2a

Good Manufacturing Practices - GMP

Sanitary Standard Operating Procedures (SSOP's) and SOP's

General Overview
for Food Industry

Current Good Manufacturing Practices (cGMPs):

- Are published in Title 21 of the Code of Federal Regulations, Part 110 (21 CFR 110).
  - www.fda.gov/21CFR 110
- 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.
- Also serve as one basis for FDA inspections.

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.	

They are under revision as part of the Food Safety Modernization ACT

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).

Key Provisions of Food GMPs

- The current GMPs consist of seven subparts, two of which are reserved.
- These requirements are purposely very general to allow individual variations by manufacturers to implement the requirements in a manner that best suit their needs to maintain sanitary conditions and environment throughout their plant.

cGMP's Subpart A:

- General provisions and is divided in four sections as follows.
  - 110.3 Definitions
  - 110.5 Current Good Manufacturing Practices
  - 110.10 Personnel
  - 110.19 Exclusions

Subpart A: Selected definitions

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

Subpart A:continue

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

cGMP's Subpart **B**:

- Buildings and facilities outlines requirements for the maintenance, layout, and operations of food processing facilities.
  - 110.20 Plant and grounds
  - 110.35 Sanitary operations
  - 110.37 Sanitary facilities and control

cGMP's 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.
- 110.40 Equipment and utensils

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 110.37	Sanitary Facilities and Controls	Requirements for: • Water supply • Plumbing • Sewage disposal • Toilet facilities • Hand-washing facilities • Rubbish and offal disposal
Subpart C. Equipment	Section 110.40	Equipment and Utensils	• Requirements for the design, construction, and maintenance of equipment and utensils

cGMP's Subpart D and E

- Subpart D- reserved
- Subpart E – Production and Process Control
  - 110.80 Process and Controls
  - 110.93 Warehousing and distribution

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

cGMP's Subpart F and G:

- Subpart F – Reserved
- Subpart G- Defect Actions Levels

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.			

Defect actions level (DAL's)

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.

Food Safety Modernization Act

- 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 hold public meetings and is now reviewing the public comments to assist in this effort.

Food Safety Modernization Act

Presentation as written by FDA

Proposed Rules under the FDA Food Safety Modernization Act

Five Proposed Rules Establish Food Safety Framework

- Produce Safety Standards - Published Jan. 2013
- Preventive Controls for Human Food - Published Jan. 2013
- Foreign Supplier Verification Program
- Preventive Controls for Animal Food
- Accredited Third Party Certification

Key Aspects of Proposals

- Confirm industry's primary role on food safety
- Risk-based and flexible
- Address small business issues
- Extensive government, stakeholder Input

FDA Proposed Rule on Produce Safety

Key Principles

- Considers risk posed by practices, commodities
- Science- and Risk-based
  - Focus on identified routes of microbial contamination
  - Excludes certain produce rarely consumed raw
  - Excludes produce to be commercially processed (documentation required)
- Flexible
  - Additional time for small farms to comply
  - Variances
  - Alternatives for some provisions

Standards for Produce Safety

Focus on identified routes of microbial contamination

Domesticated and wild animals

Equipment, tools, buildings and sanitation

Worker health and hygiene

Agricultural water

Growing, harvesting, packing and holding activities

Biological soil amendments of animal origin

Specific requirements for sprouts

Who Would be Covered?

- Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities)
- Farms and “farm” portions of mixed-type facilities
- Domestic and imported produce
- Farms with annual sales > $25,000 per year
- Limitations on coverage are proposed

Covered Produce

“Produce” defined as fruits and vegetables

Produce includes mushrooms, sprouts, herbs and tree nuts

Produce does not include grains

Some limitations on covered produce

Limitations on Coverage

- Produce for personal or on-farm consumption
- Produce not a Raw Agricultural Commodity
- Certain produce rarely consumed raw
- Produce that will receive commercial processing
- Farms with sales of $25,000 or less per year
- Qualified exemption and modified requirements

Alternatives Permitted

- Farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin
- Alternatives must be scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration

Variances Provide Flexibility

- A state or foreign country may petition FDA for a variance from some or all provisions if deemed necessary in light of local growing conditions.
- Practices under the variance would need to provide the same level of public health protection as the proposed rule without increasing the risk of adulteration.

Recordkeeping Required But Not Burdensome

- The proposed rule would require certain records, for example, to document that certain standards are being met
  - Example: agricultural water testing results
- Records already kept for other purposes need not be duplicated

Qualitative Assessment of Risk Reflects Science Behind Rule

- Draft qualitative assessment of risk helps to inform proposed rule
- Provides a scientific evaluation of potential adverse health effects resulting from human exposure to hazards in produce
- Available for public comment as part of the proposed rule

Compliance Dates Staggered

- **Effective Date:** 60 days after final rule is published
- Not covered: Farms with sales ≤$25,000/year

Compliance Dates

- **Very small farms**
  - Average annual value of food sold >$25,000 and ≤$250,000
  - Four years after the effective date to comply
  - For some water requirements, six years

Compliance Dates

- **Small farms**
  - Average annual value of food sold > $250,000 and ≤ $500,000
  - Would have three years after the effective date to comply
  - Would have five years for some water requirements
- **Other covered farms**
  - Other covered businesses would have to comply two years after the effective date
  - Would have four years for some water requirements

Preventive Controls for Human Food

Key Principles

- Confirms industry's primary role on food safety
- Prevention of hazards
- Risk-based

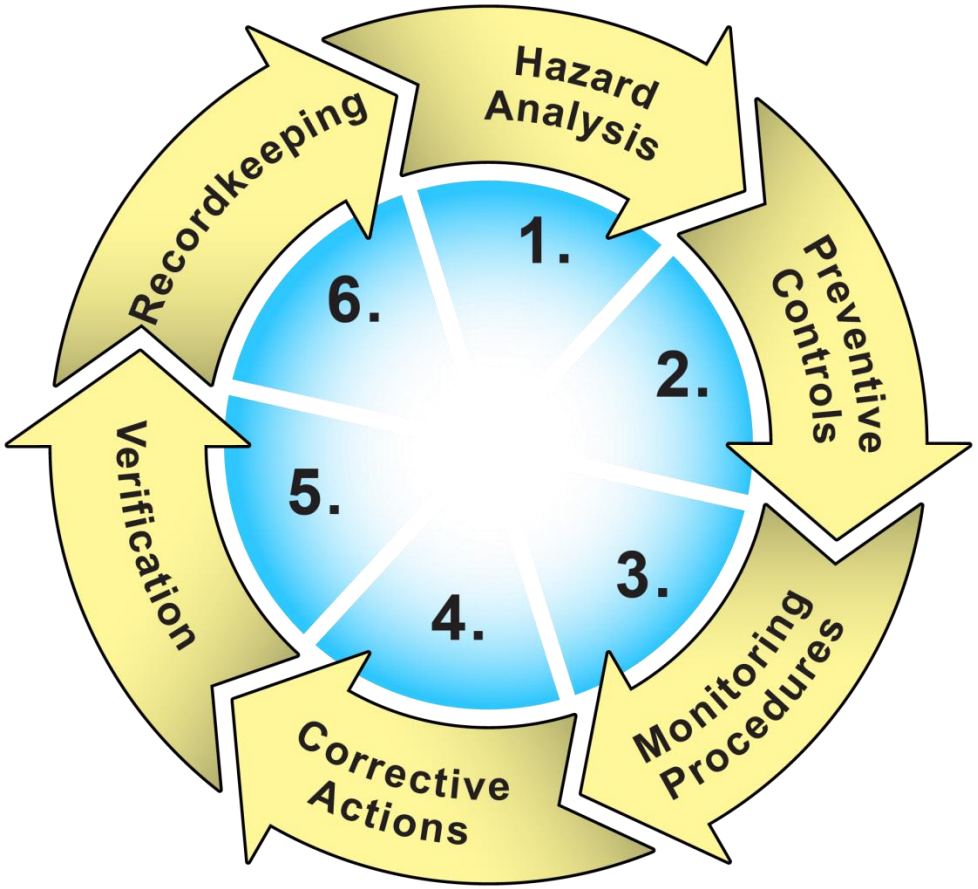
Summary of Requirements

- Hazard Analysis and Risk-Based Preventive Controls
  - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Updated Good Manufacturing Practices

Who is Covered?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- Applies to domestic and imported food
- Some exemptions and modified requirements are being proposed

Hazard Analysis and Risk-Based Preventive Controls



Preventive Controls Required

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan
- In addition, seeking comment on supplier approval and verification program

Verification Required

- Validation
- Calibration
- Review of records
- In addition, seeking comment on review of complaints, finished product and environmental testing

Updated Good Manufacturing Practices

- Protection against allergen cross-contact
- Updated language; certain provisions containing recommendations would be deleted
- Comments requested on mandating training and whether rule should require, rather than recommend, certain provisions

Exemptions and Modified Requirements

- "Qualified" facilities:
  - Very small businesses (3 definitions being proposed—less than $250,000, less than $500,000 and less than $1 million in total annual sales)

    OR
  - Food sales averaging less than $500,000 per year during the last three years AND
  - Sales to qualified end users must exceed sales to others

Exemptions and Modified Requirements

- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages

Exemptions and Modified Requirements

- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment
- Certain storage facilities such as grain elevators that store only raw agricultural commodities intended for further distribution or processing

Farm-Related Exemptions

- Activities within the definition of "farm," including farm activities that are covered by the proposed produce rule
- Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods

Effective and Compliance Dates

Effective date:

60 days after the final rule is published

Compliance Dates

Small Businesses—a business employing fewer than 500 persons would have two years after publication.

Compliance Dates (cont.)

- **Very Small Businesses**—a business having less than $250,000 (or alternatively $500,000 or $1 million) in total annual sales of food would have three years after publication to comply.
  - Very small businesses are considered “qualified” facilities and subject to modified requirements
- **Other Businesses**—a business that does not qualify for exemptions would have one year after publication of the final rule to comply.

Risk Assessment

- Draft qualitative risk assessment announced in a separate notice of availability
- Addresses activities outside the farm definition conducted in a facility co-located on a farm.
- Comments being accepted separate from the proposed rule

How to Comment on the Proposed Rules

- http://www.regulations.gov
- Link to rules on http://www.fda.gov/fsma
- Comment period is 120 days; exact due date will be in the Federal Register
- Comment periods on major FSMA proposals will be coordinated to enable comment on how the rules can best work together.

Outreach and Technical Assistance Will Continue

- Public meetings
- Presentations
- Listening sessions

- Alliances
  - Produce Safety
    Preventive Controls
    Sprouts Safety
- Guidance documents

More Information Available

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov

Sanitary Standard Operating Procedures

Overview

September 7, 2014

Sanitary Standard Operating Procedures – SSOP's

- Specific written procedures necessary to ensure sanitary conditions in the food plant.
- Include written procedures for cleaning and sanitizing to prevent product adulteration
  - They are required in all Meat and Poultry Plants – CFR Title 9 Part 416
  - They are required by FDA for HACCP in juice

    21 CFR 120 and suggested for HACCP in Fish and Seafood 12 CFR 123

What are SOPs?*

- Standard Operating Procedures (SOPs) are descriptions of particular tasks undertaken in a food processing operation.
- A specific SOP should address the following: the purpose and frequency of doing a task, who will do the task, a description of the procedure to be performed that includes all the steps involved, and the corrective actions to be taken if the task is performed incorrectly.

http://www.foodsafety.unl.edu/haccp/prerequisites/sop.html

Are SOPs different from Good Manufacturing Practices (GMPs)?

- Yes, SOPs represent a different set of jobs to be performed that may or may not be related to the safety of a food product, while GMPs refer to a set of procedures and measures taken by a plant to ensure that the food is not adulterated.

Are SOPs mandated by regulatory agencies

- FDA mandates GMPs but not SOPs.
- USDA mandated Sanitation Standard Operating Procedures (SSOPs) for Meat and Poultry Operations effective January 27, 1997. The rule calls on plant management to develop SSOPs that address daily routine sanitary procedures, before and during operations to prevent direct product contamination or adulteration. Procedures should be specific for each plant and can be as detailed as the plant wants to make them.

Example FDA – SSOP 120 for juice

Sec. 120.6 Sanitation standard operating procedures.

(a) Sanitation controls. Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing.

The SSOP shall address:

(1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

The SSOP shall address:

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

SSOP shall address:

- Monitoring. The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are appropriate both to the plant and to the food being processed.
  - Each processor shall correct, in a timely manner, those conditions and practices that are not met.
- Records. Each processor shall maintain SSOP records that, at a minimum, document the monitoring and corrections.

USDA/FSIS PRODUCTS shall comply with

- Sanitation Standard Operating Procedures (SSOP),
- Hazard Analysis Critical Control Point (HACCP),
- Salmonella Performance Standards,
- Ready-to-Eat performance standards,
- Carcass dispositions,
- Labeling requirements,
- Transportation and
- Pre-harvest
- FSIS continuous inspection.

Overview

- This was an overview of programs that applies to any food processing facility.
- The way the GMPS's, SSOP's and other prerequisites programs are established depends on the product, facility, size of the plant
- Similar requisites a required for farms, but how they implement them may vary since it can be an open facility versus a closed facility like a food processing plan.

Examples

- An example of an SOP prepared by Nebraska University is included as reference
- Also additional reference material is included in documents and references.
- Remember to go over the FSMA presentation prepared by FDA and included in separate document to maintain its integrity.