Subpart D—Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces

AUTHORITY: 21 U.S.C. 321, 342, 348, 371, 381.

SOURCE: 42 FR 14659, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 189 appear at 61 FR 14482, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; 70 FR 40880, July 15, 2005; and 70 FR 67651, Nov. 8, 2005.

Subpart A—General Provisions

§ 189.1 Substances prohibited from use in human food.

(a) The food ingredients listed in this section have been prohibited from use in human food by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food. Use of any of these substances in violation of this section causes the food involved to be adulterated in violation of the act.

(b) This section includes only a partial list of substances prohibited from use in human food, for easy reference purposes, and is not a complete list of substances that may not lawfully be used in human food. No substance may be used in human food unless it meets all applicable requirements of the act.

(c) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, pursuant to part 10 of this chapter, and will be published for comment if it contains reasonable grounds.

[42 FR 14659, Mar. 15, 1977, as amended at 54 FR 24899, June 12, 1989]

Subpart B—Prohibited Cattle Materials

§ 189.5 Prohibited cattle materials.

(a) *Definitions.* The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) apply to such terms when used in this part. The following definitions also apply:

(1) *Prohibited cattle materials* mean specified risk materials, small intestine of all cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS)(Beef). Prohibited cattle materials do not include the following:

(i) Tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, gelatin, hides and hide-derived products, and milk and milk products, and

(ii) Cattle materials inspected and passed from a country designated under paragraph (e) of this section.

(2) *Inspected and passed* means that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated (MS) (Beef)* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meets the specifications contained in 9 CFR 319.5, the U.S. Department of Agriculture regulation that prescribes the standard of identity for MS (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis,

fractured vertebral column, or metabolic conditions.

(5) *Specified risk material* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain no more than 0.15 percent insoluble impurities as determined by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a-46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave. Champaign, IL 61821. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

(8) *Gelatin* means a product that has been obtained by the partial hydrolysis of collagen derived from hides, connective tissue, and/or bone bones of cattle and swine. Gelatin may be either Type A (derived from an acid-treated precursor) or Type B (derived from an alkali-treated precursor) that has gone through processing steps that include filtration and sterilization or an equivalent process in terms of infectivity reduction.

(b) *Requirements.* (1) No human food shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials.

(2) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(c) *Records.* (1) Manufacturers and processors of a human food that is manufactured from, processed with, or otherwise contains, material from cattle must establish and maintain records sufficient to demonstrate that the food is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

(2) Records must be retained for 2 years after the date they were created.

(3) Records must be retained at the manufacturing or processing establishment or at a reasonably accessible location.

(4) The maintenance of electronic records is acceptable. Electronic records are considered to be reasonably accessible if they are accessible from an onsite location.

(5) Records required by this section and existing records relevant to compliance with this section must be available to FDA for inspection and copying.

(6) When filing entry with U.S. Customs and Border Protection, the importer of record of a human food manufactured from, processed with, or otherwise containing, cattle material must affirm that the food was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the food was manufactured in accordance with this section. If a human food is manufactured

from, processed with, or otherwise contains, cattle material, then the importer of record must, if requested, provide within 5 days records sufficient to demonstrate that the food is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material.

(7) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

(d) *Adulteration.* (1) Failure of a manufacturer or processor to operate in compliance with the requirements of paragraphs (b) or (c) of this section renders human food adulterated under section 402(a)(4) of the act.

(2) Human food manufactured from, processed with, or otherwise containing, prohibited cattle materials is unfit for human food and deemed adulterated under section 402(a)(3) of the act.

(3) *Food additive status.* Prohibited cattle materials for use in human food are food additives subject to section 409 of the act, except when used as dietary ingredients in dietary supplements. The use or intended use of any prohibited cattle material in human food causes the material and the food to be adulterated under section 402(a)(2)(C) of the act if the prohibited cattle material is a food additive, unless it is the subject of a food additive regulation or of an investigational exemption for a food additive under §170.17 of this chapter.

(e) *Process for designating countries.* A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, at the address designated in 21 CFR 5.1100. The request shall include information about a country's bovine spongiform encephalopathy (BSE) case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether specified risk materials, the small intestine of cattle except as provided in paragraph (b)(2) of this section, material from non-ambulatory disabled cattle, or MS (Beef) from cattle from the country should be considered prohibited cattle materials. FDA shall respond in writing to any such request and may impose conditions in granting any such request. A country designation granted by FDA under this paragraph will be subject to future review by FDA, and may be revoked if FDA determines that it is no longer appropriate.

[70 FR 53068, Sept. 7, 2005, as amended at 71 FR 59668, Oct. 11, 2006; 73 FR 20793, Apr. 17, 2008; 81 FR 5596, Feb. 3, 2016; 81 FR 14731, Mar. 18, 2016]

Subpart C—Substances Generally Prohibited From Direct Addition or Use as Human Food

SOURCE: 42 FR 14659, Mar. 15, 1977, unless otherwise noted. Redesignated at 69 FR 42273, July 14, 2004.

§ 189.110 Calamus and its derivatives.

(a) Calamus is the dried rhizome of *Acorus calamus* L. It has been used as a flavoring compound, especially as the oil or extract.

(b) Food containing any added calamus, oil of calamus, or extract of calamus is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of May 9, 1968 (33 FR 6967).

(c) The analytical method used for detecting oil of calamus (β-asarone) is in the ''Journal of the Association of Official Analytical Chemists,'' Volume 56, (Number 5), pages 1281 to 1283, September 1973, which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, also from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go