“§ 342. Adulterated food

A food shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.\(^1\) (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 346(a) of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 348 of this title; or (iii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 348 of this title; or (iv) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 348 of this title; or (v) it is if it is otherwise unfit for food; or (vi) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (7) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (8) if its container is compos- ed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (9) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

\(^1\) So in original. The period probably should be ‘‘; or’’.
(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 378(a) of this title.

(d) Confectionery containing alcohol or non-nutritive substance

If it is confectionery, and—

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per cent by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury under—

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(h) Reoffer of food previously denied admission

If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381(a) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this chapter, as determined by the Secretary.

(i) Noncompliance with sanitary transportation practices

If it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehi-
AMENDMENTS

2005—Par. (a). Pub. L. 109–59 added subpar. (2) and struck out former subpar. (2) which read as follows: ‘‘(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title, or (C) if it is, or if it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title; (2)(B) if a food additive)’’ in cl. (2)(A).

1996—Par. (a). Pub. L. 104–170, § 7202(a), substituted ‘‘other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346a of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title, or (C) if it is, or if it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346 of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or if it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title;’’. That part of Pub. L. 104–170 which directed the substitution of ‘‘(or (3) if it consists)’’ for ‘‘(3) if it consists’’ was executed by making the substitution for ‘‘(3) if it consists’’ to reflect the probable intent of Congress.


1992—Par. (a), Pub. L. 102–571 substituted ‘‘376a(a)’’ for ‘‘376a(a)’’.

1986—Par. (a)(2). Pub. L. 99–252 inserted provision that this clause not apply to confectionery introduced or delivered for introduction into or received or held for sale in interstate commerce if the sale is permitted under the laws of the State in which the confectionery is intended to be offered for sale.


1986—Par. (a). Pub. L. 99–477 permitted the imbedding of nonnutritive objects in confectionery foods if in the judgment of the Secretary of Health, Education, and Welfare, as provided by regulation, the imbedding of the object is of practical functional value to the confectionery product and would not render it injurious or hazardous to health, raised to one-half of 1 per centum by volume the upper limit for the allowable use of alcohol derived solely from the use of flavoring extracts, allowed the use of safe nonnutritive substances in and on confectionery foods by reason of their use for some practical and functional purpose in the manufacture, packaging, or storage of the confectionery foods if the use of the substances does not promote deception of the consumer or otherwise result in adulteration or misbranding, authorized the Secretary to issue regulations on the use of particular nonnutritive substances, and removed reference to nonnutritive masticatory substances added to chewing gum and harmless flavoring, harmless resins or glaze not in excess of four-tenths of 1 per centum, natural gum, authorized coloring, and pectin.

1985—Par. (a). Pub. L. 98–618, § 102(a)(1), substituted ‘‘other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive and except a food additive)’’ in cl. (2)(A).

1980—Par. (a)(2). Pub. L. 96–275, § 102(a)(2), amended par. (c) generally, substituting provisions deeming a food adulterated if it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376 of this title for provisions which related to food that bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 346 of this title, and struck out provisos which related to the use of color on oranges.

1976—Par. (a). Pub. L. 94–299, among other changes, inserted cl. (2)(C) relating to the use of radiated citrus red no. 2, inserted provisions relating to the use of particular nonnutritive substances, and for separately listing and for certification of batches of such color.


EFFECTIVE DATE OF 2005 AMENDMENT

PROVISIONS AMENDED: 1964

Amendment by Pub. L. 90–399 effective on first day of thirteenth calendar month after July 31, 1964, see section 108(a) of Pub. L. 90–399, set out as an Effective Date and Transitional Provisions note under section 306b of this title.

AMENDMENT BY PUB. L. 90–399

Amendment by Pub. L. 88–625 effective July 22, 1964, except that with respect to pesticide chemicals for which tolerances or exemptions have not been established under section 408 of the Federal Food, Drug, and Cosmetic Act (section 348a of this title), the amendment to section 402(a) of such Act (par. (a) of this section) made by section 203 of Pub. L. 86–618, set out as a note under section 347 of this title.

EFFECTIVE DATE: 1965

Amendment by act Mar. 16, 1965, effective July 1, 1965, see section 7 of act Mar. 16, 1965, set out as an Effective Date note under section 347 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], see section 5 of Pub. L. 111–353, title I, § 103(h), Jan. 4, 2011, 124 Stat. 102, provided that, for purposes of this section and section 135 of Title 7, Agriculture may be cited as the ‘Food Additives Transitional Provisions Amendment of 1964.’

UPDATE GUIDANCE RELATING TO FISH AND FISHERIES PRODUCTS HAZARDS AND CONTROLS

Pub. L. 111–353, title I, § 103(b), Jan. 4, 2011, 124 Stat. 3986, provided that, ‘The Secretary shall, not later than 180 days after the date of enactment of this Act [Jan. 4, 2011], update the Fish and Fisheries Products Hazards and Control Guidance to take into account advances in technology that have occurred since the previous publication of such Guidance by the Secretary.’

GUIDANCE RELATING TO POST HARVEST PROCESSING OF RAW OYSTERS

Pub. L. 111–353, title I, § 114, Jan. 4, 2011, 124 Stat. 3921, provided that, ‘(a) IN GENERAL.—Not later than 90 days prior to the issuance of any guidance, regulation, or suggested...’
amendment by the Food and Drug Administration to the National Shellfish Sanitation Program’s Model Or-
dinance, or the issuance of any guidance or regulation by
the Food and Drug Administration relating to the
Seafood Hazard Analysis Critical Control Points Pro-
gram of the Food and Drug Administration (parts 123
and 1246 of title 21, Code of Federal Regulations (or any
successor regulations))); where such guidance, regula-
tion or suggested amendment relates to post harvest
processing for raw oysters, the Secretary shall prepare
and submit to the Committee on Health, Education,
Labor, and Pensions of the Senate and the Committee
on Energy and Commerce of the House of Representa-
tives a report which shall include—

“(1) an assessment of how post harvest processing or
post harvest processing feasibly may be imple-
mented in the fastest, safest, and most economical
manner;

“(2) the projected public health benefits of any pro-
posed post harvest processing;

“(3) the projected costs of compliance with such
post harvest processing measures;

“(4) the impact post harvest processing is expected
to have on the sales, cost, and availability of raw oys-
ters;

“(5) criteria for ensuring post harvest processing
standards will be applied equally to shellfish im-
ported from all nations of origin;

“(6) an evaluation of alternative measures to pre-
vent, eliminate, or reduce to an acceptable level the
occurrence of foodborne illness; and

“(7) the extent to which the Food and Drug Admin-
istration has consulted with the States and other reg-
ulatory agencies, as appropriate, with regard to post
harvest processing measures.

“(b) LIMITATION.—Subsection (a) shall not apply to
the guidance described in section 103(h) [section 103(h)
of Pub. L. 111–533, set out as a note above].

“(c) REVIEW AND EVALUATION.—Not later than 30
days after the Secretary issues a proposed regulation or
guidance described in subsection (a), the Comptroller
General of the United States shall—

“(1) review and evaluate the report described in (a)
and report to Congress on the findings of the esti-
mates and analysis in the report;

“(2) compare such proposed regulation or guidance
to similar regulations or guidance with respect to
other regulated foods, including a comparison of risks
the Secretary may find associated with seafood and the
instances of those risks in such other regulated foods;
and

“(3) evaluate the impact of post harvest processing
on the competitiveness of the domestic oyster indus-
try in the United States and in international mar-
kets.

“(d) WAIVER.—The requirement of preparing a report
under subsection (a) shall be waived if the Secretary
issues a guidance that is adopted as a consensus agree-
ment between Federal and State regulators and the
oyster industry, acting through the Interstate Shellfish
Sanitation Conference.

“(e) Public Access.—Any report prepared under this
section shall be made available to the public.”

DOMESTIC FISH OR FISH PRODUCT COMPLIANCE
WITH FOOD SAFETY STANDARDS OR PROCEDURES DEEMED
TO HAVE MET REQUIREMENTS FOR FEDERAL COMMODITY
PURCHASE PROGRAMS

1601, provided that: “Hereafter, notwithstanding any
other provision of law, any domestic fish or fish prod-
uct produced in compliance with food safety standards
or procedures adopted by the Food and Drug Adminis-
tration as satisfying the requirements of the ‘Proce-
dures for the Safe and Sanitary Processing and Import-
ing of Fish and Fish Products’ (published by the Food
and Drug Administration as a final regulation in the
Federal Register of December 12, 1996), shall be deemed
to have met any inspection requirements of the Depart-
ment of Agriculture or other Federal agency for any
Federal commodity purchase program, including the
program authorized under section 32 of the Act of Au-
tober 24, 1935 (7 U.S.C. 612c) except that the Department
of Agriculture or other Federal agency may utilize lot
inspection to establish a reasonable degree of certainty
that fish or fish products purchased under a Federal
commodity purchase program, including the program
authorized under section 32 of the Act of August 24, 1935
(7 U.S.C. 612c), meet Federal product specifications.”

§ 343. Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If (1) its labeling is false or misleading in any
particular, or (2) in the case of a food to which
section 350 of this title applies, its advertising is
false or misleading in a material respect or its
labeling is in violation of section 350(b)(2) of this
title.

(b) Offer for sale under another name

If it is offered for sale under the name of an-
other food.

(c) Imitation of another food

If it is an imitation of another food, unless its
label bears, in type of uniform size and promi-
nence, the word ‘‘imitation’’ and, immediately
thereafter, the name of the food imitated.

(d) Misleading container

If its container is so made, formed, or filled as to
be misleading.

(e) Package form

If in package form unless it bears a label con-
taining (1) the name and place of business of the
manufacturer, packer, or distributor; and (2) an
accurate statement of the quantity of the contents
in terms of weight, measure, or numerical count,
except that under clause (2) of this para-
graph reasonable variations shall be permitted,
and exemptions as to small packages shall be es-
lished, by regulations prescribed by the Sec-
retary.

(f) Prominence of information on label

If any word, statement, or other information
required by or under authority of this chapter to
appear on the label or labeling is not promi-
nently placed thereon with such conspicuous-
ness (as compared with other words, statements,
designs, or devices, in the labeling) and in such
terms as to render it likely to be read and un-
derstood by the ordinary individual under cus-
tomary conditions of purchase and use.

(g) Representation as to definition and standard
of identity

If it purports to be or is represented as a food for
which a definition and standard of identity
has been prescribed by regulations as provided
by section 3H of this title, unless (1) it conforms
to such definition and standard, and (2) its label
bears the name of the food specified in the defi-
nition and standard, and, insofar as may be re-
quired by such regulations, the common names
of optional ingredients (other than spices, fla-
voring, and coloring) present in such food.

(h) Representation as to standards of quality and
fill of container

If it purports to be or is represented as—