Food Safety and Inspection Service, USDA

§ 331.5 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of products; application of regulations.

(a) An establishment preparing products solely for distribution within any State shall be designated as one producing adulterated products which would clearly endanger the public health, if:

(1) Any meat or meat food product prepared at the establishment is adulterated in any of the following respects:

(i) It bears or contains a pesticide chemical, food additive, or color additive, that is "unsafe" within the meaning of sections 408, 409, or 706 of the Federal Food, Drug, and Cosmetic Act or was intentionally subjected to radiation in a manner not permitted under section 409 of said Act; or if it bears or contains any other added poisonous or added deleterious substance which may render it injurious to health or make it unfit for human food; or

(ii) It consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, or unwholesome or otherwise unfit for human food (for example, it was prepared from meat or other ingredients exhibiting spoilage characteristics; or it is, or was prepared from, a carcass affected with a disease transmissible to humans and its condemnation would be required under part 309 or 310 of the Federal Meat Inspection regulations (9 CFR parts 309, 310) at federally inspected establishments; or it is a ready-to-eat pork product which has not been treated to destroy trichinae as prescribed in §318.10 of this subchapter for products at federally inspected establishments); or

(iii) It has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health (for example if insects or vermin are not effectively controlled at the establishments, or insanitary water is used in preparing meat or meat food products for human food); or (iv) It is, in whole or in part, the product of an animal that died otherwise than by slaughter; or

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

(2) Such adulterated articles are intended to be or are distributed from the establishment while capable of use as human food.

(b) When any such establishment is identified by a Program Inspector as one producing adulterated product, which would clearly endanger public health under the criteria in paragraph (a) of this section, the following procedure will be followed:

(1) The Program Inspector will informally advise the operator of the establishment concerning the deficiencies found by him and report his findings to the appropriate Regional Director for the Program. When it is determined by the Regional Director that any establishment preparing products solely for distribution within any State is producing adulterated products for distribution within such State which would clearly endanger the public health, written notification thereof will be issued to the appropriate State officials, including the Governor of the State and the appropriate Advisory Committee, for effective action under State or local law to prevent such endangering of the public health. Such written notification shall clearly specify the deficiencies deemed to result in the production of adulterated products and shall specify a reasonable time for such action under State or local law.

(2) If effective action is not taken under State or local law within the specified time, written notification shall be issued by the Regional Director to the operator of the establishment, specifying the deficiencies involved and allowing him ten days to present his views or make the necessary corrections, and notifying him that failure to correct such deficiencies may result in designation of the establishment and operator thereof as subject to the provisions of titles I and IV of the Act as though engaged in commerce.

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(3) Thereafter the Program Inspector shall survey the establishment and designate it if he determines, in consultation with the Regional Director, that it is producing adulterated products, which would clearly endanger the public health, and formal notice of such designation will be issued to the operator of the establishment by the Regional Director.

(c) Products on hand at the time of designation of an establishment under this section are subject to detention, seizure and condemnation in accordance with part 329 of this subchapter: *Provided*, That products that have been federally inspected and so identified and that have not been further prepared at any nonfederally inspected establishment may be released for distribution if the products appear to be not adulterated or misbranded at the time of such release.

(d) No establishment designated under this section can lawfully prepare

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any products unless it first obtains inspection or qualifies for exemption under \$303.1 of this subchapter. All of the provisions of the regulations shall apply to establishments designated under this section, except that the exceptions provided for in \$331.3 of this part shall apply to such establishments.

§331.6 Designation of States under section 205 of the Act; application of sections of the Act and the regulations.

Each of the following States has been designated, effective on the date shown below, under section 205 of the Act, as a State in which the provisions of the sections of the Act and regulations specified below shall apply to operators engaged, other than in or for commerce, in the kinds of business indicated below:

Sections of act and regulations	Classes of operators	State	Effective date of designation
Act, section 202; §§ 320.1, 320.2, 320.3, and 320.4.	Persons engaged (not in or for commerce) in (1) the busi- ness of slaughtering any livestock or preparing, freezing, packaging or labeling any livestock carcasses or parts or products thereof, for use as human food or animal food; (2) the business of buying or selling (as a meat broker, wholesaler, or otherwise), transporting or storing any live- stock carcasses or parts or products thereof; or (3) busi- ness as a renderer, or in the business of buying, selling, or transporting any dead, dying, disabled, or diseased live- stock that died other- wise than by slaughter.	Alaska	Nov. 19, 1976. Mar. 29, 1982.
Act, 203; § 320.5	Persons engaged (not in or for commerce) in business as a meat broker; renderer; animal food manufacturer; whole- saler or public warehouseman of livestock carcasses, or parts or products thereof; or buying, selling, or transporting any dead, dying, disabled, or diseased livestock, or parts of carcasses of any such livestock that dies otherwise than by slaughter.	Alaska Arkansas California Colorado Connecticut daho Kentucky Masyachusetts Massachusetts Michigan Nebraska Nevada New Hampshire New Jersey 	July 31, 1999. Mar. 29, 1982. Apr. 1, 1976. July 1, 1975. Oct. 1, 1975. Nov. 19, 1976. Mar. 29, 1982. Apr. 18, 1976. Mar. 29, 1982. Jan. 31, 1975. Mar. 29, 1982. Jan. 31, 1975. Jan. 31, 1975. Oct. 29, 1979.