were very broad, not specifying what exactly a facility must do to comply. This naturally created enforcement problems for the FDA. To address the ambiguity created by the umbrella GMPs, FDA next tried to develop industry-specific GMPs through the mid-1970s. By the late 1970s, however, FDA decided to improve the umbrella GMPs rather than adopting industry-specific GMPs. The revisions were finalized in 1986 and printed in 21 CFR 110. Specific GMPs were also included and printed in 21 CFR Parts 100 through 169 for:

- Quality control procedures for nutrient content of infant formula (21 CFR 106).
- Thermally processed low-acid canned foods in hermetically sealed containers (21 CFR 113).
- Acidified foods (21 CFR 114).
- Bottled drinking water (21 CFR 129).

In July of 2002, FDA formed a Food GMP Modernization Working Group to examine the effectiveness of current food GMPs given the many changes that have occurred in the food industry since 1986. The Working Group has been researching the impact of food GMPs on food safety, as well as on the impact (including economic consequences) of revised regulations. Part of the group's current effort, as of June 2004, is to find out which elements of the food GMPs are critical to retain and which should be improved. FDA is now holding public meetings to obtain the public comments to assist in this effort.

Table 1-1: Food GMP Development Timeline

Date	Milestone
1906	The Bureau of Chemistry passes the 1906 Pure Food and Drugs Act, prohibiting interstate commerce in misbranded and adulterated foods, drinks, and drugs
1933	FDA recommends revising the 1906 Pure Food and Drugs Act
1938	FDA passes the 1938 Federal Food, Drugs, and Cosmetics Act, which provides identity and quality standards for food
Mid 1960s	FDA decides to clarify the FDCA through GMP regulations
1968	FDA proposes food GMP regulations
1969	FDA finalizes food GMP regulations
Early 1970s	FDA considers promulgating industry-specific regulations
Late-1970s	FDA decides to revise the general GMPs rather than adopting industry-specific GMPs
1986	FDA publishes revised food GMPs
2002	FDA forms Food GMP Modernization Working Group
2004	FDA announces effort to modernize food GMPs

Source: Dunkelberger, 1995; FDA, 1981b.

1.2 Key Provisions of Food GMPs

The current GMPs consist of seven subparts, two of which are reserved. The requirements are purposely general to allow individual variation by manufacturers to implement the requirements in a manner that best suit their needs. Table 1-2 summarizes the five written subparts, which are discussed in further detail below.

1.2.1 General Provisions (Subpart A)

The general provisions in Subpart A of the food GMPs are divided into four sections. The first section defines much of the terminology used in describing GMPs. The terms "shall" and "should" are also defined to differentiate between when compliance is necessary ("shall") and when procedures and practices are not directly related to insanitary conditions as specified in Section 402(4)(a) ("should").

The section on personnel delineates plant and employee responsibilities with regard to personal hygiene. For example, personnel with diseases or other conditions that could contaminate food are to be excluded from manufacturing operations. The section also outlines expectations with respect to personal hygiene and cleanliness, clothing, removal of jewelry and other unsecured objects, glove maintenance, use of hair restraints, appropriate storage of personal items, and restrictions on various activities, such as eating and smoking. The section discusses the need for appropriate food safety education and training in very general terms. The subpart further mandates the assignment of supervisory personnel to ensure compliance.

Currently, establishments that only harvest, store, or distribute raw agricultural commodities are exempt from the requirements of Subpart A, although FDA reserves the right to issue special regulations to address this sector.

1.2.2 Buildings and Facilities (Subpart B)

Subpart B of the food GMPs outlines requirements for the maintenance, layout, and operations of food processing facilities.

Section 110.20 outlines the requirements for adequate maintenance of the grounds, including litter control, waste removal and treatment, and grounds maintenance and drainage. The subpart requires

that plants be designed and built to reduce the potential for contamination. Some detail is provided on how to achieve this, but the requirements are largely focused on the end result of a sanitary facility rather than specific practices. The language also includes many general terms to allow flexible implementation of the requirements.

Section 110.35 describes sanitary operations. Physical facilities, equipment, and utensils are to be sanitized in a way that protects against food contamination. Storage of cleaning materials and toxic materials permitted are outlined to prevent contamination with chemicals. The section also briefly addresses pest control and cleaning of various food contact surfaces, as well as the frequency of cleaning.

Section 110.37 describes the requirements for adequate sanitary facilities and controls, including the water supply, plumbing, toilet and hand-washing facilities, and rubbish and offal disposal. Some of the requirements of the section are fairly specific, such as the requirement of self-closing doors for toilet facilities, whereas others remain general, such as plumbing of adequate size and design.

1.2.3 Equipment (Subpart C)

Subpart C describes the requirements and expectations for the design, construction, and maintenance of equipment and utensils so as to ensure sanitary conditions. It also adds a specific requirement; an automatic control for regulating temperature or an alarm system to alert employees to a significant change in temperature. Other requirements of the subpart are fairly general and intended to prevent contamination from any source.

1.2.4 Production and Process Controls (Subpart E)

The first section of Subpart E lists the general sanitation processes and controls necessary to ensure that food is suitable for human consumption. It uses more general words (e.g., “adequate,” “reasonable,” etc.) and covers many aspects not discussed in previous subparts. This section also addresses the monitoring of physical factors (critical control points), such as time, temperature, humidity, pH, flow rate, and acidification.

The second section outlines very general requirements for warehousing and distribution. The section requires finished foods to be stored and distributed under conditions that protect against physical,

chemical, and microbial contamination. The container and the food must also be protected from deterioration.

1.2.5 Defect Action Levels (DALs) (Subpart G)

The last subpart of the food GMPs allows FDA to define maximum defect action levels (DALs) for a defect that is natural or unavoidable even when foods are produced under GMPs as set out in the other subparts of the regulations. Generally, these defects are not hazardous to health at low levels; they include rodent filth, insects, or mold. The DALs are defined for individual commodities and may be obtained by request from FDA, which produces a Handbook on Defect Action Levels for Food. They are also available from the FDA Web site (http://www.cfsan.fda.gov/~dms/dalbook.html). Table 1-3 provides examples of the maximum DALs for select food products. Manufacturers are expected to use quality control operations that reduce the level of the defect to the lowest possible levels. Those exceeding maximum DALs will be considered in violation of Section 402 (3)(a) of the FDCA.

The section bans blending of food with a defect level above a maximum DAL with other food. It also stresses that compliance with DALs does not excuse violations of Section 402(4)(a) of the FDCA or that of the other subparts of 21 CFR 110.

Table 1-2: Summary of 21 CFR Part 110: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

Subpart A. General Provisions		
Section 110.3	Definitions	Definitions of: • Acid foods/acidified foods • Adequate • Batter • Blanching • Critical control point • Food • Food-contact surfaces • Lot • Microorganisms • Pest • Plant • Quality control operation • Rework • Safe-moisture level • Sanitize • Shall • Should • Water activity
Section 110.5	Current good manufacturing practice	• Criteria for determining adulteration • Food covered by specific GMPs is also covered by umbrella GMPs
Section 110.10	Personnel	Requirements for: • Disease control • Cleanliness • Education and training • Supervision of personnel with regards to these requirements
Section 110.19	Exclusions	• Excluded operations (raw agricultural commodities) • FDA can issue special regulations to cover excluded operations
Subpart B. Buildings and Facilities		
Section 110.20	Plant and Grounds	• Description of adequate maintenance of grounds • Plant construction and design to facilitate sanitary operations and maintenance
Section 110.35	Sanitary Operations	Requirements for: • Cleaning/sanitizing of physical facilities, utensils, and equipment • Storage of cleaning and sanitizing substances • Pest control • Sanitation of food contact surfaces • Storage and handling of cleaned portable equipment and utensils
Section 110.20	Sanitary Facilities and Controls	Requirements for: • Water supply • Plumbing • Sewage disposal • Toilet facilities • Hand-washing facilities • Rubbish and offal disposal

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Subpart C. Equipment		
Section 110.40	Equipment and Utensils	• Requirements for the design, construction, and maintenance of equipment and utensils
Subpart E. Production and Process Controls		
Section 110.80	Processes and controls	Delineates processes and controls for: • Raw materials and other ingredients • Manufacturing operations
Section 110.93	Warehousing and distribution	Storage and transportation of food must protect against contamination and deterioration of the food and its container
Subpart G. Defect Action Levels		
Section 110.10		• FDA has established maximum defect action levels (DALs) for some natural or unavoidable defects • Compliance with DALs does not excuse violation of 402 (a)(4) • Food containing defects above DALs may not be mixed with other foods

Source: Federal Register 51, 1986.

Table 1-3: Maximum Defect Action Levels for Selected Food Products

Food Product	Maximum Defect Action Level
Allspice (ground)	• Average of 30 or more insect fragments per 10 grams • Average of 1 or more rodent hairs per 10 grams
Broccoli (frozen)	• Average of 60 or more aphids, thrips, and/or mites per 100 grams
Cocoa beans	• More than 4% of beans by count are moldy • More than 4% of beans by count are insect-infested or insect-damaged • More than 6% of beans by count are insect-infested or moldy (**NOTE: Level differs when both filth and mold are present)** • Average of 10 mg or more mammalian excreta per pound
Pitted olives	• Average of 1.3 percent or more by count of olives with whole pits and/or pit fragments 2 mm or longer measured in the longest dimension
Pineapple juice	• Average mold count of 15% or more • Mold count of any 1 subsample is 40% or more
Tomatoes (canned)	• Average of 10 or more fly eggs per 500 grams • 5 or more fly eggs and 1 or more maggots per 500 grams • 2 or more maggots per 500 grams

Source: FDA, 2004.

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