

subchapter, will be granted by the circuit supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by paragraph 1(n) of the Act.

(2) The circuit supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the Washington, DC, office of the Labeling and Packaging Staff and will retain one copy in a temporary approval file for the establishment.

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the circuit supervisor (showing any modifications required by the circuit supervisor) to the Labels and Packaging Staff, Meat and Poultry Inspection, Food Safety and Inspection Service, USDA, Washington, DC 20250, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the circuit supervisor must receive approval as required by §§ 316.7, 317.3, and 317.4, of this subchapter or their use must be discontinued.

(4) The circuit supervisor will also review all shipping containers to insure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of self-destructive pressure sensitive tape or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of this

subchapter must be destroyed or removed from the official establishment.

(f) Sections 320.1, 320.2, 320.3, 320.4, 320.5, 325.20, and 325.21 apply to operations and transactions not in or for commerce in a State designated under paragraph 301(c) only if the State is also designated under section 205 of the Act and if such provisions are applicable as shown in § 331.6.

(g) Section 321.1(a) of this subchapter will not apply to States designated under paragraph 301(c) of the Act.

(h) Parts 322 and 327 and § 325.3 of this subchapter relating to exports and imports do not apply to operations and transactions solely in or for intrastate commerce.

(i) Part 325 of this subchapter will apply to establishments required to have inspection under § 302.1(a)(2) of this subchapter and to operations and transactions solely in or for intrastate commerce, except as provided in paragraphs (h) and (j) of this section.

(j) Sections 325.4, 325.15, and 325.1(b) of this subchapter will not apply to require a certificate, or evidence thereof, for the distribution solely within any designated State of products that are U.S. inspected and passed and so marked.

[35 FR 19667, Dec. 29, 1970, as amended at 36 FR 12004, June 24, 1971; 41 FR 18089, Apr. 30, 1976; 62 FR 45026, Aug. 25, 1997; 64 FR 56416, Oct. 20, 1999]

§ 331.4 Control and disposal of non-federally-inspected products in States designated under paragraph 301(c) of the Act.

Upon the effective date of designation of a State under paragraph 301(c) of the Act, no products can be prepared within the State unless they are prepared under inspection pursuant to the regulations in this subchapter or are exempted from the requirement of inspection under § 303.1 of this subchapter, and no unexempted products which were prepared without any inspection can lawfully be distributed within the State. For a period of 90 days from the effective date of such designation, products which were prepared and inspected and passed under the supervision of a responsible State

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or local inspection agency can be distributed solely within the State, provided they are not adulterated or misbranded, except that the official inspection legend is not required. Within the 90-day period, products that have been inspected by the State or local inspection agency may be further prepared and otherwise handled in official establishments required to have inspection under § 302.1(a)(2) of this subchapter or at establishments exempted from the requirements of such inspection under § 303.1 of this subchapter, and may be distributed as provided in this section but otherwise shall be handled in accordance with § 305.4 of this subchapter. Such products shall not bear any [Federal] official inspection legends. After said 90-day period, only federally inspected and passed products may be distributed within the designated State, except as provided in § 303.1 of this subchapter.

§ 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