

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2007

Section VII. Shellfish Federal Regulations

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Authority: Secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-393); secs. 301, 351, 354-360F, 361 of the Public Health Service Act (42 U.S.C. 241, 262, 263b-

263n, 264).

Source: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A - General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978 as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.3 Definitions.

- (a) *Agency* means the Food and Drug Administration.
- (b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.
- (c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.
- (d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.
- (e) [Reserved]
- (f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. Product does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.
- (g) *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.
- (h) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

- (i) *Recalling firm* means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.
- (j) *Market withdrawal* means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.
- (k) *Stock recovery* means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.
- (l) *Recall strategy* means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.
- (m) *Recall classification* means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.
 - (1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
 - (2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
 - (3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
- (n) *Consignee* means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979]

§ 7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

§ 7.13 Suggested forms of guaranty.

- (a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:
 - (1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale. (Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification)

are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:

(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

- (f) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.
- (g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.
- (h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Subpart B - [Reserved]

Subpart C - Recalls (Including Product Corrections) - Guidelines on Policy, Procedures, and Industry Responsibilities

Source: 43 FR 26218, June 16, 1978, unless otherwise noted.

§ 7.40 Recall policy.

- (a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well being from products that present a risk of injury or gross deception or are otherwise defective. This section and § 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.
- (b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors,

or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

- (c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.41 Health hazard evaluation and recall classification.

- (a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:
- (1) Whether any disease or injuries have already occurred from the use of the product.
 - (2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
 - (3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
 - (4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
 - (5) Assessment of the likelihood of occurrence of the hazard.
 - (6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.
- (b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

§ 7.42 Recall strategy.

- (a) *General.*

- (1) A recall strategy that takes into account the following factors will be developed by

the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

- (i) Results of health hazard evaluation.
- (ii) Ease in identifying the product.
- (iii) Degree to which the product's deficiency is obvious to the consumer or user.
- (iv) Degree to which the product remains unused in the market place.
- (v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) *Elements of a recall strategy.* A recall strategy will address the following elements regarding the conduct of the recall:

(1) *Depth of recall.* Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

- (i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or
- (ii) Retail level, including any intermediate wholesale level; or
- (iii) Wholesale level.

(2) *Public warning.* The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

- (i) General public warning through the general news media, either national or local as appropriate, or
- (ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) *Effectiveness checks.* The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

- (i) Level A-100 percent of the total number of consignees to be contacted;
- (ii) Level B-Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;
- (iii) Level C-10 percent of the total number of consignees to be contacted;
- (iv) Level D-2 percent of the total number of consignees to be contacted; or
- (v) Level E-No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14363, Mar. 28, 1994]

§ 7.45 Food and Drug Administration requested recall.

- (a) The Commissioner of Food and Drugs or his designee under § 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:
 - (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
 - (2) That the firm has not initiated a recall of the product.
 - (3) That an agency action is necessary to protect the public health and welfare.
- (b) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.
- (c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug

Administration any or all of the information listed in § 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's determination of the need for the recall or how the recall should be conducted.

§ 7.46 Firm-initiated recall.

- (a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:
- (1) Identity of the product involved.
 - (2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
 - (3) Evaluation of the risk associated with the deficiency or possible deficiency.
 - (4) Total amount of such products produced and/or the time span of the production.
 - (5) Total amount of such products estimated to be in distribution channels.
 - (6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.
 - (7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.
 - (8) Proposed strategy for conducting the recall.
 - (9) Name and telephone number of the firm official who should be contacted concerning the recall.
- (b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.
- (c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.
- (d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly

understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

§ 7.49 Recall communications.

(a) *General.* A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

- (1) That the product in question is subject to a recall.
- (2) That further distribution or use of any remaining product should cease immediately.
- (3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
- (4) Instructions regarding what to do with the product.

(b) *Implementation.* A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "drug [or food, biologic, etc.] recall [or correction]". The letter and the envelope should be also marked: "urgent" for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) *Contents.*

- (1) A recall communication should be written in accordance with the following guidelines:
 - (i) Be brief and to the point;
 - (ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;
 - (iii) Explain concisely the reason for the recall and the hazard involved, if any;
 - (iv) Provide specific instructions on what should be done with respect to the recalled products; and
 - (v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

- (2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication.
- (d) *Responsibility of recipient.* Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

§ 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were affected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 7.53 Recall status reports.

- (a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.
- (b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:
 - (1) Number of consignees notified of the recall, and date and method of notification.
 - (2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
 - (3) Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).
 - (4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
 - (5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

§ 7.55 Termination of a recall.

- (a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.
- (b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

§ 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

- (a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§ 7.40 through 7.49, 7.53, and 7.55.
- (b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.
- (c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

PART 101 - FOOD LABELING

Subpart A - General Provisions

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§ 101.3 Identity labeling of food in packaged form.

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§ 101.8 Labeling of food with number of servings.

- § 101.9 Nutrition labeling of food.
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[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993]

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Subpart A - General Provisions

§ 101.1 Principal display panel of package form food.

The term "principal display panel" as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:

- (a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;
- (b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference;
- (c) In the case of any otherwise shaped container, 40 percent of the total surface of the container: Provided, however, that where such container presents an obvious "principal display panel" such as the top of a triangular or circular package of cheese, the area shall consist of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 101.2 Information panel of package form food.

- (a) The term "information panel" as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:
- (1) If the part of the label immediately contiguous and to the right of the principal display panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.
 - (2) If the package has one or more alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel.
 - (3) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.
- (b) All information required to appear on the label of any package of food pursuant to §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, 101.36, subpart D of part 101 and Part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.
- (c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than one-sixteenth inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§ 101.105(h) (1) and (2) and 101.15.
- (1)(i) Soft drinks packaged in bottles manufactured before October 31, 1975 shall be exempt from the requirements prescribed by this section to the extent that information which is blown, lithographed, or formed onto the surface of the bottle is exempt from the size and placement requirements of this section.
 - (ii) Soft drinks packaged in bottles shall be exempt from the size and placement requirements prescribed by this section if all of the following conditions are met:
 - (a) If the soft drink is packaged in a bottle bearing a paper, plastic foam jacket, or foil label, or is packaged in a non-reusable bottle bearing a label lithographed onto the surface of the bottle or is packaged in metal cans, the product shall not be exempt from any requirement of this section other than the exemptions created by § 1.24(a)(5) (ii) and (v) of this chapter and the label shall bear all required information in the specified minimum type size, except the label will not be required to bear the information required by § 101.5 if this information appears on the bottle closure or on the lid of the can in a type size not less than one-sixteenth inch in height, or if embossed on the lid of the can in a type size not less than one-eighth inch in height.
 - (b) If the soft drink is packaged in a bottle which does not bear a paper, plastic foam jacket or foil label, or is packaged in a reusable bottle bearing a label lithographed onto the surface of the bottle:

- (1) Neither the bottle nor the closure is required to bear nutrition labeling in compliance with § 101.9, except that any multiunit retail package in which it is contained shall bear nutrition labeling if required by § 101.9; and any vending machine in which it is contained shall bear nutrition labeling if nutrition labeling is not present on the bottle or closure, if required by § 101.9.
- (2) All other information pursuant to this section shall appear on the top of the bottle closure prominently and conspicuously in letters and/or numbers no less than one thirty-second inch in height, except that if the information required by § 101.5 is placed on the side of the closure in accordance with § 1.24(a)(5)(ii) of this chapter, such information shall appear in letters and/or numbers no less than one-sixteenth inch in height.
- (3) Upon the petition of any interested person demonstrating that the bottle closure is too small to accommodate this information, the Commissioner may by regulation establish an alternative method of disseminating such information. Information appearing on the closure shall appear in the following priority:
 - (i) The statement of ingredients.
 - (ii) The name and address of the manufacturer, packer, or distributor.
 - (iii) The statement of identity.
- (2) Individual serving-size packages of food served with meals in restaurants, institutions, and on board passenger carriers, and not intended for sale at retail, are exempt from type-size requirements of this paragraph, provided:
 - (i) The package has a total area of 3 square inches or less available to bear labeling;
 - (ii) There is insufficient area on the package available to print all required information in a type size of 1/16 inch in height;
 - (iii) The information required by paragraph (b) of this section appears on the label in accordance with the provisions of this paragraph, except that the type size is not less than 1/32 inch in height.
- (d)(1) Except as provided by § 101.9 (j) (13) and (j) (17) and 101.36 (i) (2) and (i) (5), all information required to appear on the principal display panel or on the information panel under this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as provided by § 101.9 (j) (17) and 101.36 (i) (5), any vignettes, design, and other non-mandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required under any given section or part shall all appear on the same panel. A food whose

label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

(2) Any food, not otherwise exempted in this section, if packaged in a container consisting of a separate lid and body, and bearing nutrition labeling pursuant to § 101.9, and if the lid qualifies for and is designed to serve as a principal display panel, shall be exempt from the placement requirements of this section in the following respects:

- (i) The name and place of business information required by § 101.5 shall not be required on the body of the container if this information appears on the lid in accordance with this section.
- (ii) The nutrition information required by § 101.9 shall not be required on the lid if this information appears on the container body in accordance with this section.
- (iii) The statement of ingredients required by § 101.4 shall not be required on the lid if this information appears on the container body in accordance with this section. Further, the statement of ingredients is not required on the container body if this information appears on the lid in accordance with this section.

(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.

(f) If the label of any package of food is too small to accommodate all of the information required by § 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, and 101.36, subpart D of part 101 and Part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted under Part 10 of this chapter.

[42 FR 14308, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 42 FR 45905, Sept. 13, 1977; 42 FR 47191, Sept. 20, 1977; 44 FR 16006, Mar. 16, 1979; 49 FR 13339, Apr. 4, 1984; 53 FR 16068, May 5, 1988; 58 FR 44030, Aug. 18, 1993; 60 FR 17205, Apr. 5, 1995; 62 FR 43074, Aug. 12, 1997; 62 FR 49847, Sept. 23, 1997; 63 FR 14817, Mar. 27, 1998]

§ 101.3 Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

- (1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,
- (2) The common or usual name of the food; or, in the absence thereof,

- (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.
- (c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.
- (d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.
- (e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.
- (1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.
- (2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:
- (i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.
- (ii) Its label bears a common or usual name that complies with the provisions of § 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.
- (3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to Part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to Part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.
- (4) Nutritional inferiority includes:
- (i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of § 101.9,

and provided the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in Part 105 of this chapter.

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Daily Reference Value (DRV) of protein listed under § 101.9(c)(7)(iii) and of potassium listed under § 101.9 (c) (9) per reference amount customarily consumed and 2 percent or more of the Reference Daily Intake (RDI) of any vitamin or mineral listed under § 101.9 (c) (8) (iv) per reference amount customarily consumed, except that selenium, molybdenum, chromium, and chloride need not be considered.

(iii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

(f) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to Subpart B of Part 102 of this chapter.

(g) Dietary supplements shall be identified by the term “dietary supplement” as a part of the statement of identity, except that the word “dietary” may be deleted and replaced by the name of the dietary ingredients in the product (e.g., calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (e.g., herbal supplement with vitamins).

[42 FR 14308, Mar. 15, 1977, as amended at 48 FR 10811, Mar. 15, 1983; 58 FR 2227, Jan. 6, 1993; 60 FR 67174, Dec. 28, 1995; 62 FR 49847, Sept. 23, 1997]

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with § 101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

(2) The descending order of predominance requirements of paragraph (a)(1) of this section do not apply to ingredients present in amounts of 2 percent or less by weight when a listing of these ingredients is placed at the end of the ingredient statement following an appropriate quantifying statement, e.g., "Contains ___ percent or less of ___," or "Less than ___ percent of ___." The blank percentage within the quantifying statement shall be filled in with a threshold level of 2 percent, or, if desired, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No

ingredient to which the quantifying phrase applies may be present in an amount greater than the stated threshold.

- (b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:
- (1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of § 101.22.
 - (2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:
 - (i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in this Subchapter B of this chapter that has specific labeling provisions for optional ingredients, optional ingredients may be declared within the parenthetical listing in accordance with those provisions.
 - (ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.
 - (3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk" or "nonfat milk".
 - (4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk".
 - (5) Bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk or cultured buttermilk".
 - (6) Sweet cream buttermilk, concentrated sweet cream buttermilk, reconstituted sweet cream buttermilk, and dried sweet cream buttermilk may be declared as "buttermilk".
 - (7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as "whey".
 - (8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as "cream".
 - (9) Butter oil and anhydrous butterfat may be declared as "butterfat".
 - (10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as

"eggs".

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as "egg whites".

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as "egg yolks".

(13) [Reserved]

(14) Each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., "beef fat", "cottonseed oil") in its order of predominance in the food except that blends of fats and/or oils may be designated in their order of predominance in the foods as "-shortening" or "blend of - oils", the blank to be filled in with the word "vegetable", "animal", "marine", with or without the terms "fat" or "oils", or combination of these, whichever is applicable if, immediately following the term, the common or usual name of each individual vegetable, animal, or marine fat or oil is given in parentheses, e.g., "vegetable oil shortening (soybean and cotton-seed oil)". For products that are blends of fats and/or oils and for foods in which fats and/or oils constitute the predominant ingredient, i.e., in which the combined weight of all fat and/or oil ingredients equals or exceeds the weight of the most predominant ingredient that is not a fat or oil, the listing of the common or usual names of such fats and/or oils in parentheses shall be in descending order of predominance. In all other foods in which a blend of fats and/or oils is used as an ingredient, the listing of the common or usual names in parentheses need not be in descending order of predominance if the manufacturer, because of the use of varying mixtures, is unable to adhere to a constant pattern of fats and/or oils in the product. If the fat or oil is completely hydrogenated, the name shall include the term "hydrogenated", or if partially hydrogenated, the name shall include the term "partially hydrogenated". If each fat and/or oil in a blend or the blend is completely hydrogenated, the term "hydrogenated" may precede the term(s) describing the blend, e.g., "hydrogenated vegetable oil (soybean, cottonseed, and palm oils)", rather than preceding the name of each individual fat and/or oil; if the blend of fats and/or oils is partially hydrogenated, the term "partially hydrogenated" may be used in the same manner. Fat and/or oil ingredients not present in the product may be listed if they may sometimes be used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:", e.g., "vegetable oil shortening (contains one or more of the following: cottonseed oil, palm oil, soybean oil)". No fat or oil ingredient shall be listed unless actually present if the fats and/or oils constitute the predominant ingredient of the product, as defined in this paragraph (b)(14).

(15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in §§ 137.105, 137.200, 137.220 and 137.225 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is "flour", "white flour", "wheat flour", or "plain flour"; the first ingredient designated in the ingredient list of durum flour is "durum flour"; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole

wheat flour is "whole wheat flour", "graham flour", or "entire wheat flour"; and the first ingredient designated in the ingredient list of whole durum wheat flour is "whole durum wheat flour".

- (16) Ingredients that act as leavening agents in food may be declared in the ingredient statement by stating the specific common or usual name of each individual leavening agent in parentheses following the collective name "leavening", e.g., "leavening (baking soda, monocalcium phosphate, and calcium carbonate)". The listing of the common or usual name of each individual leavening agent in parentheses shall be in descending order of predominance: Except, that if the manufacturer is unable to adhere to a constant pattern of leavening agents in the product, the listing of individual leavening agents need not be in descending order of predominance. Leavening agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:".
- (17) Ingredients that act as yeast nutrients in foods may be declared in the ingredient statement by stating the specific common or usual name of each individual yeast nutrient in parentheses following the collective name "yeast nutrients", e.g., "yeast nutrients (calcium sulfate and ammonium phosphate)". The listing of the common or usual name of each individual yeast nutrient in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of yeast nutrients in the product, the listing of the common or usual names of individual yeast nutrients need not be in descending order of predominance. Yeast nutrients not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", or "contains one or more of the following:".
- (18) Ingredients that act as dough conditioners may be declared in the ingredient statement by stating the specific common or usual name of each individual dough conditioner in parentheses following the collective name "dough conditioner", e.g., "dough conditioners (L-cysteine, ammonium sulfate)". The listing of the common or usual name of each dough conditioner in parentheses shall be in descending order of predominance: *Except*, That if the manufacturer is unable to adhere to a constant pattern of dough conditioners in the product, the listing of the common or usual names of individual dough conditioners need not be in descending order of predominance. Dough conditioners not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", or "contains one or more of the following:".
- (19) Ingredients that act as firming agents in food (e.g., salts of calcium and other safe and suitable salts in canned vegetables) may be declared in the ingredient statement, in order of predominance appropriate for the total of all firming agents in the food, by stating the specific common or usual name of each individual firming agent in descending order of predominance in parentheses following the collective name "firming agents". If the manufacturer is unable to adhere to a constant pattern of firming agents in the food, the listing of the individual firming

agents need not be in descending order of predominance. Firming agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:"

- (20) For purposes of ingredient labeling, the term sugar shall refer to sucrose, which is obtained from sugar cane or sugar beets in accordance with the provisions of § 184.1854 of this chapter.
- (21) [Reserved]
- (22) Wax and resin ingredients on fresh produce when such produce is held for retail sale, or when held for other than retail sale by packers or repackers shall be declared collectively by the phrase "coated with animal-based wax, to maintain freshness" or the phrase "coated with food-grade vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin, to maintain freshness" as appropriate. The terms "food-grade" and "to maintain freshness" are optional. The term lac-resin may be substituted for the term shellac.
- (23) When processed seafood products contain fish protein ingredients consisting primarily of the myofibrillar protein fraction from one or more fish species and the manufacturer is unable to adhere to a constant pattern of fish species in the fish protein ingredient, because of seasonal or other limitations of species availability, the common or usual name of each individual fish species need not be listed in descending order of predominance. Fish species not present in the fish protein ingredient may be listed if they are sometimes used in the product. Such ingredients must be identified by words indicating that they may not be present, such as "or", "and/or", or "contains one or more of the following:" Fish protein ingredients may be declared in the ingredient statement by stating the specific common or usual name of each fish species that may be present in parentheses following the collective name "fish protein", e.g., "fish protein (contains one or more of the following: Pollock, cod, and/or pacific whiting)".
- (c) When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as "water" in the ingredient statement.
- (d) When foods characterized on the label as "nondairy" contain a caseinate ingredient, the caseinate ingredient shall be followed by a parenthetical statement identifying its source. For example, if the manufacturer uses the term "nondairy" on a creamer that contains sodium caseinate, it shall include a parenthetical term such as "a milk derivative" after the listing of sodium caseinate in the ingredient list.
- (e) If the percentage of an ingredient is included in the statement of ingredients, it shall be shown in parentheses following the name of the ingredient and expressed in terms of percent by weight. Percentage declarations shall be expressed to the nearest 1 percent,

except that where ingredients are present at levels of 2 percent or less, they may be grouped together and expressed in accordance with the quantifying guidance set forth in paragraph (a) (2) of this section.

(f) Except as provided in § 101.100, ingredients that must be declared on labeling because there is no label for the food, including foods that comply with standards of identity, shall be listed prominently and conspicuously by common or usual name in the manner prescribed by paragraph (b) of this section.

(g) When present, the ingredient list on dietary supplement products shall be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label and shall be preceded by the word “Ingredients,” unless some ingredients (i.e., sources) are identified within the nutrition label in accordance with § 101.36 (d), in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words “Other ingredients.” Ingredients in dietary supplements that are not dietary ingredients or that do not contain dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, shall be included in the ingredient list.

(h) The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be consistent with the names standardized in Herbs of Commerce, 1992 edition, which is incorporated by reference in accordance with 5 U.S.C. 552 (a) and 1 CFR part 51. Copies may be obtained from the American Herbal Products Association, 8484 Georgia Ave., suite 370, Silver Spring, MD 20910, ³⁰¹⁻⁵⁸⁸⁻¹¹⁷¹, FAX 301-588-1174, ahpa@ahpa.org or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 Capital St. NW., suite 700, Washington, DC. The listing of these names on the label shall be followed by statements of:

(1) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., “Garlic bulb” or “Garlic (bulb)”), except that this designation is not required for algae. The name of the part of the plant shall be expressed in English (e.g., “flower” rather than “flos”);

(2) The Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in the reference entitled: Herbs of Commerce for the common or usual name listed on the label, and, when required, the Latin binomial name may be listed before the part of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the International Code of Botanical Nomenclature and shall include the designation of the author or authors who published the Latin name, when a positive identification cannot be made in its absence. The International Code of Botanical Nomenclature (Tokyo Code), 1994 edition, a publication of the International Association for Plant Taxonomy, is incorporated by reference in accordance with 5 U.S.C. 552 (a) and 1 CFR part 51. Copies of the International Code of Botanical Nomenclature may be obtained from Koeltz Scientific Books, D-61453 Königstein, Germany, and University Bookstore, Southern Illinois University, Carbondale, IL 62901-4422, ⁶¹⁸⁻⁵³⁶⁻³³²¹, FAX 618-453-5207, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the Federal Register, 800 North

Capitol St. NW., Suite 700, Washington DC.

- (3) On labels of single-ingredient dietary supplements that do not include an ingredient list, the identification of the Latin binomial name, when needed, and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

[42 FR 14308, Mar. 15, 1977, as amended at 43 FR 12858, Mar. 28, 1978; 43 FR 24519, June 6, 1978; 48 FR 8054, Feb. 25, 1983; 55 FR 17433, Apr. 25, 1990; 58 FR 2875, Jan. 6, 1993; 62 FR 49847, Sept. 23, 1997; 62 FR 64634, Dec. 8, 1997; 64 FR 50448, Sept. 17, 1999; 66 FR 17358, Mar. 30, 2001; 66 FR 66742, Dec. 27, 2001; 68 FR 15355, Mar. 31, 2003]

§ 101.5 Food; name and place of business of manufacturer, packer, or distributor.

- (a) The label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.
- (b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.
- (c) Where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such food; such as "Manufactured for -----", "Distributed by -----", or any other wording that expresses the facts.
- (d) The statement of the place of business shall include the street address, city, State, and ZIP code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of non-consumer packages, the ZIP code shall appear either on the label or the labeling (including invoice).
- (e) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such food was manufactured or packed or is to be distributed, unless such statement would be misleading.

[Code of Federal Regulations]
[Title 21, Volume 2, Parts 100 to 169]
[Revised as of April 1, 1997]

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TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND
HUMAN SERVICES - CONTINUED

PART 109 - UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN
CONSUMPTION AND FOOD-PACKAGING MATERIAL - Table of Contents

Subpart A - General Provisions

Sec. 109.4 Establishment of tolerances, regulatory limits, and action levels.

- (a) When appropriate under the criteria of Sec. 109.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.
- (b) When appropriate under the criteria of Sec. 109.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.
- (c)(1) When appropriate under the criteria of Sec. 109.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.
 - (2) Whenever an action level is established or changed, a notice shall be published in the Federal Register as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.
- (d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

[42 FR 52819, Sept. 30, 1977, as amended at 55 FR 20785, May 21, 1990]

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TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND
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PART 109 - UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN
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Subpart A - General Provisions

Sec. 109.6 Added poisonous or deleterious substances.

- (a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive, will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under sections 406, 408, or 409 of the act by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (d) of this section.
- (b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:
- (1) The substance cannot be avoided by good manufacturing practice.
 - (2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.
 - (3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.
- (c) A regulatory limit for an added poisonous or deleterious substance in any food may be established when each of the following criteria is met:
- (1) The substance cannot be avoided by current good manufacturing practices.
 - (2) There is no tolerance established for the substance in the particular food under sections 406, 408, or 409 of the act.

- (3) There is insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may affect the appropriateness of a tolerance. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.
- (d) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level for an added poisonous or deleterious substance in any food may be established at a level at which the Food and Drug Administration may regard the food as adulterated within the meaning of section 402(a)(1) of the act, without regard to the criteria in paragraph (b) of this section or in section 406 of the act. An action level will be withdrawn when a tolerance or regulatory limit for the same substance and use has been established.
- (e) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 of the act, if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

[42 FR 52819, Sept. 30, 1977, as amended at 55 FR 20785, May 21, 1990]

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

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§ 110.110 Natural and unavoidable defects in food 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 24475, June 19, 1986, unless otherwise noted.

Subpart A - General Provisions

§ 110.3 Definitions.

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

- (a) "*Acid foods* or *acidified foods*" means foods that have an equilibrium pH of 4.6 or below.
- (b) "*Adequate*" means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) "*Batter*" means a semi fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) "*Blanching*," except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) "*Critical control point*" means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- (f) "*Food*" means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- (g) "*Food-contact surfaces*" are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "*Food-contact surfaces*" includes utensils and food-contact surfaces of equipment.
- (h) "*Lot*" means the food produced during a period of time indicated by a specific code.

- (i) "*Microorganisms*" means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.
- (j) "*Pest*" refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
- (k) "*Plant*" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- (l) "*Quality control operation*" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
- (m) "*Rework*" means clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
- (n) "*Safe-moisture level*" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.
- (o) "*Sanitize*" means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
- (p) "*Shall*" is used to state mandatory requirements.
- (q) "*Should*" is used to state recommended or advisory procedures or identify recommended equipment.
- (r) "*Water activity*" (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 110.5 Current good manufacturing practice.

- (a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under unsanitary 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 surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.
- (b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:
 - (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
 - (2) Maintaining adequate personal cleanliness.
 - (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
 - (4) Removing all 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.
 - (6) Wearing, where appropriate, in an effective manner, hairnets, 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 unsanitary practices.
- (d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.19 Exclusions.

- (a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.
- (b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B - Buildings and Facilities

§ 110.20 Plant and grounds.

- (a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:
 - (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
 - (2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
 - (3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place 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 structures 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 harborage 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 vapors (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 cups, 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.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 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 contacts 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 systems that discharge wastewater 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 employees 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 airflow 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, of 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 so 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 in the receiving, 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 failures 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, 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, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials 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, a_w , 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 a_w 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 a 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 detectors, 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, breading, 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 a_w 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_w 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 a_w 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 4.6 or below. Compliance with this requirement may be accomplished by any 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.

[51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

§ 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 foods 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 requirements 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 feasible.

(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 final 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 Center for Food Safety and Applied Nutrition, (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[51 FR 24475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

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TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES - CONTINUE
PART 123 - FISH AND FISHERY PRODUCTS

Subpart A - General Provisions

Sec.

- 123.3 Definitions.
- 123.5 Current good manufacturing practice.
- 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan.
- 123.7 Corrective actions.
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- 123.9 Records.
- 123.10 Training.
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- 123.12 Special requirements for imported products.
- 123.20 General.
- 123.28 Source controls.

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393); secs. 301, 307, 361 of the Public Health Service Act (42 U.S.C. 241, 242l, 264).

Subpart B - Smoked and Smoke-Flavored Fishery Products

123.15 General.

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Subpart C - Raw Molluscan Shellfish

Source: 60 FR 65197, Dec. 18, 1995, unless otherwise noted.

Effective Date Note: At 60 FR 65197, Dec. 18, 1995, part 123 was added, effective December 18, 1997.

Subpart A - General Provisions

Sec. 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

- (a) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.
- (b) Critical control point means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.
- (c) Critical limit means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.
- (d) Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.
- (e) Fishery product means any human food product in which fish is a characterizing ingredient.
- (f) Food safety hazard means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
- (g) Importer means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.
- (h) Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

- (i) Preventive measure means physical, chemical, or other factors that can be used to control an identified food safety hazard.
- (j) Process-monitoring instrument means an instrument or device used to indicate conditions during processing at a critical control point.
- (k)(1) Processing means, with respect to fish or fishery products:

Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

- (i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
 - (ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
 - (iii) The operation of a retail establishment.
- (l) Processor means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.
 - (m) Scombrotoxin-forming species means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.
 - (n) Shall is used to state mandatory requirements.
 - (o) Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.
 - (p) Shellstock means raw, in-shell molluscan shellfish.
 - (q) Should is used to state recommended or advisory procedures or to identify recommended equipment.
 - (r) Shucked shellfish means molluscan shellfish that have one or both shells removed.
 - (s) Smoked or smoke-flavored fishery products means the finished food prepared by:
 - (1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

Sec. 123.5 Current good manufacturing practice.

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

Sec. 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan.

(a) Hazard analysis. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) The HACCP plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

- (i) Natural toxins;
 - (ii) Microbiological contamination;
 - (iii) Chemical contamination;
 - (iv) Pesticides;
 - (v) Drug residues;
 - (vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;
 - (vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
 - (viii) Unapproved use of direct or indirect food or color additives; and
 - (ix) Physical hazards;
- (2) List the critical control points for each of the identified food safety hazards, including as appropriate:
- (i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and
 - (ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;
- (3) List the critical limits that must be met at each of the critical control points;
- (4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
- (5) Include any corrective action plans that have been developed in accordance with Sec. 123.7(b), to be followed in response to deviations from critical limits at critical control points;
- (6) List the verification procedures, and frequency thereof, that the processor will use in accordance with Sec. 123.8(a);
- (7) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.
- (d) Signing and dating the HACCP plan.

- (1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.
- (2) The HACCP plan shall be dated and signed:
 - (i) Upon initial acceptance;
 - (ii) Upon any modification; and
 - (iii) Upon verification of the plan in accordance with Sec. 123.8(a)(1).
- (e) Products subject to other regulations. For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.
- (f) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 123.11(b) they need not be included in the HACCP plan, and vice versa.
- (g) Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

Sec. 123.7 Corrective actions.

- (a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:
 - (1) Following a corrective action plan that is appropriate for the particular deviation, or
 - (2) Following the procedures in paragraph (c) of this section.
- (b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:
 - (1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and
 - (2) The cause of the deviation is corrected.

- (c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:
- (1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;
 - (2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Sec. 123.10;
 - (3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
 - (4) Take corrective action, when necessary, to correct the cause of the deviation;
 - (5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.
- (d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 123.8(a)(3)(ii) and the record keeping requirements of Sec. 123.9.

Sec. 123.8 Verification.

- (a) Overall verification. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:
- (1) Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 123.6(c).
 - (2) Ongoing verification activities. Ongoing verification activities including:
 - (i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
 - (ii) The calibration of process-monitoring instruments; and,

- (iii) At the option of the processor, the performing of periodic end product or in-process testing.
- (3) Records review. A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:
- (i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
 - (ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and
 - (iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.
- (b) Corrective actions. Processors shall immediately follow the procedures in Sec. 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.
- (c) Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10.
- (d) Record keeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the record keeping requirements of Sec. 123.9.

Sec. 123.9 Records.

- (a) General requirements. All records required by this part shall include:
- (1) The name and location of the processor or importer;
 - (2) The date and time of the activity that the record reflects;

- (3) The signature or initials of the person performing the operation; and
- (4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) Record retention.

- (1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.
- (2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.
- (3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d) Public disclosure.

- (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in Sec. 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in Sec. 20.61 of this chapter.
- (2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) Tags. Tags as defined in Sec. 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of Sec. 123.28(c).

(f) Records maintained on computers. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

Sec. 123.10 Training.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

- (a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);
- (b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and
- (c) Performing the record review required by Sec. 123.8(a)(3); The trained individual need not be an employee of the processor.

Sec. 123.11 Sanitation control procedures.

- (a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.
- (b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:
 - (1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
 - (2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
 - (3) Prevention of cross-contamination from unsanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
 - (4) Maintenance of hand washing, hand sanitizing, and toilet facilities;
 - (5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

- (6) Proper labeling, storage, and use of toxic compounds;
 - (7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
 - (8) Exclusion of pests from the food plant. The processor shall correct in a timely manner, those conditions and practices that are not met.
- (c) Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of Sec. 123.9.
- (d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

Sec. 123.12 Special requirements for imported products.

This section sets forth specific requirements for imported fish and fishery products.

- (a) Importer verification. Every importer of fish or fishery products shall either:
- (1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or
 - (2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:
 - (i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act because it may be injurious to health or have been processed under unsanitary conditions, and,
 - (ii) Affirmative steps that may include any of the following:
 - (A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;
 - (B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

- (C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;
 - (D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;
 - (E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,
 - (F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.
- (b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.
 - (c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Sec. 123.9.
 - (d) Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B - Smoked and Smoke-Flavored Fishery Products

Sec. 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

Sec. 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Subpart C - Raw Molluscan Shellfish

Sec. 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

Sec. 123.28 Source controls.

- (a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.
- (b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.
- (c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licenser requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in Sec. 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in Sec. 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:
 - (1) The date of harvest;
 - (2) The location of harvest by State and site;
 - (3) The quantity and type of shellfish;
 - (4) The date of receipt by the processor; and
 - (5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.
- (d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with Sec. 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

- (1) The date of receipt;
- (2) The quantity and type of shellfish; and
- (3) The name and certification number of the packer or repacker of the product.

PART 161 - FISH AND SHELLFISH

Subpart A - General Provisions

- 161.170 Canned Pacific salmon.
- 161.173 Canned wet packed shrimp in transparent or nontransparent containers.
- 161.175 Frozen raw breaded shrimp.
- 161.176 Frozen raw lightly breaded shrimp.
- 161.190 Canned tuna.
- 161.130 Oysters.
- 161.30 Declaration of quantity of contents on labels for canned oysters.
- 161.136 Olympia oysters.
- 161.145 Canned oysters

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

Source: 42 FR 14464, Mar. 15, 1977, unless otherwise noted.

Subpart A - General Provisions

§ 161.30 Declaration of quantity of contents on labels for canned oysters.

- (a) For many years packers of canned oysters in the Gulf area of the United States have labeled their output with a declaration of the drained weight of oysters in the containers. Packers in other areas have marketed canned oysters with a declaration of the total weight of the contents of the container. Investigation reveals that under present day practice consumers generally do not discard the liquid packing medium, but use it as a part of the food. Section 403(e)(2) of the Federal Food, Drug, and Cosmetic Act and the regulations there under require food in package form to bear an accurate label statement of the quantity of food in the container.
- (b) It is concluded that compliance with the label declaration of quantity of contents requirement will be met by an accurate declaration of the total weight of the contents of the can. The requirements of § 161.145(c), establishing a standard of fill of container for canned oysters and specifying the statement of substandard fill

Subpart B - Requirements for Specific Standardized Fish and Shellfish

§ 161.130 Oysters.

- (a) Oysters, raw oysters, shucked oysters, are the class of foods each of which is obtained by

shucking shell oysters and preparing them in accordance with the procedure prescribed in paragraph (b) of this section. The name of each such food is the name specified in the applicable definition and standard of identity prescribed in § 161.131 to 161.140, inclusive.

(b) If water, or salt water containing less than 0.75 percent salt, is used in any vessel into which the oysters are shucked the combined volume of oysters and liquid when such oysters are emptied from such vessel is not less than four times the volume of such water or salt water. Any liquid accumulated with the oysters is removed. The oysters are washed, by blowing or otherwise, in water or salt water, or both. The total time that the oysters are in contact with water or salt water after leaving the shucker, including the time of washing, rinsing, and any other contact with water or salt water is not more than 30 minutes. In computing the time of contact with water or salt water, the length of time that oysters are in contact with water or salt water that is agitated by blowing or otherwise, shall be calculated at twice its actual length. Any period of time that oysters are in contact with salt water containing not less than 0.75 percent salt before contact with oysters, shall not be included in computing the time that the oysters are in contact with water or salt water. Before packing into the containers for shipment or other delivery for consumption the oysters are thoroughly drained and are packed without any added substance.

(c) For the purposes of this section:

(1) "Shell oysters" means live oysters of any of the species, *Ostrea virginica*, *Ostrea gigas*, *Ostrea lurida*, in the shell, which, after removal from their beds, have not been floated or otherwise held under conditions which result in the addition of water.

(2) "Thoroughly drained" means one of the following:

(i) The oysters are drained on a strainer or skimmer which has an area of not less than 300 square inches per gallon of oysters, drained, and has perforations of at least 1/4 of an inch in diameter and not more than 1 1/4 inches apart, or perforations of equivalent areas and distribution. The oysters are distributed evenly over the draining surface of the skimmer and drained for not less than 5 minutes; or

(ii) The oysters are drained by any method other than that prescribed by paragraph (c)(2)(i) of this section whereby liquid from the oysters is removed so that when the oysters are tested within 15 minutes after packing by draining a representative gallon of oysters on a skimmer of the dimensions and in the manner described in paragraph (c)(2)(i) of this section for 2 minutes, not more than 5 percent of liquid by weight is removed by such draining.

§ 161.136 *Olympia* oysters.

Olympia oysters, raw *Olympia* oysters, shucked *Olympia* oysters, are of the species *Ostrea lurida* and conform to the definition and standard of identity prescribed for oysters in § 161.130.

§ 161.145 Canned oysters.

(a) *Identity.*

- (1) Canned oysters is the food prepared from one or any mixture of two or all of the forms of oysters specified in paragraph (a)(2) of this section, and a packing medium of water, or the watery liquid draining from oysters before or during processing, or a mixture of such liquid and water. The food may be seasoned with salt. It is sealed in containers and so processed by heat as to prevent spoilage.
- (2) The forms of oysters referred to in paragraph (a)(1) of this section are prepared from oysters which have been removed from their shells and washed and which may be steamed while in the shell or steamed or blanched or both after removal there from, and are as follows:
 - (i) Whole oysters with such broken pieces of oysters as normally occur in removing oysters from their shells, washing, and packing.
 - (ii) Pieces of oysters obtained by segregating pieces of oysters broken in shucking, washing, or packing whole oysters.
 - (iii) Cut oysters obtained by cutting whole oysters.
- (3)(i) When the form of oysters specified in paragraph (a)(2)(i) of this section is used, the name of the food is "Oysters" or "Cove oysters", if of the species *Ostrea virginica*; "Oysters" or "Pacific oysters", if of the species *Ostrea gigas*; "Oysters" or "Olympia oysters", if of the species *Ostrea lurida*.
 - (ii) When the form of oysters specified in paragraph (a)(2)(ii) of this section is used, the name of the food is "Pieces of ----", the blank being filled in with the name "Oysters" or "Cove oysters", if of the species *Ostrea virginica*; "Oysters" or "Pacific oysters", if of the species *Ostrea gigas*; "Oysters" or "Olympia oysters", if of the species *Ostrea lurida*.
 - (iii) When the form of oysters specified in paragraph (a)(2)(iii) of this section is used, the name of the food is "Cut --", the blank being filled in with the name "Oysters" or "Cove oysters", if of the species *Ostrea virginica*; "Oysters" or "Pacific oysters", if of the species *Ostrea gigas*; "Oysters" or "Olympia oysters", if of the species *Ostrea lurida*.
 - (iv) In case a mixture of two or all such forms of oysters is used, the name is a combination of the names specified in this paragraph (a)(3) of the forms of oysters used, arranged in order of their predominance by weight.
- (4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container.*

- (1) The standard of fill of container for canned oysters is a fill such that the drained weight of oysters taken from each container is not less than 59 percent of the water capacity of the container.
- (2) Water capacity of containers is determined by the general method provided in § 130.12(a) of this chapter.
- (3) Drained weight is determined by the following method: Keep the un-opened canned oyster container at a temperature of not less than 68° or more than 95° Fahrenheit for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute its contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth under "2.38 mm (No. 8)" in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), Table 1, "Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)," under the heading "Definitions of Terms and Explanatory Notes," which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.
- (4) If canned oysters fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter in the manner and form therein specified, followed by the statement, "A can of this size should contain --- oz. of oysters. This can contains only --- oz.", the blanks being filled in with the applicable figures.

[42 FR 14464, Mar. 15, 1977, as amended at 47 FR 11832, Mar. 19, 1982; 49 FR 101-02, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2884, Jan 6, 1993; 63 FR 14035, Mar. 24, 1998]

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TITLE 21 - FOOD AND DRUGS
 CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND
 HUMAN SERVICES - (Continued)

PART 509 - UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL - Table of Contents

Subpart A - General Provisions

Sec. 509.3 Definitions and interpretations.

- (a) Act means the Federal Food, Drug, and Cosmetic Act.
- (b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.
- (c) A naturally occurring poisonous or deleterious substance is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.
- (d) An added poisonous or deleterious substance is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.
- (e) Food includes pet food, animal feed, and substances migrating to food from food-contact articles.

[Code of Federal Regulations]
[Title 21, Volume 6, Parts 500 to 599]
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TITLE 21 - FOOD AND DRUGS
CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES - (Continued)

PART 509 - UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL - Table of Contents

Subpart A - General Provisions

Sec. 509.4 Establishment of tolerances, regulatory limits, and action levels.

- (a) When appropriate under the criteria of Sec. 509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

- (b) When appropriate under the criteria of Sec. 509.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.
- (c)(1) When appropriate under the criteria of Sec. 509.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.
- (2) Whenever an action level is established or changed, a notice shall be published in the Federal Register as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.
- (d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

[42 FR 52821, Sept. 30, 1977, as amended at 55 FR 20786, May 21, 1990]