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## Table. A side by side comparison of what is considered an adulterated food in *human food* v. *animal food* in the Proposed Rule (*Emphasis mine*)

|  |  |
| --- | --- |
| **Human food** | **Animal food** |
| A. Proposed § 117.1 - Applicability and StatusFDA is proposing to redesignate current § 110.5(a) as proposed § 117.1(a) with associated editorial changes described in section IX.G of this document. Current § 110.5(a) establishes that the criteria and definitions in part 110 apply in determining whether a [human] *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 FD&C Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.* Current § 110.5(a) also establishes that the criteria and definitions in part 110 apply in determining whether a food is in violation of *section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264).* FDA is proposing to retain the provisions of current § 110.5(a) in proposed § 117.1(a). The provisions of current § 110.5(a) as re-established in proposed § 117.1(a) would continue to apply to all provisions that currently are established in part 110 and would be re-established in proposed part 117. Under this proposed rule, proposed § 117.1 also would apply to new provisions of proposed part 117, including provisions that would be added under the authority of sections *402(a)(3), 402(a)(4),* or *418 of the FD&C Act, section 361 of the PHS Act, or a combination of those authorities*. The Agency notes that section 418(a) of the FD&C Act provides that facilities subject to that section must *“identify and implement preventive controls to … provide assurances that … food is not adulterated under section 402 [of the FD&C Act]”* and that similar references to preventing adulteration under section 402 of the FD&C Act also appear in section 418(c) and (e). The Agency tentatively concludes that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions in proposed part 117 in determining whether, under particular circumstances, a food is adulterated under section *402(a)(3) or (a)(4) or in violation of section 361 of the PHS Act.* | A. Proposed § 507.1--Applicability and StatusFDA is proposing in § 507.1(a) that the criteria and definitions in part 507 apply in determining whether an *animal food* is adulterated: *(1) within the meaning of section 402(a)(3) of the FD&C Act in that the animal 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 FD&C Act in that the animal food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.* Proposed § 507.1(a) also would establish that the criteria and definitions in part 507 apply in determining whether an animal food is in violation of *section 361 of the Public Health Service* *Act (the PHS Act) (42 U.S.C. 264).* --blank--The Agency notes that section 418(a) of the FD&C Act provides that facilities subject to that section must *"identify and implement preventive controls to… provide assurances that… food is not adulterated under section 402 [of the FD&C Act]"* and that similar references to preventing adulteration under section 402 of the FD&C Act also appearin section 418(c) and (e). The Agency tentatively concludes that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions in proposed part 507 in determining whether, under particular circumstances, an *animal* food is adulterated under section *402(a)(3) or (a)(4) or in violation of section 361 of the**PHS Act.* |

The law, as it is written, in the Federal Food, Drug & Cosmetic Act (FD&C Act) as it pertains to adulterated food:

**§ 342. Adulterated food [Section 402}**

(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]](http://www.law.cornell.edu/uscode/text/21/342#FN-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](http://www.law.cornell.edu/uscode/text/21/346) of this title; or

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section [346a](http://www.law.cornell.edu/uscode/text/21/346a) [(a)](http://www.law.cornell.edu/uscode/text/21/usc_sec_21_00000346---a000-#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 [348](http://www.law.cornell.edu/uscode/text/21/348) of this title; or

(ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section [360b](http://www.law.cornell.edu/uscode/text/21/360b) of this title; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) 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

(5) 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

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) 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](http://www.law.cornell.edu/uscode/text/21/348) of this title.

(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 [379e](http://www.law.cornell.edu/uscode/text/21/379e) [(a)](http://www.law.cornell.edu/uscode/text/21/usc_sec_21_00000379---e000-#a) of this title.

(d) **Confectionery containing alcohol or nonnutritive 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 centum 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](http://www.law.cornell.edu/uscode/text/5/554) and [556](http://www.law.cornell.edu/uscode/text/5/556) of title [5](http://www.law.cornell.edu/uscode/text/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  [[2]](http://www.law.cornell.edu/uscode/text/21/342#FN-2) (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](http://www.law.cornell.edu/uscode/text/5/part-I/chapter-5) of title [5](http://www.law.cornell.edu/uscode/text/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](http://www.law.cornell.edu/uscode/text/21/381) [(a)](http://www.law.cornell.edu/uscode/text/21/usc_sec_21_00000381----000-#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 vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section [350e](http://www.law.cornell.edu/uscode/text/21/350e) of this title.

[[1]](http://www.law.cornell.edu/uscode/text/21/342#FN-1REF)  So in original. The period probably should be “; or”.

[[2]](http://www.law.cornell.edu/uscode/text/21/342#FN-2REF)  So in original. Probably should be “subparagraph”.

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