## §381.225

Paragraphs of act and regulations	Classes of operators	State	Effective date
Act, 11(c); § 381.179	Persons engaged (not in or for commerce) in business as a	Alaska	July 31, 1999.
	poultry products broker; renderer; animal food manufac-	Arkansas	Apr. 1, 1976.
	turer; wholesaler or public warehouseman of poultry car-	California	July 1, 1975.
	casses, or parts or products thereof; or buying, selling, or	Colorado	Oct. 1, 1975.
	transporting dead, dying, disabled, or diseased poultry or	Connecticut	Nov. 12, 1976.
	parts of carcasses of any poultry that died otherwise than	Georgia	Nov. 19, 1976.
	by slaughter.	Guam	Nov. 12, 1976.
		Idaho	Apr. 18, 1973.
		Kentucky	Nov. 12, 1976.
		Maryland	Jan. 12, 1976.
		Massachusetts	Nov. 12, 1976.
		Michigan	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Oct. 29, 1979.
		New Hampshire	July 1, 1975.
		New Jersey	July 16, 1975.
		New York	July 23, 1973.
		Northern Mariana	Oct. 29, 1979.
		Islands.	Jan. 31, 1975.
		Oregon	
		Pennsylvania	May 2, 1974.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		South Dakota	Nov. 12, 1976.
		Tennessee	Oct. 1, 1975.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.
			Nov. 12, 1976.
Act, 11(d); 381.194	Persons engaged (not in or for commerce) in the business of	Alaska	July 31, 1999.
	buying, selling or transporting any dead, dying, disabled or	Arkansas	Nov. 12, 1976.
	diseased poultry, or parts or carcasses of any poultry that	Georgia	Nov. 19, 1976.
	died otherwise than by slaughter.	Guam	Nov. 12, 1976.
		Idaho	Nov. 12, 1976.
		Maryland	Nov. 12, 1976.
		Michigan	Oct. 29, 1979.
		New Hampshire	Oct. 29, 1979.
		Northern Mariana Islands.	Nov. 19, 1976.
		Puerto Rico	Mar. 29, 1982.
		Rhode Island	Nov. 12, 1976.
		South Dakota	Nov. 19, 1976.
		Virgin Islands	Nov. 12, 1976.

[37 FR 9706, May 16, 1972; 65 FR 6888, Feb. 11, 2000]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting \$381.224, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

### §381.225 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of poultry products therein.

(a) An establishment in any State not listed in §381.221 that is preparing poultry products solely for distribution within such State shall be designated as one producing adulterated products which would clearly endanger the public health, if:

- (1) Any poultry product processed 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 section 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, unwholesome, or otherwise unfit for human food (for example, it was prepared from a poultry carcass or other ingredients exhibiting spoilage characteristics); or it is, or was prepared from, a poultry carcass which would be required to be condemned under subpart K at official 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 establishment, or insanitary water is used in preparing poultry products for human food); or
- (iv) It is, in whole or in part, the product of poultry 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 an inspector as one producing adulterated poultry products which would clearly endanger public health under the criteria in paragraph (a) of this section, the following procedure will be followed:
- (1) The 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 Inspection Service. When it is determined by the Regional Director that any establishment preparing poultry products solely for distribution within any State is producing adulterated poultry 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 ap-

- propriate 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 poultry 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 10 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 sections 1 through 4, 6 through 10, and 12 through 22 of the Act as though engaged in commerce.
- (3) Thereafter the inspector shall survey the establishment and designate it if he determines, in consultation with the Regional Director, that it is producing adulterated poultry 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) Poultry products on hand at the time of designation of an establishment under this section are subject to retention or detention, and seizure and condemnation in accordance with §381.145 or subpart U of this part: *Provided*, That poultry 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 any poultry products unless it first obtains inspection or qualifies for exemption under §381.10 of this subpart. All other provisions of the regulations shall apply to establishments designated under this section to the same extent and in the same manner as if

#### §381.300

they were engaged in commerce, except that the exceptions provided for in §381.222 shall apply to such establishments

# Subpart X—Canning and Canned Products

Source:  $51\ FR\ 45634$ , Dec. 19, 1986, unless otherwise noted.

#### §381.300 Definitions.

- (a) Abnormal container. A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.
- (b) Acidified low acid product. A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.
- (c) *Bleeders*. Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.
- (d) Canned product. A poultry food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term "product" as used in this subpart G shall mean "canned product."
- (e) Closure technician. The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated by the establishment to perform such examinations.
- (f) Code lot. All production of a particular product in a specific size container marked with a specific container code.
- (g) *Come-up time.* The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.
- (h) *Critical factor*. Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Crit-

ical factors are established by processing authorities.

- (i) *Headspace*. That portion of a container not occupied by the product.
- (1) Gross headspace. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).
- (2) Net headspace. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.
- (j) Hermetically sealed containers. Airtight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.
- (1) Rigid container. A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm²) (i.e., normal firm finger pressure).
- (2) Semirigid container. A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm²) (i.e., normal firm finger pressure).
- (3) Flexible container. A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.
- (k) *Incubation tests.* Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.
- (l) *Initial temperature.* The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.
- (m) Low acid product. A canned product in which any component has a pH value above 4.6.