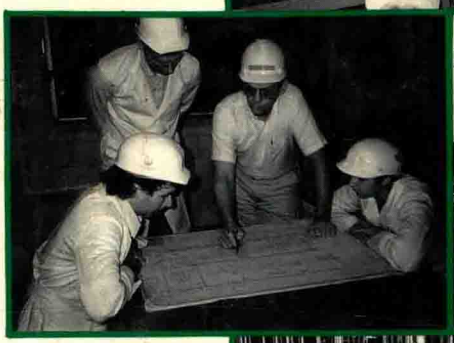
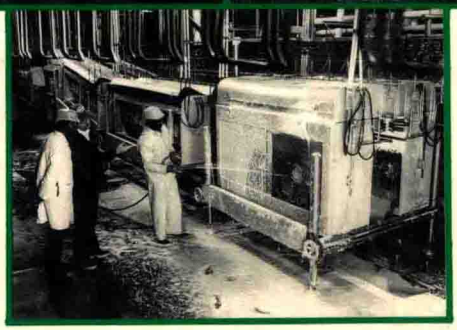
CGMP's/ FOOD PLANT SANITATION





CGMP's/ FOOD PLANT SANITATION

by

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PREFACE

The food industry has one common goal, that is, to prepare, process, package, and preserve high quality foods that make for repeat sales. Consumers make the decision to single out products at the market place and purchase that product if it satisfies their needs. Once consumers find a product that satisfies their need, they will tend to continue to purchase that product until the product does not meet that need. Generally the first prerequisite to change a product in the eye of the consumers comes about because the product does not satisfy their standards of quality. Consumers standards of quality are based first on things they can visually see in that product. If a product has defects present or has signs of use of defective materials detectable by smell or flavor, consumers will change products and the ultimate loser is the original processor. Therefore, it behooves the food industry to maintain and constantly improve the products they manufacture for continued repeat business.

This book was developed to help the personnel responsible for food plant sanitation understand the areas of major concern in the manufacturing of high quality foods. The book, also, presents the pertinent parts of the Food Laws and Regulations to guide the industry in the understanding of the Current Good Manufacturing Practices and how they apply to food plant sanitation. Practical control and cleaning procedures are discussed as well as the problem areas to be concerned with keeping a food plant clean. Emphasis is given to the development of the training of employees and their role in the processing of clean, defect free, and safe foods.

Every effort has been made to present the material in this text in practical terms for the help of all personnel from the worker to the sanitation crew through to management to better understand "the need for", "the why of," and "the how to" aspects of food plant sanitation.

Wilbur A. Gould

ACKNOWLEDGEMENTS

I am deeply indebted to my former students, both undergraduate and graduate students, and my former colleagues at The Ohio State University for their interest in the development of my Sanitation Course and their participation therein. Also, I am deeply indebted to the many industry personnel who have taken my Good Manufacturing Practices/Food Plant Sanitation Seminars and Workshops over the past 20 years. Their comments and suggestions have been most helpful and an inspiration to put my handouts and materials together in book form. Further, I sincerely thank the many supply firms for their inputs with photos, visuals, suggestions, and text quotes.

The selected use of material from the Food and Drug Administration, the National Food Processors Association, and the Food Processors Institute as well as many publications in the field of food plant sanitation has been most helpful and my sincere thanks to all concerned.

I am most appreciative of the assistance of Ronald W. Gould in his critique of this book and his valuable suggestions throughout the writing of same and to Jessie Gould for her constant help and valuable suggestions. Finally, my sincere thanks to Art Judge, II and Randy Gerstmyer for their valuable help and aid in completing this book and presenting it to the industry.

This copy of
CGMP's/Food Plant Sanitation
belongs to:

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CHAPTER 1

The Implications Of Current Good Manufacturing Practices (CGMP's) And Food Plant Sanitation

In the production of foods for human consumption, the art and practice of modern food plant sanitation principles and the adoption of current good manufacturing practices are mandatory for public acceptance of your products. These principles and practices are constantly being up-graded as man's knowledge increases with the ultimate production of higher quality food for all concerned.

During the past 100 years, great changes have taken place in the concepts and practices of sanitation. In the early days, gross sources of contamination included insects, rodents, sticks, stones, straw, wood, sand and dirt. Man has learned that most of these sources of contamination can be eliminated by maintaining physical cleanliness in and around the food plant. Looking beyond these gross sources of contamination, today one is concerned with microbiological sources of contamination. Microorganisms may come from people working in the plant or handling the food, from raw products or ingredients, or from lack of proper cleaning of the food plant equipment or the food plant. A third problem area is potential chemical contamination. This source of contamination can be controlled by proper usage of pesticides. That is, using the right pesticides on the right crop, at the right time, and in the right amount. This same principle applies to chemicals used in the manufacturing of the food, that is, the proper use and application of food additives and/or chemicals used in the cleaning and sanitizing of the food plant.

After the passage of the Food Drug and Cosmetic Act of 1938 many changes in food plant sanitation have been adopted. Criteria for contamination and adulteration have brought to the forefront the need for better plant sanitation. Much more has happened during the past

15 years since the enactment of the GMP's and the Current GMP's. These GMP's have eluclidated refinements in equipment, plant food handling practices, personnel standards, etc. that have aided food plant management in better understanding the public health concerns of producing clean, safe, and wholesome foods. Today we know how to do it, but we don't always practice the knowledge that we have.

Nearly every person working in the food industries is there to produce, process, pack, and distribute foods for human consumption. Each person has a legal and a moral obligation to perform all unit operations in clean surroundings and with due regards to the basic principles of sanitation. Everyone should understand and practice the motto of the National Sanitation Foundation. This motto is as follows:

> *Sanitation is a way of life. It is the quality of living that is expressed in the clean home, the clean farm, the clean business and industry, the clean neighborhood, the clean community. Being a way of life it must come from within the people; it is nourished by knowledge and grows as an obligation and an ideal in human relations.*

Thus, sanitation is the production, manufacture and distribution of clean and wholesome foods by people.

From a practical standpoint, the ultimate in food plant sanitation is to attain the highest goal in quality of the products being produced

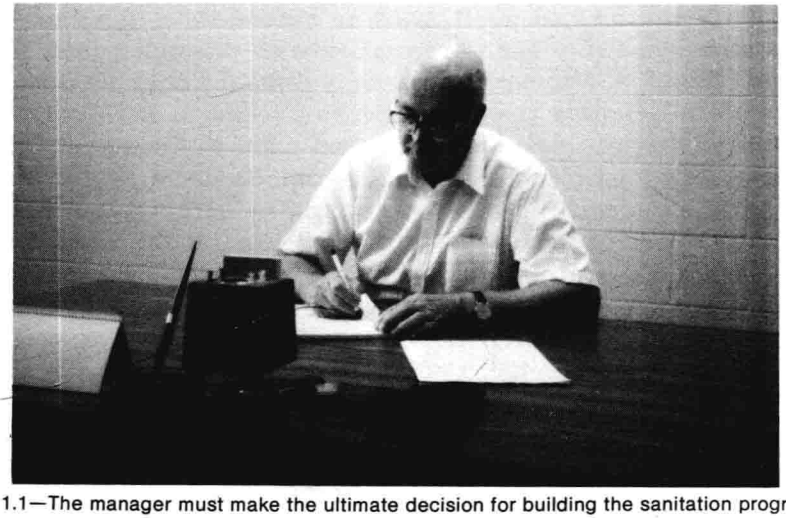

Fig. 1.1—The manager must make the ultimate decision for building the sanitation program.

and doing this at proper and reasonable total costs. Foods for human consumption must be safe, wholesome and appealing to the consumer. What was good enough yesterday, generally is not good enough today.

Every food firm must have a goal for every manufactured product. This goal may be defined in terms of specifications understood by purchasing, processing and distribution. Specifications are a means of communication between management, plant employees, vendors, and the ultimate consumers. Without specifications sanitation standards are vague and only concepts in the eyes of the workers, management, vendors, and, yes, even the eyes of the consumers. Specifications help everyone better understand what is wanted. If specifications are properly written and understood,they provide all with facts that can be followed to produce acceptable products in a clean plant from clean raw materials and ingredients, on clean equipment, by knowledgable people in clean environments.

Sanitation is every person's job in a food plant. Sanitation should be a part of the everyday policy of the food firm. Only through the individual efforts of each person working a food plant can a firm expect to maintain the respect that your products demand by the consumer. Sanitation is a responsibility that every person handling or working with food must consistantly fulfill.

If properly practiced, sanitation should remove the worry about the spreading of communicable diseases or potential food poisoning. Further, if sanitation is properly maintained, a product free of contamination will be produced and waste and spoilage will be eliminated. All of these are moral obligations.

From a legal obligation standpoint, the FD&C Act states in Section 402 (a) 3 that a food shall be deemed to be adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food" and in Section 402 (a) 4 it states: "if it has been prepared, packed, or held under insanitary conditions whereby it may become contaminated with filth, or whereby it may have been rendered injurious to health". These definitions of adulteration and contamination are, in great part, the essence of any good manufacturing practice and/or food plant sanitation program.

The value of a planned sanitation program utilizing good manufacturing practices includes the following:

1. A better product to meet the competition's demands and consumer's expectations.
2. A more efficient food plant operation.
3. Greater employee productivity.

4. Fewer food plant employee accidents.
5. Fewer consumer complaints.

Thus, the manufacture of foods that are safe, wholesome and nutritious are moral and legal obligations. Constant updating of the knowledge of sanitation principles and good manufacturing practices are fundamental requirements. Further, the training of all plant personnel in sanitation principles and the communicating of specifications to all is mandatory.

CHAPTER 2

Current Good Manufacturing Practices—The Regulation

Congress in 1938 authorized the Secretary of the Agency to promulgate regulations for the enforcement of the Act. Specifically, in Chapter VII Section 701 (a) "The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary". This authority was not extensively used prior to the late '60's. In 1969 the Secretary published the first GMP's as Part 128 of the Code of Federal Regulations. In 1977 this was recodified as Part 110 and was revised and updated in 1986.

For the readers not familiar with the Code of Federal Regulations, the following may be helpful. The proposed regulations are generally first published in the Federal Register, a daily publication setting forth rules by the Executive Department and the agencies of the Federal Government. Annually, these changes are codified and published as the Code of Federal Regulations. The Code is divided into 50 titles which represent broad areas subject to Federal regulations. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas. Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16 ..... as of January 1
Title 17 through Title 27 ..... as of April 1
Title 28 through Title 41 ..... as of July 1
Title 42 through Title 50 ..... as of October 1

"To keep up-to-date in changes in the Code of Federal Regulations, one must have access to the Federal Register. To determine whether a Code volume has been amended since its revision date, consult the "List of CFR Sections Affected" which is issued monthly, and the "Cumulative List of Parts Affected," which appears in the Reader Aids section of the daily Federal Register. These two lists will identify the Federal Register page number of the latest amendment of any rule."

Title 7 is for Agriculture with some 36 Chapters

Title 21 is for Food and Drugs with 2 Chapters. The first Chapter has over 1300 Parts and is published in 9 volumes. Volume I contains Part

1-99, Volume II Part 100-169, Volume III Part 170-199, Volume IV Part 200-299, Volume V Part 300-499, Volume VI Part 500-599, Volume VII 600-799, Volume VIII 800-1299 and 1300-end. The first 8 Volumes deal with Food and Drug Administration, Department of Health and Human Services and Volume IX deals with Drug Enforcement Administration, Department of Justice.

Part 110 is found in Volume II or Subchapter B of Chapter I. Subchapter B starts with Part 100 and goes through Part 169, although not all Parts are complete. The reader should be aware of, at least, Part 108 "Emergency Permit Control", Part 109 "Unavoidable contaminants in food for human consumption and food-packaging materials", Part 110 "Current good manufacturing practice in manufacturing, packing, or holding human foods", Part 113 "Thermally processed low-acid foods packaged in hermetically sealed containers", Part 114 "Acidified Foods", and Part 129 "Processing and Bottling of bottled drinking water". Other Parts may be germane, depending on the readers interest.

Part 110 is reproduced as follows:

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PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Subpart A—General Provisions

Sec.

110.3 Definitions.
110.5 Current good manufacturing practice.
110.10 Personnel.
110.19 Exclusions.

Subpart B—Buildings and Facilities

110.20 Plant and grounds.
110.35 Sanitary operations.
110.37 Sanitary facilities and controls.

Subpart C—Equipment

110.40 Equipment and utensils.

Subpart D—[Reserved]

Subpart E—Production and Process Controls

110.80 Processes and controls.
110.93 Warehousing and distribution.

Subpart F—[Reserved]

Subpart G—Defect Action Levels

110.110 Natural or unavoidable defects in food or human use that present no health hazard.

AUTHORITY: Secs. 302, 303, 304, 402(a), 701(a), 52 Stat. 1043-1046 as amended, 1055 (21 U.S.C. 332, 333, 334, 342(a), 371(a)); sec. 361, 58 Stat. 703 (42 U.S.C. 264); 21 CFR 5.10, 5.11.

SOURCE: 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) "Acid foods or acidified foods" means foods that have an equilibrium pH of 4.6 or below.

(b) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) "Batter" means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) "Blanching," except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) "Critical control point" means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) "Food" means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) "Food-contact surfaces" are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

(h) "Lot" means the food produced during a period of time indicated by a specific code.

(i) "Microorganisms" means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.

(j) "Pest" refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) "Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) "Rework" means clean unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) "Safe-moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate

data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

(o) "Sanitize" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) "Shall" is used to state mandatory requirements.

(q) "Should" is used to state recommended or advisory procedures or identify recommended equipment.

(r) "Water activity" (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all insecure jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

§ 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B—Buildings and Facilities

§ 110.20 Plant and grounds.

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractive, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.