

Thursday, June 19, 1986



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**Food and Drug  
Administration**

**MANUFACTURING, PACKING,  
OR HOLDING  
HUMAN FOOD**

**PREAMBLE OF REGULATIONS  
ESTABLISHING GOOD  
MANUFACTURING PRACTICES**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 20 and 110

[Docket No. 78N-0296]

#### Current Good Manufacturing Practice In Manufacturing, Packing, or Holding Human Food; Revised Current Good Manufacturing Practices

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule that revises the current good manufacturing practice (CGMP) regulations for human foods. The primary purpose of the revision is to establish new, updated, or more detailed provisions for the food industry to help ensure a safe and sanitary food supply.

**DATES:** This final rule will become effective on December 16, 1986; comments by August 16, 1986.

**ADDRESS:** Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville MD 20857.

#### FOR FURTHER INFORMATION CONTACT:

Prince G. Harrill, Center for Food Safety and Applied Nutrition (HFF-210), Food and Drug Administration 200 C St. SW., Washington, DC 20204, 202-485-0097.

#### SUPPLEMENTARY INFORMATION:

#### History

In the Federal Register of June 8, 1979 (44 FR 33238), FDA published a proposal to revise the current good manufacturing practice (CGMP) regulations for the manufacturing, processing, packing, and holding of human foods, the umbrella CGMP regulations (21 CFR Part 110). FDA sought to establish new, updated, and more detailed CGMP provisions concerning food industry personnel; plants and grounds; sanitary facilities, controls, and operations; equipment and utensils; processes and controls; product coding; warehousing and distribution; recordkeeping; and natural or unavoidable defect levels. FDA designed the proposed revision of the umbrella CGMP regulations to address the problems associated with foods for which specific CGMP regulation, had not been promulgated and thus better ensure the production of safe and sanitary foods. FDA provided a period of 204 days, ending on December 31, 1979 for the filing of comments on the proposed revision.

To gather information and opinion on the impact of the proposed revision, FDA also held hearings in Chicago, IL, on September 11, 1979, in San Francisco, CA, on October 3, 1979, and in Atlanta, GA, on October 24, 1979. Approximately 250 persons attended the 3 hearings. Of the roughly 50 persons who made presentations at the hearings, nearly two-thirds represented small businesses. Because FDA was particularly interested in the impact that the revised regulations would have on small businesses, the agency solicited comments from small businesses and trade associations representing small businesses. The hearings resulted in a voluminous hearing record.

In addition to the comments received at the hearings, FDA has received 132 written communications reflecting the comments of suppliers, manufacturers and processors, trade associations, operators of small businesses, consumers, and other interested persons.

#### Revision in Response to Comments

The comments on the 1979 proposal, including those received at the hearings, suggested revisions of practically every section of the proposed rule. In response FDA has adopted many of these suggestions in the regulation.

The most significant revision responds to comments concerned the proposed requirements for coding and recordkeeping. The vast majority of these comments questioned the need for these requirements for segments of the food industry that contend (1) their products pose little or no risk to the public health and (2) their products, in the rare event a risk arose, could be removed from the market expeditiously and effectively without the need to comply with the costly proposed requirements. Most comments also pointed out that the cost of coding and recordkeeping would be excessive, especially to small businesses.

To evaluate more fully the validity of Industry's comments concerning the cost of the proposed regulations, FDA contracted for a study of compliance costs associated with the 1979 proposal as FDA then had considered modifying the proposal in response to comments. The study was conducted by ICF, Inc., Washington, DC, and is part of the record of this proceeding. ICF concluded that total compliance costs were \$81 million. The costs were primarily attributable to the proposed recordkeeping (\$76 million and coding (\$4.5 million provisions. (Costs are adjusted to represent 1985 dollars.) ICF also found that 95 percent of the large manufacturers sampled and 93 percent

of the small manufacturers sampled were already coding their products sufficiently to be in compliance with the proposed regulation. The recordkeeping costs would have been high because, although all manufacturers have detailed records, few have recordkeeping systems based on lot numbers which the proposed regulation would have required.

The purpose of proposing coding and recordkeeping was to facilitate a manufacturer's recall of suspect products in case such a recall was recommended by FDA. Although such information is potentially useful in determining the production time period which is effected by a recall, thereby limiting manufacturers' risk exposure, it is not needed to protect consumers from products that have been purchased but not ingested. Furthermore, all manufacturers either currently code all their products or keep shipping records. In the ordinary course of business, or do both. As these sources can provide most of the information which would have been required in the proposed rule, and all of the information needed for a recall, it is not necessary to impose other economically burdensome recordkeeping requirements. This decision will save manufacturers and consumers approximately \$80.5 million annually (1985 dollars) in foregone costs, costs which would have been incurred if the regulation had gone forward as proposed in the notice of proposed rulemaking.

For consumer protection, the most effective safeguard is product, not lot, identification and swift dissemination of such information by mass media. These mechanisms will in no way be compromised by the deletion of coding and recordkeeping requirements.

In addition, the product most likely to involve risk of recall (low acid food) are already subject to coding and recordkeeping requirements.

Accordingly, because industry voluntarily codes and keeps records adequate for consumer protection, FDA has decided not to require coding or recordkeeping. FDA, after reviewing comments and the ICF study, has concluded that an industry confronted with little likelihood of recalls of products subject to the proposed rule could decide that removal of all offending products from the market in the presence of a recall would protect the public health and would be more cost effective than maintaining records and coding products. On the other hand, an industry confronted with a high frequency of recalls or with the apparent potential for infrequent, but serious

contamination of a limited quantity of product. could decide that coding and recordkeeping are essential to accomplishing a recall. Under either option, the public would be protected and industry would have the opportunity to decide which recall strategy is appropriate.

Nevertheless, FDA encourages firms to code their products and to maintain appropriate records. FDA also reserves the option to reconsider this decision if future evidence indicates the cost effectiveness of mandatory coding and recordkeeping.

Because FDA is not requiring coding or recordkeeping in the final rule, FDA will not discuss in this preamble the detailed comments received on these topics.

FDA has decided to publish a final rule instead of a tentative final rule or revised proposal. The final rule is "in character with the original scheme" (*South Terminal Corp. v. EPA*, 504 F. 2d 64 6658 (1st Cir. 1974) and contains changes that are "logical outgrowths" of the comments received in response to the proposal (*AFL-CIO v. Marshall*, 617 F. 2d 606 676 (D.C. Cir. 1979)). Thus, FDA concludes that to issue a tentative final rule or a revised proposal is not necessary because it has provided the public "a reasonable and meaningful opportunity to participate in the rulemaking process" (*McCulloch Gas Processing Corp. v. Department of Energy*, 650 F. 2d 121 61221 (Em. Appl. 1981)).

Although FDA is publishing a final rule, it is providing a comment period. If FDA decides on the basis of the comments received that any changes in the final rule are necessary, it will publish those changes in the Federal Register.

### Costs

The industrywide compliance costs associated with this final rule would be between \$272,000 and \$623,000 per year. These costs are for the installation and maintenance of temperature indicating thermometers in industries where food products or processing techniques would allow the growth of microorganisms. The agency concludes that this rule is not a "major" rule under Executive Order 12291 and that it does not impose a significant burden on small businesses. No recordkeeping or reporting requirements are associated with the final rule.

### General Comments

1. Several comments suggested that the proposed umbrella CGMP regulations be withdrawn because specific legislation effecting the food

industry was before Congress and may become law.

FDA believes it inappropriate to await enactment of new legislation. Of course, if new legislation is enacted, FDA will make appropriate changes in the regulations.

2. Several comments questioned whether FDA inspectors would interpret the umbrella CGMP regulations differently for different food-processing operations or industries. Some comments expressed concern that inspectors might find violations of regulations that were not applicable to a particular processor or industry. One comment offered to assist FDA in training its personnel in specific food-processing methods.

FDA has an agency review procedure to ensure that any corrective action recommended by investigators is in accordance with agency policy and that a regulation has been properly interpreted before regulatory action is taken. FDA has trained and will continue to train appropriate personnel to understand and interpret the umbrella CGMP regulations properly. In the past, industry has been helpful in aiding in training FDA personnel, and FDA hopes that this cooperation will continue.

3. Several comments expressed the opinion that FDA had not fairly considered the wide array of manufactured foods affected by the revised umbrella CGMP regulations.

FDA believes that the agency did consider the wide array of foods, then decided that revising the umbrella CGMP regulations is more efficient than issuing repetitive proposed and final regulations on specific food industries.

4. Many comments suggested that broad or general performance standards that allowed for innovation in achieving the desired result would be more useful to the food industry than specific mandated techniques. Several comments suggested that the umbrella CGMP regulations be rewritten as a series of suggested guidelines, and that the "shalls" be changed to "shoulds," because the regulations are intended to be a broad performance standard for the entire food industry. Other comments stated that several sections were too general and interpretation of the intent would be impossible.

FDA agrees, in part, with the comments. FDA considers the CGMP regulations to have a twofold purpose: (1) To provide guidance on how to reduce insanitary manufacturing practices and on how to protect against food becoming contaminated; and (2) to state explicit, objective requirements that enable industry to know what FDA expects when an investigator visits one

of its plants. The agency has critically reviewed each provision of the regulations to determine which provisions should be mandatory and thereby carry the force and effect of law. Wherever possible FDA has structured the regulations to provide general guidance to industry for ensuring the maintenance of good sanitary practices in the manufacturing, packing, and holding of food. The agency believes that several provisions of the regulations are necessary to ensure the maintenance of good sanitary practices and therefore, that these provisions should be made mandatory.

5. A number of comments requested that the umbrella CGMP regulations be printed in two type faces to allow industry and FDA inspectors to differentiate more easily between the "shoulds" or general guidelines, and the "shalls" or mandatory requirements.

The Office of the Federal Register is unable to accommodate this request. Therefore, the umbrella CGMP regulations are not printed in two type faces.

6. Numerous comments requested that the term "prevent contamination" be changed to "minimize contamination" or "minimize the potential for contamination" or other similar words in various parts of the regulations.

FDA agrees and has changed the wording to reflect that the regulations are designed to protect against or to minimize the contamination of food. See the response to comment 125.

7. Several comments asserted that suggestions, lists of processes, analytical tests, and other enumerated techniques make the regulations confusing because they do not encompass all the possible relevant options. These comments requested that illustrative examples be deleted from the regulations.

The use throughout the regulations of prefatory phrases such as "Includes, but not limited to," "may be accomplished by," and "including" establishes that the enumerated items are not all inclusive. The use of a suggested technique is not required. For these reasons, FDA is retaining in the final rule most of the lists of examples.

8. Several comments suggested that the regulations place greater emphasis on Federal and State agency coordination to help achieve more uniform guidelines and requirements for the food industry. One comment expressed concern that FDA did not expand the preliminary draft review procedures to include State food control agencies.

FDA agrees that interagency coordination is important in the development of CGMP regulations for any regulated commodity. Prior to publishing this final rule, FDA submitted preliminary drafts for review and comment to the Department of Agriculture and the Department of Commerce. FDA included recommendations from these agencies in the proposal. However, FDA did not submit a preliminary draft of the final rule to State food regulatory agencies because 21 CFR 20.81 provides that if a preliminary draft of a regulation is made available to persons outside of Federal agencies, it must then be made available to all interested persons. FDA believes that the comment period for the proposal was sufficient for all interested persons to submit their comments and suggested changes to the agency. FDA has made many changes in the final rule based on the comment submitted by industry, consumers, regulatory agencies at all levels of government, and other interested persons.

9. Several comments from the shellfish industry, including trade associations and other interested persons, stated that the proposed umbrella CGMP regulations would have severe economic impact on the shellfish industry and, because of this impact, any action to promulgate the regulations without an economic analysis of the effect of such regulations on the shellfish industry, prepared jointly by the Department of Health and Human Services and Department of Commerce, would violate the intent of the Coastal Zone Management Act. This statute provides that:

At least 60 days prior to the promulgation of any regulations concerning the National Shellfish Safety Program, the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, shall publish an analysis (1) of the economic impact of such regulations on the domestic shellfish industry and (2) the cost of such national shellfish safety program relative to the benefits that it is expected to achieve.

FDA disagrees with the contentions in the comments. The quoted provision is concerned with regulation specifically concerning the National Shellfish Safety Program (NSSP). Neither the statutory language nor its legislative history evince any intent to require additional scrutiny of regulation of broad impact that do not concern NSSP or otherwise single out the shellfish industry in any even FDA's economic analysis of the regulations' effect on the food industry, including the shellfish industry, shows that industrywide the compliance costs are between \$272,000 and \$623,000 per year. A copy of FDA's analysis is on file

in the administrative record of this proceeding.

10. Several comments requested that the CGMP regulations for cacao products and confectionery (21 CFR Part 118), which FDA proposed to revoke on September 7, 1979 (44 FR 52257), be retained because they satisfactorily set forth all the necessary elements for the sanitary manufacture and distribution of confectionery and chocolate products. One comment suggested that FDA incorporate into the umbrella CGMP regulations some of the unique features found in Part 118.

FDA proposed revocation of Part 118 because many of the requirements of Part 118 were incorporated in the proposal to amend Part 110, the umbrella CGMP. Elsewhere in this issue of the Federal Register, the agency is revoking the CGMP regulations for cacao products and confectionery, proposing to revoke CGMP regulations for frozen raw breaded shrimp, as well as withdrawing the proposed CGMP regulations for bakery foods and for peanuts and tree nuts.

11. Several comments requested clarification of whether the umbrella CGMP regulations will be applicable to the retail food store industry.

FDA does not interpret the umbrella CGMP regulations as applicable to retail food establishments. Although FDA's regulatory authority extends to food held for sale after shipment in interstate commerce, the agency has concentrated its regulatory efforts on ensuring the safety and sanitation of food up to the point when it reaches the retailer. In the Federal Register of July 23, 1982 (47 FR 31984) FDA announced the availability of a model retail food store sanitation code intended for adoption by State and local governments. The model code provides uniform food protection requirements for the operation of retail food stores.

#### Definitions

12. A number of comments on proposed § 110.3 suggested that definitions for microorganisms, rapid growth, ingredients, initial distribution, contamination, lot number, packaging lot, confectionery, process, processes, control, raw materials, mw food, and packaging lot be added to the definition section. Several comments suggested that raw materials be differentiated from ingredients. Some comments stated that the umbrella CGMP regulations should be concerned only with microorganisms of known adverse public health significance.

FDA believes that most of the terms are commonly understood. The term "microorganisms," however, seems to be

misunderstood. Accordingly, FDA has added to the final rule § 110.3(i) which defines microorganisms as including yeasts, molds, bacteria, and viruses. The paragraph also defines the term "undesirable" microorganisms to be not just those that are of public health significance but also those 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. The regulations are designed to prevent the growth of undesirable microorganisms. The scope of the definition is not limited to microorganisms of public health significance because these regulations are also concerned with sanitation, decomposition, and filth.

Regarding the second point, it is not possible to categorically distinguish between mw materials and other ingredients because raw materials and ingredients are food within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). To stress this fact, FDA has added a definition for "food" to the regulations. The definition provides, correctly, that "food" includes mw materials and other ingredients. For emphasis and clarity, however, FDA often in the preamble and the final rule refers to "raw materials" or to "ingredients" as appropriate.

FDA also has added a new definition for "pest" (§ 110.3(j)). This definition eliminates any confusion as to the scope of the regulations that may have been caused by the agency's use of such terms as vermin, rodents, insects, etc.

Also, on its own initiative, FDA has modified the definition of "food-contact surfaces" in § 110.3(g). The definition now provides that food-contact surfaces also include utensils and food-contact surfaces of equipment.

13. Several comments suggested that, for clarity and comprehensiveness, the definition in proposed § 110.3(a) on acid foods or acidified foods be made the same as the definitions in the acidified foods CGMP regulations (21 CFR 114.3 (a) and (b)).

The proposed definition for "acid foods or acidified foods" is adequate for these regulations. The more comprehensive definition of acidified foods in 21 CFR Part 114 is necessary to inform processors of the scope of those regulations. The term proposed for the umbrella CGMP regulations is more general because it covers current good manufacturing practice for all foods. Therefore, FDA is making no change in the final rule.

14. One comment suggested that the definition should include only foods with an equilibrium pH of 4.5 or below instead of the 4.6 proposed. No reason was given for the suggested change. The acidified foods CGMP regulations (21 CFR Part 114) defines acid foods and acidified foods as those having a pH of 4.6 or below. This definition has been satisfactory to the agency and industry alike. Therefore, because the comment offered no reason for the suggested change to a pH of 4.5, FDA is making no change in the final rule.

15. Several comments considered the definition of "adequate" in proposed § 110.3(b) to be vague. Two comments were concerned that processors could be subject to inequitable interpretations, depending on the FDA investigator conducting the inspection. Two comments suggested that the definition be changed to "that which is needed to accomplish the intended purpose set forth in the guidelines of this part" instead of "the intended purpose in keeping with good public health practices" as proposed.

The agency recognizes the need for consistency in its inspection programs. Accordingly, FDA thoroughly trains its investigators on how to conduct an inspection and how to interpret and apply the regulations. To further ensure that actions taken by FDA are consistent nationwide, FDA District Offices submit proposed regulatory actions to FDA Headquarters for review and concurrence before regulatory action may be taken. Inconsistent interpretations of the definition of "adequate" are not likely to occur.

FDA does not agree with the suggested change in wording. Although 21 CFR Part 110 contains advisory information, it also specifies requirements that must be met to produce safe and wholesome food and, therefore, is not a guideline. For these reasons, FDA has not made the requested change in the final rule.

16. Several comments requested that batter for bakery items be added to the definition in proposed § 110.3(c)

FDA agrees and has changed the definition accordingly.

17. A number of comments requested that the definition for blanching be amended in proposed § 110.3(d) to permit blanching by dry heat. It also was noted that blanching is used for purposes other than the inactivation of enzymes.

FDA agrees and has changed the definition accordingly.

18. One comment pointed out that proposed § 110.3(d) is inconsistent with the word usage under 21 CFR

164.110(e)(2) concerning the blanching of peanuts.

FDA agrees and has excluded tree nuts and peanuts from this definition in the final rule.

19. A number of comments suggested that the term "corrosion-free" in proposed § 110.3(e) be defined as "corrosion-resistant" or "free of visible rust or scale build-up."

FDA agrees that "corrosion-resistant" is the more appropriate term. FDA believes, however, that as now worded, the term is self explanatory. Accordingly, FDA has deleted the definition from the final rule.

20. One comment suggested that "critical control point" in proposed § 110.3(f) should not be used in the umbrella CGMP regulations because it has a specific definition in training schools and textbooks, in connection with canned foods. The comment also mentioned that the definition used in the umbrella CGMP is slightly different from that given by FDA officials in public statements.

The critical control point concept is significant for all food, not just canned foods. The agency agrees, however, that the definition proposed should more closely reflect FDA's previous use of the terminology. FDA has revised § 110.3(e) of the final rule accordingly.

21. One comment suggested that the applicability of "food-contact surfaces" in proposed § 110.3(g) be restricted to human foods.

The title of the regulations makes it clear that the regulations apply only to "human" foods. FDA has clarified the definition in the final rule so that, in any event, there should be no misunderstanding concerning its scope.

22. Several comments suggested that the size, type, and style of product should not be included in the definition of "lot" in proposed § 110.3(h). Many of these comments recommended that the definitions of lot in 21 CFR 113.3(m) and 114.3(c) would be more appropriate in this regulation. A number of comments expressed the opinion that the responsibility for determining lot size should be with the manufacturer. The size of a lot varies greatly in the food industry and the purpose of any given lot size is to allow segregation of products into identifiable lots that can be effectively recalled from the market. Comments also suggested that lot size should not be limited to a day's production. Other comments suggested that a lot size should be the production of 3 days or a week or more.

FDA agrees that the manufacturer has the primary responsibility for determining the size of a lot. However, FDA also is responsible to the

conduct of recalls and, as the comments recognized, a purpose of designating a lot is to facilitate recalls of a product. In that context, FDA believes that a manageable lot size is advantageous to the manufacturer and the agency. FDA has structured the regulations accordingly. FDA agrees that the definition of lot should be more consistent with FDA practice, and is adopting in this final rule a definition of "lot" that is compatible with that found in 21 CFR Parts 113 and 114.

23. Several comments on proposed § 110.3(h) suggested changing the term "lot" to "consignment" or "batch" in order to be consistent with the terminology in their particular industries.

FDA understands that the term "lot" is most widely used by the food industry, and, therefore, has not incorporated the suggested changes in the final rule.

24. Several comments said that the definition of "plant" in proposed § 110.3(i) (§ 110.3(k) of the final rule) is too broad. The comments pointed out that it would cover all food storage and display facilities of warehouses and retail stores as well as processing facilities, even though in these facilities food is received in prepackaged form and there may be little or no possibility of contamination of food.

The definition of plant in proposed § 110.3(i) is broad, intentionally. The comments are correct that the definition extends to facility where there is the possibility of contaminated food and, therefore, applies to facilities where even foods in prepackaged form are received.

Although the definition could apply to retail establishments, FDA does not so interpret the provision.

25. A number of comments on proposed § 110.3(j) "quality control operation" (§ 110.3(i) of the final rule) asserted that it is impossible to ensure that finished food is "free" from adulteration. They pointed out that the purpose of a quality control operation is to minimize contamination in the manufacturing process to the greatest extent possible to reduce the possibility of adulteration in the finished food. One comment requested that the word "ensure" be changed to read "insure that the food is safe and wholesome."

FDA believes that the primary purpose of a quality control operation is to provide a systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act. FDA has revised the definition to clarify this point. See also the agency's response comment 125.

26. One comment asked whether the definition of quality control reflects recognition of the variety of tests and control procedures that may be used for manufacturing and marketing purposes.

FDA advises that, as, discussed above, for the purpose of these regulations, the definition of a quality control operation is limited to actions necessary to prevent food from being adulterated within the meaning of the act. The agency encourages manufacturers to expand these quality control operations to incorporate other procedures to ensure that the quality attributes of the food are maintained throughout production and storage.

27. Another comment suggested replacing the term "quality control operation" with "sanitation control operation" to emphasize that safety measures are a sanitation function.

FDA agrees that an adequate quality control operation carries with it many sanitation responsibilities. However, the agency does not agree that the phrase "sanitation operation" is an appropriate replacement for the proposed phrase "quality control operation." The umbrella CGMP regulations apply to both insanitary production conditions and other practices that might cause food to be adulterated.

28. Several comments on proposed § 110.3(k) "rework" (§ 110.3(m) of the final rule) requested that the definition allow the use of food that can be considered safe and wholesome only after proper treatment or reprocessing.

FDA points out that food that is adulterated because it contains undesirable microorganisms often cannot be successfully reconditioned but agrees that where food has been satisfactorily reconditioned it can be included in the term "rework." FDA has changed the definition accordingly.

29. One comment on proposed § 110.3(k) stated that the definition for rework is vague and asked for clarification of the point at which food would be removed for "rework."

FDA is rephrasing the definition to make clear what is included. However, it would be inappropriate to state the point at which food is to be removed to become "rework." Various manufacturers have different needs concerning "rework," and manufacturers should have the flexibility to use the term in a manner consistent with accepted usage for given operations.

30. One comment on proposed § 110.3(1) "safe-moisture level" (§ 110.3(n) of the final rule) recommended deleting the definition. The comment argued that for purposes of microbial control the concept of

"water activity": (a..) best reflects the microbial availability of water in a food system and therefore should be the criterion upon which to estimate microbial stability.

FDA disagrees. The definition of "safe-moisture level" is necessary to properly interpret *aw* as used in § 110.80(b)(14) because different *aw*'s are required to attain a safe moisture level in different foods.

31. Several comments on proposed § 110.3(1) suggested enlarging the definition of safe moisture level to include the level of moisture necessary to prevent the growth of undesirable microorganisms "under the intended condition of processing, storage, and distribution." These comments argue that this change, plus a new definition for "microorganisms," would aid manufacturer<sup>4</sup> in netting appropriate levels.

FDA agrees and has changed the definition to include the level of moisture.

32. Some comments on proposed § 110.3(1) suggested that a particular *a*, be considered adequate if data exist in the literature or in company files showing that the *a*, is safe for a particular food, rather than requiring the manufacturer to provide such data.

FDA agrees and is replacing the word "provided" with "available" in the final rule.

33. One comment on proposed § 110.3(l) stated: "This definition should be specified i.e. 'semi-moist or 'intermediate moisture' type foods. This designation would clarify the difference between foods with naturally high moisture contents and those with lowered (*aw*'s) that have been designed for that purpose."

FDA does not agree that the designations are necessary in this regulation. Identification of points like "semi-moist" or "intermediate moisture" along a gradient from a "natural" or "normal" moisture level to the safe moisture level is unnecessary in a document that is intended to specify the point at or below which microorganisms will not grow. Therefore, FDA has not changed the final rule in this regard.

34. Several comments on proposed § 110.3(m) "sanitize" (§ 110.3(o) of the final rule) requested that the definition be revised to refer to effective means of reducing the number of microorganisms because there is no method available to demonstrate absolute destruction of microorganisms.

FDA advises that the definition of "sanitize" relates to a process that is effective in destroying or reducing the number of microorganisms. The definition does not purport to include

the total destruction of microorganisms. Therefore, FDA has made no change in the final rule.

35. One comment on proposed § 110.3(m) suggested that because "The GMPs repeatedly distinguished non-food contact surface; (see, for example, §§ 110.35(c)(3) and 110.40(a)), it is appropriate that the definition of 'sanitize' contain the inclusive term 'food contact surfaces.' "

FDA agrees and has changed the definition accordingly.

36. One comment on the meaning of proposed § 110.3(n) (§ 110.3(p) of the final rule) suggested that, in the definition of "shall," the term "mandatory requirements" be changed to "food safety requirements."

The umbrella CGMP regulations pertain to more than food safety. For example, the regulations are also concerned with contamination by filth or decomposition which may or may not raise safety concerns. Therefore, FDA has not changed the final rule.

#### Current Good Manufacturing Practice

37. Some comments on proposed § 110.5 suggested deleting the reference to section 402(a)(3) of the act which provides that a food is adulterated if it has been manufactured under such conditions that it is unfit for food. One comment stated that a food may be unfit due to many things, including changes in texture, flavor, etc., and still not be adulterated.

The comments reflect a misunderstanding of the meaning of proposed § 110.5. Section 402(a)(3) of the act states that a food is adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; <sup>11</sup> ". FDA agrees with the comment that a product is not unfit for food because it fails to meet the flavor or texture standards of the manufacturer. Other aspects of the food, however, e.g., contamination with pests, might render it unfit within the meaning of section 402(a)(3) of the act. FDA, therefore, has not changed the final rule.

38. Two comments on proposed § 110.5(b) read this paragraph to provide that the umbrella CGMP regulations are intended solely to prevent and control communicable diseases. A related comment suggested that the reference to the prevention and control of communicable diseases be combined with § 110.5(a) to include the concept of complying with section 361 of the Public Health Service Act, as well as avoiding adulteration within the meaning of section (3) and (4) of the act.

FDA believes that the first set of comments have misinterpreted this section. The umbrella CGMP regulations are not designed solely to prevent and control communicable diseases, but are also designed to prevent food adulteration within the meaning of the act. Accordingly, the regulations apply to food that may be harmful as well as to food that may be contaminated, in whole or in part, with filth. As suggested by the one comment, the portion of § 110.5(b) concerning section 361 of the Public Health Service Act has been reworded and is a part of § 110.5(a) in the final rule.

### Personnel

39. Several comments on proposed § 110.10(a) "disease control" objected to the proposed requirement that a person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wound, or any other abnormal source of microbial contamination be excluded from working in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated or of disease being transmitted by that person to other individuals. Two comments stated that compliance with the proposed requirement is essentially impossible because a disease may be present in its communicable stage before symptoms are discernible to plant management. One comment noted that this requirement would prevent individuals having mild communicable diseases, such as upper respiratory tract infections, from working in an area such as the boiler room due to the possibility of transmitting this infection to a fellow worker in this same nonfood handling environment. The comment requested that the scope of the requirement be limited to food-borne transmission. Another comment described the "virtual inability of plant management personnel to detect workers with sores or boils covered by clothing . . . ."

FDA agrees that the provision should be clarified. The goals of the proposed requirement are met and the concerns expressed in the comments alleviated by changing the final rule to read as follows: "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 this condition is corrected. Personnel shall be instructed to report such health condition to their supervisors." This wording does not mandate that medical examinations be performed in order to comply with the requirement of § 110.10(a).

40. A number of comments on proposed § 110.10(b) "cleanliness" stated that the term "proper outer garments" is vague and should be deleted or clarified. Another comment suggested that the words "clean and" be added after the word "wearing."

In response to the comment, FDA is changing § 110.10(b)(1) to read as follows: "Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials."

41. Two comments on proposed § 110.10(b)(2) suggested either deleting the phrase "a high degree of" in the proposed statement, or replacing it with "adequate."

FDA agrees and has changed the provision accordingly.

42. One comment on proposed § 110.10(b)(3) suggested revising it to require that hands be washed thoroughly to prevent contamination by "unsafe" microorganisms not "undesirable" microorganisms as proposed. The comment related their proposed change to other comments urging that FDA be concerned only with microorganisms that are "present at a level sufficient to be of recognized adverse public health significance." The comment asserted that " . . . relatively harmless microorganisms which may cause spoilage but not a health risk should not require the same action."

Because these regulations are based on section 402(a) (3) and (i) of the act as discussed above, the agency has not limited the application of the regulations only to microorganisms that may be injurious to health. A food may be adulterated under the act if it contains any filthy substance or if it has been prepared, packed or held under conditions where it may have become contaminated with filth. Accordingly, the word "undesirable" is more consistent with legal requirements than the word "unsafe." Therefore, FDA has not revised § 110.10(b)(3) as requested.

43. One comment addressing proposed § 110.10(b)(4) suggested that jewelry be removed when employees are in food-handling areas where such jewelry "could fall into production handling equipment or empty product containers . . . ."

FDA agrees with this comment and also believes that the requirement

should be expanded to include other objects that could fall into equipment or containers. FDA has made appropriate changes in the final rule.

44. One comment favored a prohibition on all jewelry in food-handling areas, while another comment requested that the phrase "or cover with a sanitary glove" be added to accommodate hand jewelry which could not be adequately sanitized.

FDA recognizes that some hand jewelry may not be readily removed, but can be prevented from becoming a source of contamination by sanitizing or by the use of a sanitary covering, such as a clean, sanitized, nonporous glove. Therefore, it is not necessary to prohibit all jewelry in food-handling areas when such items can be prevented from being a source of contamination. FDA agrees that provision should be made for effective covering of hand jewelry and has changed § 110.10(b)(4) of the final rule to that effect.

45. Some comments on proposed § 110.10(b)(6) requested that the paragraph be reworded to eliminate specific examples of hair restraints, such as caps, which these comments did not believe to be effective hair restraints. Several comments stated that some manufacturers maintain restrictive standards and do not allow employees to wear beards or mustaches while working in the plant. These comments suggested that a "broad performance standard" be adopted to allow for the differing policies of various manufacturers. Other comments requested that the final regulation be changed to exempt individual, employed in plant operations where there is no reasonable possibility of their hair contaminating either the food or food-contact surfaces.

It is the manufacturer's obligation to see that effective measures are taken to prevent the adulteration of food. When a manufacturer believes that the use of a particular hair restraint, such as a cap, is ineffective under the conditions of a particular operation, or that the wearing of beards or mustaches will adversely affect the integrity of the food manufactured at that specific installation, the manufacturer must adopt suitable controls. The requirement in no way restricts management from taking appropriate, positive action. The requirement does recognize, however, that in some food-manufacturing operations use of the enumerated hair restraints is an effective means of protecting against contamination of the food. Section 110.10(b) of the final rule requires hair restraints only where a reasonable possibility of contamination

from hair exists. In light of the apparent potential for misinterpretation of the scope of these requirements, FDA has changed § 110.10(b)(6) in the final rule so that this item in the list of methods of maintaining cleanliness reads as follows: "Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints."

46. A number of comments addressing § 110.10(b)(7) suggested that the wording of the requirement prohibiting the storage of clothing or other personal belongings in areas where food is exposed, or in areas used for washing equipment or utensils, be changed to a positive instruction. These comments also suggested that plant management be required to designate areas for the storage of personal belongings.

FDA agrees and has changed § 110.10(b)(7) in the final rule so that this item in the list of methods for maintaining cleanliness reads as follows: "Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed." FDA believes that the comments' request for the language stating that the storage areas for belongings be only those designated by plant management is not sufficiently specific, and therefore FDA has made no change in the final rule in this regard.

47. A number of comments on proposed § 110.10(b)(8) requested that the prohibition against the consumption of food and beverages and the use of tobacco in areas where food is exposed, or in areas for washing equipment or utensils, be changed to a more positive directive, and that these activities be limited to designated areas. Two comments were concerned that chewing gum be among these restricted activities.

FDA has changed § 110.10(b)(8) in the final rule in response to these comments. Also, chewing gum in areas where food is exposed now is a restricted activity.

48. One comment suggested that language be added to § 110.10(b)(8) to clarify that taste testing is allowed in certain areas, to ensure production of a palatable and acceptable product.

FDA recognizes that certain industries use taste testing as a routine quality control operation to ensure that certain textural and flavor characteristics are present in the food. Section 110.10(b)(8) does not prohibit taste testing provided it does not cause food to be adulterated within the meaning of the act.

Accordingly, no change in this provision is needed.

49. Two comments on proposed § 110.10(c) "education and training"

requested that personnel responsible for identifying sanitation failures or food contamination be required to have a background of education or experience and that foodhandlers and supervisors be required to have appropriate training in the principles of food sanitation.

The agency believes that the provisions of this section, if properly applied, are sufficient to maintain our supply of clean and safe food. More education of food handlers is always desirable, but is not always necessary.

50. A number of comments on proposed § 110.10(d) "supervision" requested that the proposed mandatory requirement that competent supervisory personnel be assigned the responsibility for assuring compliance by all personnel with the requirements of these regulations be changed to an advisory statement. Other comments noted that experienced educators and supervisors within the plants need to be competent sanitarians as well.

The agency does not agree that paragraph (d) should be merely advisory. For plant personnel to comply with the requirements for current good manufacturing practice, they must be instructed and supervised by adequately informed plant personnel. Although FDA cannot require that supervisors be trained sanitarians, even though that training is desirable, there is little chance of compliance with the many requirements of these regulations without the clear designation of responsibility for these supervisory functions to qualified persons. Therefore, FDA has made no change in the final rule.

#### Exclusions and Exemptions

51. Several comments on proposed § 110.19 "exclusions" objected to excluding any operation from coverage under these regulations because consumers deserve the same protection from "raw agricultural commodities" as that expected from food-processing establishments. One comment asked whether the holding or transportation of shell oysters before further processing is an excluded category.

FDA advises that because these regulations are concerned specifically with the manufacturing, packing, and holding of foods it is not reasonable to apply them to raw agricultural commodities. Accordingly, raw agricultural commodities, as defined by section 201(r) of the act (21 USC 321(r)), will continue to be regulated simply under the adulteration provisions of the act (section 402) and not under these regulations. FDA further advises that oyster shell stock prior to receipt at a processing plant is similarly excluded

from the umbrella CGMP regulations and is regulated under the adulteration provisions of the act.

52. Comments from representatives of specific industries or manufacturers sought exemption of their particular operations. For example, the bakers' association challenged the necessity for good manufacturing practice regulations for their industry in light of the allegedly low health risks associated with bakery foods and the cost of implementing the regulations. Similarly, the molluscan shellfish industry argued that the safety and quality of shellfish are adequately controlled under the National Shellfish Sanitation Program, enforced by State control agencies. The shellfish industry generally urged an exemption for it or alternatively, the addition of a grandfather clause that would allow processors who are producing safe shellfish to continue their present methods of operation.

Likewise, the wine and beer industries emphasized that because they are under the jurisdiction of the Department of the Treasury's Bureau of Alcohol, Tobacco and Firearms they should not be required to comply with FDA's umbrella CGMP regulations. The wine industry added that its voluntary sanitation program provide, adequate protection. Soft drink bottlers and their trade associations argued for exemption from the coding and recordkeeping regulations on the grounds that their present methods allow for prompt product recall. Similar arguments were put forth by bakers and other producers of products subject to frequent delivering and frequent removal of outdated merchandise. Ice producers and salt producers also asked for exemption on the ground that their products are less subject to contamination affecting health. Similarly, the dairy industry sought exemption on the ground that sufficient controls already exist to protect the public from unhealthful dairy products. Honey producers also claimed their products are unlikely to be contaminated and, therefore, the proposed regulations should not apply to the honey industry.

FDA is not granting any blanket exemptions as requested by these comments because it believes that the regulations as modified establish reasonable sanitation and health standards for the food industry generally, including those that requested exemptions. Each industry that commented is involved in food manufacturing and, therefore, is subject to adulteration provisions of the act, as well as to the provisions of the final



adequately unobstructed and of adequate width to permit employees to perform their duties and to minimize the potential for contamination of food or food-contact surfaces with clothing or personal contact."

FDA agrees, in principle, and has changed the final rule accordingly.

61. One comment on proposed § 110.20(b)(6) suggested that the reference to "steam" is "noxious fume or vapor" is contrary to the traditional use of steam in food processing.

FDA agrees and has changed the final rule.

62. One comment on proposed § 110.20(b)(6) suggested changing this paragraph to state that fans and other air-blowing equipment shall be located and operated in a manner that "minimizes the potential to cause contamination of raw materials, work-in-process, rework, finished foods, food-packaging materials, and food-contact surfaces."

FDA agrees and has changed the final rule accordingly.

63. Several comments on proposed § 110.20(b)(7) suggested that "adequate" be substituted for "effective" screening against pests because "adequate" is defined in § 110.3(b), and because it would be consistent with other parts of the regulation.

FDA agrees and has changed the final rule accordingly.

### Sanitary Operations

64. One comment on proposed § 110.35(a) "general maintenance" suggested that the requirement that the buildings, fixtures, and other physical facilities be kept "in good repair" should be eliminated because the quoted phrase may be subject to a variety of interpretations. The comment suggested that a statement requiring that these items be kept in a sanitary condition would be sufficient.

FDA agrees and has changed the first sentence of the final rule to read as follows: "Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act."

65. One comment on proposed § 110.35(a) (§ 110.35(b) of the final rule) suggested the deletion of the requirements dealing with (1) the microbial quality, the safety and the efficacy of cleaning and sanitizing chemicals; (2) the storage of toxic materials in the plant; and (3) the prevention of contamination of food and food-packaging material from the use and storage of cleaning compounds, sanitizing agents, and pesticide

chemicals. The comment reasoned that the proposed requirement that all applicable regulations of the Environmental Protection Agency (EPA) be followed "basically encompassed" the requirements enumerated in the proposed regulation.

FDA cannot compel manufacturers to comply with requirements that FDA cannot enforce. FDA is changing the sentence regarding EPA regulations from mandatory compliance to advisory compliance with all regulations promulgated by Federal, State, and local government agencies other than FDA provided of course that the regulations are applicable to the umbrella CGMP regulations. However, FDA is retaining the specifically mentioned subjects of concern in the final rule, because failure to comply with these requirements may adversely affect the safety and wholesomeness of food.

66. Several comments on proposed § 110.35(a) concerned the sentence which reads: "Detergents, sanitizers and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses." One comment suggested that it is impractical to test detergents for contamination with microbial contamination. Another comment argued that users should be able to rely on the claims or warranties of the manufacturers of these products to satisfy the requirements of the regulations.

FDA is aware that many businesses do not have the resources to verify, through in-house testing procedures, that the cleaning and sanitizing chemicals they employ are of acceptable microbial quality and are safe and adequate for their intended use. For this reason, FDA is adding to § 110.35(b)(1) of the final rule a sentence allowing compliance with the requirement to be verified by any effective means, including purchase under a supplier's guarantee or certification, a examination of these materials for contamination.

67. Two comments on proposed § 110.35(a) suggested that the term "effective" be changed to "adequate." One comment argued that this change is appropriate because an absolute absence of contamination may be unattainable. The comment added that it is important to require that every necessary effort be made to minimize contamination.

FDA agrees and has changed § 110.35(b)(1) of the final rule accordingly.

68. A number of comments on proposed § 110.35(a) noted that the term "plant" could be misinterpreted to

include warehouses and distribution centers.

FDA agrees and has modified the last sentence in § 110.35(b)(1) in the final rule to read as follows: "Only the following toxic materials that are required to maintain sanitary conditions may be used or stored in a plant where food is processed or exposed: (i) Those required to maintain clean and sanitary conditions; (ii) Those necessary for use in laboratory testing procedures; (iii) Those necessary for plant and equipment maintenance and operation; and (iv) Those necessary for use in manufacturing operations." FDA advises that requirements regarding maintenance of acceptable conditions specifically during warehousing and distribution are provided under § 110.93.

69. Two comments on proposed § 110.35(b) "animal and vermin control" (§ 110.35(c) "pest control" in the final rule) suggested that this paragraph be modified to exempt guard dogs and guide dogs, under certain conditions, from the requirements of the first sentence of the proposed paragraph.

FDA agrees and has added the following sentence to the final rule: "Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces or food-packaging materials."

70. One comment on proposed § 110.35(b) (§ 110.35(c) of the final rule) said that the sentence providing for the use of insecticides and rodenticides under precautions and restrictions that would protect against the contamination of food and food-packaging materials should be deleted since it duplicated existing EPA regulations.

FDA disagrees that the regulation results in an unnecessary requirement. Food that becomes contaminated with these compounds may be actionable under section 402 of the act.

Accordingly, regulations specifying current good manufacturing practice for the food industry should stress the need for taking effective precautions in this area and are not duplicative. Therefore, the agency is retaining this sentence in the final rule.

71. Several comments on proposed § 110.35(c) (§ 110.35(d) of the final rule) concerned the proposed requirement that food-contact surfaces used for the processing or holding of low-moisture raw materials or food be in a dry, sanitary condition at the time of use. Some comments suggested that phrases such as "when necessary" or "where applicable" be added to this sentence, but failed to explain the reasoning behind the suggested addition. Other

adequately unobstructed and of adequate width to permit employees to perform their duties and to minimize the potential for contamination of food or food-contact surfaces with clothing or personal contact."

FDA agrees, in principle, and has changed the final rule accordingly.

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FDA agrees and has changed the final rule accordingly.

### Sanitary Operations

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FDA agrees and has changed the first sentence of the final rule to read as follows: "Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act."

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chemicals. The comment reasoned that the proposed requirement that all applicable regulations of the Environmental Protection Agency (EPA) be followed "basically encompassed" the requirements enumerated in the proposed regulation.

FDA cannot compel manufacturers to comply with requirements that FDA cannot enforce. FDA is changing the sentence regarding EPA regulations from mandatory compliance to advisory compliance with all regulations promulgated by Federal, State, and local government agencies other than FDA provided of course that the regulations are applicable to the umbrella CGMP regulations. However, FDA is retaining the specifically mentioned subjects of concern in the final rule, because failure to comply with these requirements may adversely affect the safety and wholesomeness of food.

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FDA is aware that many businesses do not have the resources to verify, through in-house testing procedures, that the cleaning and sanitizing chemicals they employ are of acceptable microbial quality and are safe and adequate for their intended use. For this reason, FDA is adding to § 110.35(b)(1) of the final rule a sentence allowing compliance with the requirement to be verified by any effective means, including purchase under a supplier's guarantee or certification, a examination of these materials for contamination.

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FDA agrees and has changed § 110.35(b)(1) of the final rule accordingly.

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include warehouses and distribution centers.

FDA agrees and has modified the last sentence in § 110.35(b)(1) in the final rule to read as follows: "Only the following toxic materials that are required to maintain sanitary conditions may be used or stored in a plant where food is processed or exposed: (i) Those required to maintain clean and sanitary conditions; (ii) Those necessary for use in laboratory testing procedures; (iii) Those necessary for plant and equipment maintenance and operation; and (iv) Those necessary for use in manufacturing operations." FDA advises that requirements regarding maintenance of acceptable conditions specifically during warehousing and distribution are provided under § 110.93.

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FDA agrees and has added the following sentence to the final rule: "Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces or food-packaging materials."

70. One comment on proposed § 110.35(b) (§ 110.35(c) of the final rule) said that the sentence providing for the use of insecticides and rodenticides under precautions and restrictions that would protect against the contamination of food and food-packaging materials should be deleted since it duplicated existing EPA regulations.

FDA disagrees that the regulation results in an unnecessary requirement. Food that becomes contaminated with these compounds may be actionable under section 402 of the act. Accordingly, regulations specifying current good manufacturing practice for the food industry should stress the need for taking effective precautions in this area and are not duplicative. Therefore, the agency is retaining this sentence in the final rule.

71. Several comments on proposed § 110.35(c) (§ 110.35(d) of the final rule) concerned the proposed requirement that food-contact surfaces used for the processing or holding of low-moisture raw materials or food be in a dry, sanitary condition at the time of use. Some comments suggested that phrases such as "when necessary" or "where applicable" be added to this sentence, but failed to explain the reasoning behind the suggested addition. Other

comments remarked that, just as it is not always necessary to sanitize wet-cleaned surfaces before use, it is not always necessary to dry wet-cleaned surfaces thoroughly before subsequent use. Another comment noted that lubricants, and sometimes moisture, are necessary on certain food-contact surfaces during the baking process. The comments recommended that the phrase " \* \* \* , unless otherwise required by the demands of the baking process itself " be added to this sentence.

FDA believes that all the concerns raised by these comments can be satisfied by the new wording of the second sentence: "When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use."

72. In reference to the requirement in proposed § 110.35(c)(2) (§ 110.35(d)(2) of the final rule) that food-contact surfaces be cleaned and sanitized after any interruption during which these surfaces may have become contaminated, one comment noted that "any interruption" could be read to include such routine events as quality control checks. Another comment stated that the word "interruption" must be defined as to time period.

FDA recognizes that the possibility of contamination exists even during short, scheduled interruptions, such as quality control checks. The agency does not agree that the length of time of the interruption is of central concern. What is important is whether the utensils and other food-contact surfaces may become contaminated. FDA has changed the final rule to clarify this point.

73. Two comments on proposed § 110.35(c)(2) (§ 110.35(d)(2) of the final rule) criticized the requirement that food-contact surfaces in a continuous production operation be cleaned and sanitized according to a predetermined schedule. The comments claimed that cleaning functions should be based on need, such as a change in bacterial levels, rather than lapse of time.

FDA agrees and has changed § 110.35(d)(2) of the final rule.

74. One comment on proposed § 110.35(c)(5) (§ 110.35(d)(5) of the final rule) suggested that the term "effective," in the proposed requirement that sanitizing agents be effective and safe under conditions of use, be changed to "adequate."

FDA agrees and has changed the provision.

75. One comment on proposed § 110.35(d) (§ 110.35(e) of the final rule) "storage and handling of cleaned portable equipment and utensils" suggested requiring that cleaned and sanitized equipment that has been

stored be rinsed and sanitized before subsequent use.

It is not always necessary to rinse and sanitize equipment with food-contact surfaces or utensils that have previously been cleaned and sanitized, if the equipment has been properly protected from contamination during storage. Therefore, the suggested change is not necessary and no such change is made in the final rule.

76. Another comment on proposed § 110.35(d) requested clarification of whether flour dust in a baking area is included in the phrase "other contamination" in the advisory statement that cleaned and sanitized food-contact surfaces should be stored in such a way as to protect these surfaces "from splash, dust, and other contamination."

The phrase "other contamination" refers to all other substances not specifically listed that may cause the food-contact surfaces to be considered insanitary. FDA does not consider airborne flour which settles on stored equipment to be a contaminant, unless it renders the surfaces of the equipment insanitary. Therefore no such change is made in the final rule.

#### Sanitary Facilities and Controls

77. One comment on proposed § 110.37 stated that this section should apply only to new construction and that compliance should be deferred for 2 years after the issuance of the final rule. The comment considered these changes necessary to protect small bakeries and to permit a period for design and construction of new facilities.

The proposed requirements of this section were essentially the same as the then existing requirements (21 CFR 110.35), with the exception of a new paragraph that prohibited backflow or cross-connection between piping systems that carry water for food processing and piping systems that discharge waste water or sewage. Because the requirements are not new, FDA believes that the effective date for this final rule provides adequate time for industry compliance.

78. One comment on proposed § 110.37(a) "water supply" suggested requiring that the water supply be obtained from a State-approved source and be monitored for bacterial and chemical contamination as required by the Safe Drinking Water Act, administered by EPA. The comment also suggested a requirement that any water used in the final rinse, fluming, and spray contact of the product or equipment be of potable quality.

FDA believes that the concerns raised by this comment are covered in the

wording of the final rule. The water supply is required to be sufficient for the operations intended and derived from an adequate source. Water contacting food or food-contact surfaces must be safe and of adequate sanitary quality.

79. One comment on proposed § 110.37(a) requested that the requirement that "running water at a suitable temperature and under pressure as needed shall be provided in all areas where required for the processing, the cleaning of equipment, utensils, or containers, or for employee sanitary facilities," be changed by replacing the phrase "at a suitable temperature" with the phrase "suitable and/or ambient temperatures." The comment stated that the use of hot water in a segment of the seafood industry would hinder effective cleaning operations.

The wording of the provision in no way prevents the use of water at ambient temperature for cleaning, provided the temperature is suitable for the specific conditions encountered. Therefore, FDA has made no change in the provision.

80. One comment on proposed § 110.37(b) "plumbing" asked whether all plants would be required to replace standard hand-operated toilets with foot-operated high-pressure sanitary facilities regardless of additional cost.

One should not draw this interpretation from the requirements. If the present plumbing and toilet facilities are adequate and do not present a source of adulteration to the food, they need not be replaced.

81. One comment on proposed § 110.37(b)(5) stated that the word "ensure" in the proposed requirement that there be no backflow from, nor cross-connection between, waste water or sewage systems and water systems for food or food-processing use, should be changed to "provide." The comment suggested the change to alleviate the concern that industry would routinely be obligated to furnish blueprints of plumbing systems. The comment added that this type of submission should not be required unless there is reasonable evidence of a possible contamination problem.

FDA agrees and has changed the final rule accordingly.

82. Also with regard to the requirement in proposed § 110.37(b)(5) that there be no backflow from, or cross-connection between, piping systems that carry water for food or food manufacturing use and piping systems that discharge waste water or sewage, two comments suggested reversing the proposed order in which the piping systems are mentioned.

FDA agrees and has incorporated the changes into the final rule.

83. One comment on proposed § 110.37(b)(5) requested that the phrase "waste water" in the requirement prohibiting backflow from, and cross-connection between, piping systems be defined or differentiated more clearly from the water used for food or food manufacturing. The comment noted the economic importance of the counter current flow design used in some industry processes and expressed concern that the proposed requirement would prohibit this accepted design.

Under the regulations, waste water is water contaminated to a level above that considered acceptable for use in food manufacturing. FDA believes that the modified wording, as discussed in previous paragraphs of this preamble, conveys this meaning. Therefore, FDA has not attempted to expand on the meaning of "waste water" in this requirement in the final rule.

85. One comment on proposed § 110.37(b)(5) requested permitting the use of existing plumbing facilities that are maintained in a sanitary manner because the expenditures necessary to assure that there would be no backflow from piping systems that discharge waste water or sewage into piping systems that carry water for food or food manufacturing use are not justified.

FDA disagrees. Interruptions in water pressure can draw water from nonpotable sources into the processing water supply system unless backflow prevention devices or other suitable means are in effect. FDA considers the points expressed in paragraph (b)(5) to be basic to manufacturing safe and wholesome food. For this reason FDA has retained the substance and the spirit of this paragraph, as proposed in the final rule.

85. Comments on proposed § 110.37(c) "sewage disposal" and § 110.37(f) "rubbish and offal disposal" stated that references to appropriate EPA regulations should be added to these proposed paragraphs. One of the comments stated that industry has difficulty locating various agencies regulations governing a specific operation.

FDA is sympathetic to the concerns expressed in the comments, but believes that other agencies need to be the source of information on their applicable regulations to ensure that the information provided is accurate and up-to-date. Accordingly, FDA has not added the requested citations in these regulations.

86. A number of comments on proposed § 110.37(d) requested that the provision allow, because of geographic

location or ground conditions, the location of toilet facilities outside the plant. One comment suggested providing only that the toilet facilities be readily accessible.

The agency agrees with the suggestion and has changed the final rule accordingly.

87. Two comments on proposed § 110.37(e) stated that the requirement of adequate and readily accessible hand-washing facilities and, if necessary, sanitizing facilities for employees handling unprotected food, unprotected packaging materials, and food-contact surfaces could be interpreted to require that hand-washing facilities be installed at receiving stations or in processing areas that could be adequately serviced by sanitizing stations. One comment suggested that the proposed requirement be replaced with the wording of the current CGMP regulations (21 CFR 110.35(e)).

FDA agrees in principle and has modified the final rule accordingly.

88. One comment on proposed § 110.37(e) suggested replacing the phrase "suitable drying services" in the requirement that specifies the components of a suitable handwashing and sanitizing facility, with the phrase "suitable drying devices." One comment requested that cloth towel dispensers be allowed as long as the towel dispensers are so constructed that only a clean and unused portion of towel is provided for each use.

FDA agrees with the comments and has changed the final rule accordingly.

89. Several comments on proposed § 110.37(e) objected to the specificity of "water control valves." One comment interpreted this phrase to describe only foot-operated control valves and stated that these valves are notorious for harboring undesirable microorganisms.

In response to these comments, FDA has expanded the scope of this paragraph to suggest the use of devices or fixtures, such as water control valves, that are designed and constructed to protect against recontamination of clean, sanitized hands. The phrase "water control valves" should not be interpreted as limited to foot-operated valves. For example valves of the automatic shutoff variety and wing fixtures designed for shut-off the water flow by pressure from the elbow are other methods that are superior to traditional valves using manual shut-off in minimizing the possibility of recontamination. FDA has no information showing that the valve mechanism of food-operated water control valves is a source of contamination. However, the agency

encourages anyone having such information to submit to FDA.

### Equipment and Utensils

90. Several comments on proposed § 110.40(a) objected to the proposed requirement that food-contact surfaces be "corrosion-free," suggesting that full compliance would be impossible.

FDA agrees and has substituted the term corrosion-resistant for corrosion-free in the final rule.

91. Some comments on proposed § 110.40(a) suggested that food-contact surfaces, while nontoxic should be nonreactive with food components to prevent unwanted quality changes.

It is in the interest of the manufacturer to have foodcontact surfaces that do not cause unwanted quality changes in food. Therefore, the final rule now requires that food-contact surfaces be made of nontoxic materials and designed to withstand the environment of their intended use.

92. One comment on proposed § 110.40(a) stated that daily cleaning of some equipment is not feasible because the equipment is of an enclosed nature and is operated at elevated temperatures for weeks at a time without shutting down.

The comment misunderstood what was proposed. However, FDA agrees that it is not necessary to clean such equipment on a daily basis as there is no opportunity for growth of microorganisms. However, it is current good manufacturing practice to clean equipment at a frequency that is sufficient to avoid potential contamination. Therefore, FDA is making no change in the final rule.

93. A number of comments on proposed § 110.40(b) objected to the proposed requirement that seams on food-contact surfaces be smoothly bonded.

The provision does not require smooth, bonded seams. As an alternative, seams on food-contact surfaces may be maintained so as to minimize accumulation of food particles, dirt, and organic matter. Therefore, FDA has made no change in the final rule in this respect.

94. One comment on proposed § 110.40(b) urged exclusion of baking pans and conveying systems from the requirement of this paragraph because wire mesh belting and metal "take-apart" joints of canvas conveyor belting, including metal seams, are in common use in the baking industry and do not cause problems.

The regulations allow the use of baking pans and the conveying systems mentioned provided they are properly

maintained. Because more detail is not needed, FDA has made no change in the provision.

95. A number of comments on proposed § 110.40(d) suggested that it is not always necessary to clean a gravimetric, pneumatic, closed, or automated system. Another comment suggested that the requirement be changed from "to be cleaned to "to be maintained in an appropriate sanitary condition".

FDA agrees with the comments and has changed the final rule to include the suggested wording.

96. One comment on proposed § 110.40(e) suggested that this paragraph be deleted or combined with proposed § 110.40(g).

FDA agrees and has modified § 110.40(f) of the final rule to combine the two paragraphs.

97. One comment said that proposed § 110.40(e) would apply to ethylene oxide treatment, making it difficult to demonstrate that a measuring device or control is effective in minimizing the growth of microorganisms in the product.

FDA advises that the basis for this comment has been mooted by the change discussed in paragraph 96 above.

98. One comment on proposed § 110.40(e) stated that FDA should suggest, but not require, that plants have temperature control equipment.

Because the regulation of temperature is important in protecting against the growth of microorganisms, FDA has retained the requirement for temperature controls.

99. Some comments on proposed § 110.40(f) (§ 110.40(e) of the final rule) suggested that FDA require temperature-recording devices or an alarm mechanism for all freezers and cold storage compartments rather than permit a thermometer for this purpose. Other comments stated that recorders and alarms should be required only for storage rooms at 45 ° F or below and that bakeries do not need temperature-recording devices or alarms on small coolers.

Although it is desirable to have temperature-recording devices or alarms in freezers or cold storage compartments, FDA believes that an accurate thermometer is satisfactory for most coolers, regardless of whether they are kept at, above, or below 45 ° F. The requirement for temperature indicating, measuring, or controlling devices applies only to freezing and cold storage compartments used for storing raw materials or foods capable of supporting the growth of microorganisms. Therefore, FDA has not changed the final rule.

100. One comment on proposed § 110.40(g) (§ 110.40(f) of the final rule) suggested that the word "precise" be changed to "accurate" in the proposed requirement that instruments used for measuring or regulating conditions that control or prevent microbial growth in food be precise and properly maintained. Another comment requested that "properly" be changed to "adequately".

FDA agrees with the comments and has changed the final rule accordingly.

101. A number of comments on proposed § 110.40(h) (§ 110.40(g) of the final rule) pointed out that compressed air and other gases mechanically introduced into foods may already be suitable for contact with food or food-contact surfaces and may not need to be filtered or washed. The comments further suggested that, since air or gases are sometimes used to add oil or other ingredients to the food, properly filtered or washed should be deleted or modified.

FDA agrees and has changed the final rule accordingly.

102. FDA received two comments on proposed § 110.40(i) Section 110.40(i) pertains to the proper control of sources of PCB contamination. The comments suggested that the section should require the use of catchpans to control the leakage of PCB's from sealed electrical transformers and capacitors. The comments also requested clarification regarding what the proposed language "in and around food plants" was meant to include.

FDA has deleted proposed § 110.40(i) from the final rule. The proposed requirements are no longer necessary. In the Federal Register of August 25, 1982 (47 FR 37342), the Environmental Protection Agency (EPA) published a final rule that prohibits the use of PCB transformers with a dielectric fluid PCB concentration of 500 parts per million or greater posing an exposure risk to food or feed. The final rule became effective October 1, 1985. EPA's final rule also prohibits the use of large PCB capacitors after October 1, 1988, unless they are located in restricted access electrical substations or in contained and restricted access indoor installations. EPA's final rule provides, in FDA's view, sufficient safeguards against the risk of contamination of food and feed from PCB-containing electrical equipment. Accordingly, FDA has deleted proposed § 110.40(i). In the Federal Register of July 18, 1985 (50 FR 29233), FDA also withdrew a rule it proposed (45 FR 30984; May 9, 1980) to revise proposed § 110.410(i) and other regulations that deal with PCB's.

## Processes and Controls

103. Some comments on proposed § 110.80, *Processes and controls* suggested deleting the reference to quality control operations because they are not always necessary and would add the unnecessary expense of placing a quality control person in each plant or of using an outside laboratory.

FDA disagrees. Even the smallest operation should have some quality control system that results in the production of safe, clean, and wholesome foods. This does not mean that the manufacturer needs to hire a quality control specialist, nor does it mean that an outside laboratory must be used. Therefore, FDA has made no change in the final rule with respect to quality control operations.

104. One comment on proposed § 110.30 suggested the addition of a listing of quality control operations.

FDA advises that it is not necessary to list all possible quality control operations because they include all actions necessary to prevent food from becoming adulterated within the meaning of the act.

105. Several comments on proposed § 110.80 requested that it allow the use of some raw materials that are not fit for food until they have undergone processing or have been processed into an ingredient that is then incorporated into the finished product. Another comment noted that quality control operations should be concerned with both raw materials and ingredients.

FDA agrees with both comments and has changed the final rule accordingly.

106. Some comments on proposed § 110.80 challenged FDA's authority to require that the maintenance of the sanitation of the plant be under the supervision of an individual assigned responsibility for this function. Other comments suggested that the regulations require that the individual assigned be competent. Another comment stated that the term "over-all" is too broad and requested that responsibility for sanitation be allowed to be assigned to more than one individual.

FDA believes that every plant must have one or more individuals responsible for the sanitation of the plant and the personal hygiene of the employees. Courts have observed that the act embodies the simple and understandable expectation of the American public that food be manufactured, packed, and held with a reasonable degree of cleanliness. See, e.g., *United States v. An Article of Food - Pasteurized Whole Eggs*, 339 F. Supp. 131,141 (N.D. Ga. 1972).

Accordingly, courts have encouraged the development of reasonable plant standards specifying steps to be taken to ensure that a reasonable degree of care and cleanliness be accorded the manufacture of food. See, e.g., *United States v. 1,500 Cans More or Less*, 236 F.2d 208, 212 (7th Cir. 1956). The reasonable requirement that every plant assign one or more competent individuals as responsible for plant sanitation is, thus, clearly authorized.

FDA has made the final rule consistent with the latter comments to provide that the responsible individuals be "competent" and to clarify that the responsibility for the sanitation of a plant and the personal hygiene of the employees may be shared by several individuals.

107. One comment on proposed § 110.80 requested a more specific definition for the phrase "adequate sanitation principles."

The phrase must be broad so that industry can easily adapt adequate sanitation principles to its existing procedures. Therefore, FDA has not made the suggested change.

108. Some comments on proposed § 110.80 suggested that the sentence beginning with "chemical, microbiological or extraneous-material testing . . ." be expanded to include a phrase indicating that supplier's guarantees or certification be permitted to verify compliance with FDA regulations, guidelines, or action levels where applicable.

FDA disagrees. This paragraph refers primarily to sanitation within the plant. FDA has no objection to the manufacturer obtaining a supplier's guarantee or certification, as specifically mentioned in § 110.80(a) (2), (3), and (4).

109. A comment suggested that proposed § 110.80(a) state that although incoming raw materials and other ingredients should be inspected, as necessary, there are also other appropriate means of ensuring the cleanliness and fitness of ingredients.

FDA agrees and has changed the final rule accordingly.

110. A comment on proposed § 110.80(a)(1) suggested that there should be parallel programs by the U.S. Department of Agriculture (USDA) and the Interstate Commerce Commission (ICC) to cover the handling of raw materials and ingredients.

Although parallel programs are desirable, they are not a prerequisite to the proposed provision. Affected firms should contact USDA and ICC directly for information about their programs.

111. A comment on proposed § 110.80(a)(1) stated that the term "fit" is used in an unfamiliar context and

suggested that it be changed to "appropriate" or "suitable."

FDA agrees and has substituted "suitable" for "fit" in the final rule.

112. Other comments on proposed § 110.80(a)(1) questioned whether the proposed provision that "raw materials shall be washed or cleaned as required" applies to grapes and oyster shell stock.

FDA advises that the handling of grapes and oyster shell stock would be covered if they are used as raw materials in a food-processing plant. FDA has clarified the quoted language by changing "required" to "necessary" in the final rule.

113. Several comments on proposed § 110.80(a)(1) pointed out that the conservation of water used for washing, rinsing, or conveying is important. The comment urged that this water be allowed to be reused if any possible microbial contamination harmful to humans has been minimized.

FDA agrees and has changed the final rule to provide that water may be reused for washing, rinsing, or conveying products, so long as it will not increase the level of contamination of food.

114. A comment on proposed § 110.80(a)(2) suggested deleting this paragraph, and other comments suggested that the goal should be to "control" microorganisms not necessarily to "destroy" them.

FDA does not agree that the paragraph should be deleted. The requirement is important because the use of untreated raw materials and other ingredients may contain high levels of potentially toxic microorganisms. FDA agrees in principle with the other suggestions, and has changed the final rule to clarify that if raw materials and ingredients contain levels of undesirable microorganisms, they must either not be used or else must be pasteurized or otherwise treated during manufacturing operations to prevent the food from being adulterated within the meaning of the act.

115. A comment suggested that a supplier's guarantee or certification should be permitted to verify compliance with FDA regulations, guidelines, or action levels for raw materials.

FDA agrees and has changed the final rule accordingly.

116. Several comments on proposed § 110.80(a)(3) stated that there is a lack of technically efficient methods for determining the presence of aflatoxins in spices and many other raw materials. Some of the comments also stated that it would not be practical or necessary to test for aflatoxin in certain commodities. Some comments also argued that this

paragraph not apply to public warehouses.

Although there is a lack of adequate methods for determining the presence of aflatoxins in spices, methods do exist for other raw materials. Without further elaboration, the comment is too vague to respond to. FDA has, however, clarified the paragraph, which now provides:

raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished products. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

This paragraph does not require public warehouses to test routinely for the presence of aflatoxins.

117. A comment on proposed § 110.80(a)(3) noted that USDA has an average limit of 25 parts per billion (ppb) of aflatoxin in its peanut certification programs, while FDA has established an action level for this substance at 20 ppb. The comment questioned whether a "USDA negative aflatoxin certificate" (i.e., aflatoxin not greater than 25 ppb) would be considered a supplier's certification in light of this difference in action levels.

Since 1969 FDA has taken the position that it will not object to movement in interstate commerce of lots of raw shelled peanuts with aflatoxins not exceeding 25 ppb, provided the peanuts are destined for further processing that will result in levels in the consumer product that meet the FJJA guidelines. Therefore, a lot covered by such a USDA certificate and destined for further effective processing would satisfy the requirements of this action if the FDA requirements are met after further processing.

118. A comment on proposed § 110.80(a)(3) asserted that this requirement would place an inflationary burden on smaller wholesale bakers because it would require each baker, regardless of size, to set up a laboratory and to hire trained laboratory personnel.

FDA disagrees. The provision allows compliance to be accomplished by purchasing materials under a supplier's guarantee or certification. The agency believes that this provision, together with the other changes made in the final rule, alleviates the concerns expressed.

119. Several comments on proposed § 110.80(a)(4) stated that the word

"ingredients" should be added just after the words "raw materials."

FDA agrees and has changed the final rule to reflect that the paragraph refers to raw materials and other ingredients.

120. Some comments on proposed § 110.80(a)(4) suggested that for compliance purposes, raw material suitability may be verified by any effective means, including a supplier's guarantee or certification.

FDA agrees and has modified the final rule accordingly.

121. A comment on proposed § 110.80(a)(4) stated that in this context the word "rework" is confusing, and recommended that the list of possible sources of contamination be removed.

As discussed elsewhere in this preamble, FDA has revised the definition of "rework" in § 110.3(m). Section 110.80(a)(4) identifier "rework" as one of several possible sources of contamination. These examples are consistent with other sections of the final rule and are of assistance to the manufacturer in ensuring an unadulterated product. Therefore, FDA has not changed § 110.80(a)(4) in the final rule.

122. A comment on proposed § 110.80(a)(4) stated that the "requirements" and "action levels" referred to in proposed § 110.80(a)(4) are voluntary, and recommended that the "shall" be changed to "should."

Because the regulations and action levels referred to are mandatory, FDA has not changed the final rule as requested.

123. Some comments on proposed § 110.80(a)(5) suggested adding the terms "ingredients and rework."

FDA agrees and has modified the final rule.

124. A comment on proposed § 110.80(a)(5) said that, in the case of many ingredients, normal ambient conditions are adequate to prevent contamination and that the words "when required" should be added to the reference to temperature.

The requested change in the final rule is unnecessary, because the provision does not mention a specific temperature and is sufficiently general to allow storage of ingredients under normal ambient conditions if this practice prevents a product from becoming adulterated within the meaning of the act.

125. Several comments on proposed § 110.80(a)(5) suggested changing the word "adulteration" to "contamination."

FDA usually uses the word "contamination" in the regulations because industry is more familiar with that word as it may affect a particular practice. FDA recognizes that it may be

impossible to prevent the contamination of food and, accordingly, the regulations stress that one must "protect against" or "minimize" the contamination of food. The level of care that one must exercise to do this is the same as that level necessary to "prevent" food from being adulterated within the meaning of the act. Because the regulations provide procedures for preventing food from becoming adulterated within the meaning of the act, FDA frequently refers in the regulations to the statutory term "adulteration" rather than the word "contamination." FDA believes that the term "adulterated" is appropriate in the context of § 110.80(a)(5).

126. Some comments on proposed § 110.80(a)(5) suggested that because raw materials arrive at the processing plant in bulk, it is inappropriate to require that they be held in containers designed or constructed to prevent their contamination. One comment suggested that raw materials might be washed or cleaned, before they are held under controlled temperature or humidity, or both.

FDA agrees that raw materials may be held in bulk, and has modified the final rule accordingly. Requirements for washing and cleaning raw materials are discussed in § 110.80(a). There are no restrictions on washing or cleaning raw materials prior to storage. Therefore, FDA has made no additional change in § 110.80(a)(5).

127. A number of comments on proposed § 110.80(a)(6) pointed out that it is not always necessary to defrost frozen raw materials prior to use in the final food product. Examples given were frozen fish used in frozen breaded fish products and frozen spinach repacked into frozen sauce-in-bag products.

FDA agrees and has changed the final rule accordingly.

128. One comment on proposed § 110.80(a)(6) suggested that the words "except for the period of time actually required for processing" be removed from the regulation.

FDA agrees and has deleted these words from the final rule.

129. Several comments on proposed § 110.80(a)(6) stated that some frozen raw materials need to be defrosted prior to manufacturing. There comments also stated that defrosting may affect the materials organoleptic qualities without rendering the raw materials unsafe. Therefore, they suggested the phrase "have adverse public health consequences" be substituted for "not adversely affect their use as food."

FDA does not consider normal organoleptic quality changes to adversely affect the use of food

materials that are defrosted under current good manufacturing practice. Therefore, FDA is not adopting the suggested change. In addition, the suggested change would be too limiting. The terminology "adverse public health consequences" does not apply to food that consists in whole or in part of a filthy, putrid, or decomposed substance, or is otherwise unfit for food. For clarification, FDA is changing the sentence in question to read as follows: "If thawing in required prior to use, it shall be done in a manner that prevents the food from becoming adulterated within the meaning of the act."

130. A comment on proposed § 110.80(a)(6) suggested limiting the term "frozen raw materials" to those items that are to be used by the plant in other food products, and that the term should not include frozen products that are thawed and held under refrigeration until sold.

The provision covers only frozen raw materials and ingredients.

131. One comment on proposed § 110.80(a)(7) stated that food additives and ingredients should meet the requirements of the Food Chemicals Codex.

Food Chemicals Codex requirements are included in FDA's requirements (21 CFR 170.30(h)(1)). Therefore, FDA has made no change in the final rule.

132. One comment on proposed § 110.80(a)(7) requested the deletion of the modifying terms "direct" and "indirect," in regard to contamination.

FDA agrees and has changed the final rule accordingly.

133. A number of comments on proposed § 110.80(b)(1) pointed out that it is not always necessary to clean all processing equipment and utensils frequently. Several comments suggested that the term "frequent" be changed to "adequate."

FDA agrees with these comments, and has changed the final rule to require that containers be kept in an "acceptable" condition through appropriate cleaning and sanitizing, as necessary.

134. One comment on proposed § 110.80(b)(1) suggested that "finished product containers" be changed to "bulk product containers." The comment gave no reason for this change.

The category "finished product containers" includes bulk product containers. Therefore, FDA has made no change in the final rule.

135. A comment on proposed § 110.80(b)(2) requested that its scope be limited to health matters.

FDA disagrees. The scope of the regulations is broader than suggested

and pertains to other possible causes of adulteration under the act.

136. Two comments maintained that public warehouses are not subject to § 110.80(b)(2). The comments stated further that neither warehousemen nor retail grocers are able to conduct sophisticated water activity tests on merchandise. The comments, therefore, concluded that **this** reference is intended to apply to processing operations only.

Public warehouses are subject to § 110.80(b)(2) but not to the portions of these regulations that are applicable to food-packing or food-packaging operations. The CGMP regulations do not apply to retail grocers.

137. A comment observed that compliance with proposed § 110.80(b)(2) will involve extensive and costly recordkeeping. Further, the comment stated that, because "water activity" is foreign to baking operations, this provision could be extremely expensive for smaller bakers.

The comment misunderstood the scope of this section for it imposes no recordkeeping requirements. The monitoring of factors such as time, temperature, water activity, humidity, and pH, is a suggested way to minimize the potential for the growth of undesirable microorganisms or for the deterioration or contamination of processed food or food ingredients. Therefore, FDA has made no change in the final rule in this regard.

138. A comment on proposed § 110.80(b)(2) suggested that the phrase "vacuum internal pressure in the containers" be added to the examples listed of ways to minimize the potential for growth of undesirable microorganisms. The comment further stated that the following sentence should be included: "Effective measures shall be taken to prevent contamination of food products by 100 percent monitoring vacuum internal pressure in containers on a production line with electronic vacuum inspectors, or other suitable effective means, where feasible."

The list of physical factors and processing operations is not all inclusive. FDA believes the proposed wording adequately expresses the intent behind this provision and allows use and monitoring of vacuum internal pressure in containers without the suggested additional language. Therefore, FDA has made no change in the final rule.

139. A number of comments on proposed § 110.80(b)(3) noted that not all foods support the rapid growth of undesirable microorganisms or are subject to decomposition. These comments pointed out that certain

foods, like cheese and bakery products, pose no hazard and require no specific treatment. A comment further stated that it is not necessary to maintain frozen foods at 0 F (-17.8 °C) or below, so long as the foods remain frozen.

FDA agrees that some foods pose no microbial hazard and require no specific temperature storage treatment. These foods are not subject to paragraph (b)(3). FDA also agrees that from a public health standpoint it is not necessary to maintain frozen foods at 0 F (-17.8 °C). Therefore, FDA has revised the final rule accordingly.

140. A comment on proposed § 110.80(b)(3) suggested that, because the growth of microorganisms is essential in cheese, wine, and beer manufacture, the list of acceptable ways to hold foods should include "Establishment of continuing vigorous fermentation such as in the making and curing of natural cheese."

FDA notes that paragraph (b)(3) now applies to foods that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, or that cause food decomposition. The growth of microorganisms essential to the fermentation of cheese, wine, and beer is not considered to be restricted by § 110.80(b)(3) because this growth is not undesirable. Therefore, FDA has made no change in the final rule.

141. One comment on proposed § 110.80(b)(3) said that the maximum temperature requirement for storing cold foods should be changed from 45°F to 40°F and that the minimum temperature requirement for storing hot foods should be changed from 140°F to 150°F. Another comment stated that 140°F is too high a temperature to maintain hot food because it will dry out and become inedible. The comment further asserted that the same problem occurs when food is held at 120°F, a point above which it has not been established that bacteria of public health significance can multiply. Other comments suggested that the specific values be removed from the regulation, because they are inappropriate for some foods.

FDA agrees that a maximum storage temperature for cold foods of 40°F and a minimum temperature of 150°F for hot foods would provide a greater safety margin. However, 45°F has long been recognized as the maximum value for storage of cold foods, and 140°F has been recognized as the minimum value for storage of hot food, to minimize the growth of microorganisms. Contrary to one of the comments, studies have shown that some microorganisms of public health significance multiply at temperatures above 120°F. (Brown D.F.

and R.M. Twedt, "Assessment of Sanitary Effectiveness of Holding Temperature on Beef Cooked at Low Temperature," *Applied Microbiology* 24:4, 1972, pp. 599-603.) FDA notes that unprotected food may dry out at any temperature, depending on the relative humidity of the surrounding atmosphere. Therefore, FDA has made no change in this provision of the final rule.

142. Two comments on proposed § 110.80(b)(3) suggested that the introductory wording be changed to make it clear that the indicated storage temperatures and heat treating of acid or acidified foods are merely examples of ways to control the microbial growth.

The proposed regulation already stated that compliance could be accomplished by any effective means. Therefore, in response to these comments, FDA has made no change in the final rule.

143. One comment on proposed § 110.80(b)(4) said that the control of microorganisms of public health significance should also apply to "handling and distribution" of foods.

FDA agrees and has modified the final rule accordingly.

144. Some comments suggested that the following definition of pasteurization be added to § 110.80(b)(4):

"Pasteurization shall mean treatment by any process during manufacturing and packaging which effectively destroys, inactivates or removes microorganisms capable of continued multiplication in the package."

A definition of pasteurization is not needed in the final rule because the term is generally understood by food manufacturers and consumers.

145. One comment on proposed § 110.80(b)(5) stated that it is not necessary and is redundant because § 110.80(a) adequately addresses the matters discussed in it. Several comments stated that "rework" may contain microorganisms that cause it to be adulterated within the meaning of the act, but, with proper heat treatment, may be made entirely acceptable for use. The comments also stated that microbially contaminated rework does not necessarily meet the raw material specifications until the time it is reprocessed. Other comments suggested that rework be stored under sanitary conditions before reprocessing.

FDA believes that § 110.80(a)(5) is revised in the final rule, adequately provide for the handling of rework. Therefore FDA has deleted proposed § 110.80(b)(5). Although food that is adulterated within the meaning of the act cannot always be successfully reconditioned where it has been



satisfactorily reconditioned it is "rework" as defined in § 110.3(m) of the final rule.

146. Several comments on proposed § 110.80(b)(7) (§ 110.80(b)(6) of the final rule) questioned the practicality and reasonableness of the requirement concerning contamination between finished food and raw materials.

FDA has revised the final rule to provide that effective measures be taken to protect finished food from contamination by raw materials, other ingredients, or refuse.

147. Several comments on proposed § 110.80(b)(7) said that it is not necessary to cover conveyors to protect against contamination from extraneous material. Another comment said that conveyors need to be protected only in those locations where contamination hazards exist.

FDA agrees and has changed the final rule to require that materials and products transported by conveyor be protected as necessary.

148. Two comments on proposed § 110.80(b)(9) § 110.80(b)(8) of the final rule) stated that requiring metal detectors, which are not effective under certain circumstances, would place a financial burden on the small manufacturers.

FDA advises that metal detectors are mentioned as examples of a means which may be effective in protecting the food against contamination. The regulation, however, does not require their use.

149. One comment on proposed § 110.80(b)(9) requested the addition of traps as an effective means to prevent the inclusion of metal or other extraneous material in the finished food.

FDA agrees and has changed the final rule accordingly.

150. One comment on proposed § 110.80(b)(9) requested that a 1-to-2 year "grace period" be provided to allow industry time to change processing layouts and to purchase the devices necessary to comply with this requirement.

FDA believes that the delayed effective date for the final rule provides adequate time for industry compliance. The effective date of the final rule is delayed until December 16, 1986.

151. One comment on proposed § 110.80(b)(10) (§ 110.80(b)(9) of the final rule) noted that it may not be practical to reexamine reconditioned food, including raw materials, and other ingredients before their use in finished food. The following example was provided: "If the product is heat treated to reduce bacteria counts, it may not be possible to hold that product until the bacteria test results are available."

FDA agrees and has modified the final rule accordingly.

152. A number of comments on proposed § 110.80(b)(11) (§ 110.80(b)(10) of the final rule) stated that it is impossible to eliminate contamination completely from the food manufacturing process. The comments suggested that either the requirement be changed to an advisory statement or that the phrase "not to contaminate" be modified.

FDA agrees and has modified the final rule to read, in part, as follows: "§ 110.80(b)(11) shall be performed so as to protect food against contamination."

153. Two comments on proposed § 110.80(b)(12) (§ 110.80(b)(11) of the final rule) requested that the advisory statements regarding heat blanching and minimizing growth of thermophilic organisms be changed to mandatory requirements by the substitution of "shall" for "should." The basis for the request was concern that sufficient heat be supplied to inactivate enzymes and that equipment be cleansed and sanitized sufficiently to preclude thermophilic growth.

FDA advises that some foods are heat blanched for reasons other than enzyme inactivation and that sufficient cause has not been demonstrated by the comments to justify making these provisions mandatory. Therefore, except for clarifying editorial changes, FDA is retaining the proposed wording in the final rule.

154. One comment concerning § 110.80(b)(12) of the proposal (§ 110.80(b)(11) of the final rule) stated that the requirement that water used to wash blanched food prior to filling be safe and of adequate sanitary quality was duplicative of the requirement in § 110.80(a)(1).

Section 110.80(a)(1) deals with raw materials and other ingredients. Section 110.80(b)(11) covers processes and controls. FDA believes that these provisions are distinct and that it is appropriate to include requirement 9 for water quality in both provisions. Therefore, FDA has not made the suggested change in the final rule.

155. One comment on proposed § 110.80(b)(13) (§ 110.80(b)(12) of the final rule) requested clarification of one of the examples given of ways to protect against contamination of batters and similar preparations: "(ii) Employing adequate heat processes when applicable." The comment sought clarification in that filth problems cannot be solved through the use of heat processes.

The regulation requires the use of adequate heat processes only where applicable, not when heat is not useful. FDA believes, the regulation is

sufficiently clear and has made no revisions in response to the comment.

156. Two comments on proposed § 110.80(b)(13) suggested that example (vi) be changed to reflect the variability of various food processes.

FDA agrees and has changed the final rule accordingly.

157. Some comments on proposed § 110.80(b)(14) (§ 110.80(b)(13) of the final rule) indicated that the examples of effective compliance measures were interpreted, incorrectly, to be mandatory practices which must be followed by all parts of the food industry.

Compliance with this paragraph may be accomplished by any effective means, including the operations that are presented as examples. FDA believes that a more careful reading of this paragraph would eliminate the concerns of these comments, and has retained, but for editorial changes, the proposed wording in the final rule.

158. Several comments on proposed § 110.80(b)(15) (§ 110.80(b)(14) of the final rule) were concerned about the possible expense entailed in following the enumerated examples of effective means of compliance with the safe moisture level requirement. They stated that the examples of testing controls are beyond the resources of many manufacturers.

The regulation does not require the use of the suggested examples. Other effective, but less expensive, compliance measures may be used.

159. A number of comments on proposed § 110.80(b)(16) (§ 110.80(b)(15) of the final rule) were received regarding the requirement that foods which rely on pH for preventing the growth of undesirable microorganisms be monitored and maintained at a pH of 4.6 or below. Two comments stated that the requirement should be rephrased to read "§ 110.80(b)(16) shall rely solely on the control of pH in consideration of those foods in which pH is merely a partial control of microbial growth."

FDA agrees and is inserting the term "principally" in lieu of the suggested term "solely" in the final rule.

160. A comment on proposed § 110.80(b)(16) suggested including the following additional example of an effective practice for preventing the growth of undesirable microorganisms: "rework of the raw foods, ingredients, and finished products in a manner adequate for preventing the growth of microorganisms." No reason was given to support the suggestion.

The enumerated practices are only examples. Additional examples are not necessary.

161. A comment on proposed § 110.80(b)(16) said the term "microorganisms" should be qualified by the phrase "of public health significance" in order to clarify the use of this term.

As previously discussed in the preamble, microorganisms may render a food adulterated within the meaning of the act not only because they are harmful, but also for other reasons, such as they may constitute filth. Therefore, FDA has made no change in the final rule in response to the comment.

162. One comment on proposed § 110.80(b)(17) (§ 110.80(b)(16) of the final rule) interpreted a literal application of the requirement that ice be "manufactured in accordance with adequate standards" to be inappropriate where, for example, retail bakeries use small amounts of ice obtained from small plant freezers.

FDA agrees with this interpretation. Therefore, FDA has changed the final rule to read: "When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part."

#### Warehousing and Distribution

163. FDA received several comments on proposed § 110.93, concerning a definition for undesirable deterioration of food. The comments suggested that the regulation should be concerned only with microorganisms at levels that could be clearly identified as constituting a risk to human health. The comments also suggested that the regulations include a definition of microorganisms.

FDA defines the term "microorganisms" in § 110.3(i) of the final rule. As mentioned throughout this preamble, microorganisms may indicate contamination with filth or putrefaction, as well as harmfulness. Accordingly, FDA has not adopted the substance of the comments pertaining to microorganisms in the final rule. However, FDA has made other clarifying changes in § 110.93 of the final rule in response to the comments.

164. A comment expressed concern that manufacturers would be unable to assure completely good storage and transportation practices throughout the distribution chain.

Producers are expected to take reasonable precautions to see that food is transported and stored in such a manner that it does not become adulterated, particularly where the producer has continuing control of the products. Should evidence demonstrate

that the cause of adulteration is due to negligence or illegal practices of the shipper or warehouse operator, FDA has the authority to take appropriate regulatory action against the responsible persons

#### Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard

165. One comment on proposed § 110.110 stated that defect action levels (DAL's), which are established by FDA for natural or unavoidable defects that are not hazardous to health, should not be referenced in § 110.110 because they "are considered to be artificial values established by the Commissioner without public hearing."

FDA disagrees. DAL's are calculated and issued only when it is necessary and feasible to do so. DAL's are based on results of plant inspections, surveys, and research which may be performed in conjunction with industry, academia, or other government agencies. It is FDA's policy to publish notices in the Federal Register of the establishment of DAL's. Copies of compilations of current defect action levels may be obtained from FDA, as stated in § 110.110(e) of the final rule. As noted in § 110.110(b), DAL's are subject to change based on additional information or the development of new technology. Although DAL's are not rules that must be adhered to, and certainly are not subject to any requirement of a hearing, they offer reliable guidance on whether a particular defect may result in the product being adulterated within the meaning of the act. It is for this purpose that they are referenced in this section. Therefore, FDA has retained these proposed provisions in the final rule.

166. One comment on proposed § 110.110(c) expressed concern that violation of any of the Part 110 requirements could cause a product to be adulterated even though the levels of natural or unavoidable defects are lower than the established action levels. The comment also argued that section 402 of the act "does not provide for deeming a food adulterated if not produced in conformance with current Good Manufacturing Practice."

The purpose of this paragraph in the regulation is to specify that failure to maintain current good manufacturing practice throughout the manufacturing, packing, holding, or storage of food is not overcome by compliance with a DAL, which may or may not be affected by the violative practice. Many significant practices, such as measures that are taken to destroy or prevent the growth of microorganisms of public health significance (as covered under

§ 110.80(b)(4)), may not affect the level of natural or unavoidable defects but are nonetheless crucial to the production of food that is not adulterated within the meaning of the act. The comment concerning FDA's authority in this area overlooks the fact that courts have expressly held that FDA has the authority to promulgate and enforce substantive regulations defining current good manufacturing practice for the food industry. See *National Confectioners Ass'n v. Califano*, 569 F.2d 690 (D.C. Cir. 1976). See also *Nova Scotia Food Products Corp. v. United States*, 566 F.2d 240, 245-248 (ad Cir. 1976).

167. A number of comments on proposed § 110.110(d) objected to the provision that prohibits, without exception, the mixing of food which is above a DAL with another lot of food. Comments stated that there were instances, such as where the contamination is not due to violation of FDA's CGMP regulations, in which blending could be safely accomplished, thereby preventing the destruction of food. Therefore, it was argued that because FDA has allowed blending in individual cases, absolute prohibition of this action is improper, and the final regulations should be modified.

FDA has on rare occasion allowed the blending of food that was unavoidably contaminated with a poisonous or deleterious substance when (1) the food is shown to be safe for consumption after blending and (2) the destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply. The general concern with blending, however, is not solely whether the food after blending is safe, but whether it is otherwise adulterated within the meaning of the act. Accordingly, FDA has not modified the regulation as requested by the comments.

168. The remaining comments requested that portions of the proposal be clarified. In response to these comments and on its own initiative, FDA has made many clarifying editorial changes in the final rule.

As one of the editorial changes, FDA has deleted the word "processing" in favor of exclusive reliance on the word "manufacturing." The words are synonymous, "manufacturing" being the more appropriate for regulations dealing with current good manufacturing practice. As has already been discussed, FDA has broadly defined "food" in the regulations to include raw materials and other ingredients. For clarity and consistency, as well as emphasis, however, FDA does use the words "raw and "ingredients" where

appropriate. Similarly, because the regulations pertain to those systematic procedures to be followed to prevent "food" from being adulterated within the meaning of the act, FDA has generally avoided limiting the word "food" (for example, by using the terminology "finished food"). except where such limitations are appropriate or necessary for clarity or emphasis.

For editorial consistency, FDA is also revising 21 CFR 20.100(c)(8) to reflect a cross-reference to § 110.110(e) which contains cross-referenced action level provisions now located in § 110.99(e)

The final rule becomes effective December 16, 1986.

The agency has previously determined that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has analyzed the effects of this final rule. Compliance costs are estimated to be between \$272,000 and \$623,000 annually depending on the exact number of firms ultimately affected by this action. Thus in accordance with Executive Order 12291, the agency has determined that this final rule will not result in a major rule as defined by that Order.

In accordance with the Regulatory Flexibility Act, FDA has examined the effect that this final rule will have on small entities including small businesses. Although most of the cost of this action will be incurred by small businesses, FDA does not believe that its estimated cost of \$180 per firm per year is excessive. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

Interested persons may, on or before August 18, 1986 submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in bracket in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### **List of Subjects**

##### **21 CFR Part 20**

Freedom of information.

##### **21 CFR Part 110**

Good manufacturing practices.

PART 100-CURRENT GOOD  
MANUFACTURING PRACTICE IN  
MANUFACTURING, PACKING, OR  
HOLDING HUMAN FOOD

Subpart **A - General Provisions**

Sec.

**110.3 Definitions.**

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Subpart **C - Equipment**

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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  
bad for human use that present no  
health hazard.

Authority: Secs. 402, ~~701, 704~~ of the Federal  
Food, Drug, and Cosmetic Act (21 U.S.C. 342,  
371, 374); sec. 361 of the public Health Service  
Act (42 U.S.C. 264).

Source: 51 FR 22458, June 19, 1986, as  
amended at 54 FR 24890, June 12, 1989; 54  
39630, Sept. 27, 1989.

**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 R1th 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<sub>w</sub>). An a<sub>w</sub> will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a<sub>w</sub> 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 and public health significance, and substantially reducing number 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<sub>w</sub>) 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 Service 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 surface, 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 surface, 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 unsecured 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.

(8) 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 building or structures that may constitute an attractant breeding place, or harborage for pests.

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

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding piece for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structure shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or *more* of the following means; location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

- (i) Using protective coverings.
- (ii) Controlling areas over and around the vessels to eliminate harborages for pests.
- (iii) Checking on a regular basis for pests and pest infestation.
- (iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be

adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect ~~against~~ contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapor (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

#### §110.35 Sanitary operations.

(a) *General maintenance.* Buildings, fixtures and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.* (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate Under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these Substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed: (i) Those required

to maintain clean and sanitary conditions: (ii) Those necessary for use in laboratory testing procedures; (iii) Those necessary for plant and equipment maintenance and operation; and (iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control.* No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper and paper towels) should be

stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

#### § 110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contact<sup>8</sup> food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping system<sup>8</sup> that discharge waste. Water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant shall provide its employee<sup>8</sup> with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be to conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

### Subpart C - Equipment

#### § 110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

#### Subpart D - [Reserved]

#### Subpart E - Production and Process Controls

##### § 110.80 Processes and controls.

All operations involving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous material testing procedures shall be used where necessary to identify sanitation failure or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) *Raw materials and other ingredients.* (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during

manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the material in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen if thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations.* (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary insofar as necessary

equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, air, pH, pressure, flow rate and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 °F (7.2 °C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 °F (60 °C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected they shall not be handled simultaneously in receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.



(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detector, or other suitable effective means.

(9) Food raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breadings, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food packaging materials that are safe and suitable, as defined in §130.3 (d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food that relies on the control of water for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means including employment of one or more of the following practices:

(i) Monitoring the a. of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the aw of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.0 or below. Compliance with this requirement may be accomplished by an effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food. §110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

#### Subpart F - [Reserved]

#### Subpart G - Defect Action Levels

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

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for food whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirement in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently achievable.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the food

adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.