

conducted in a single plant or establishment, a series of plants under a single management, or all plants in an industry or region, by a manufacturer, processor, or packer.

§ 108.5 Determination of the need for a permit.

(a) Whenever the Commissioner determines after investigation that a manufacturer, processor, or packer of a food for which a regulation has been promulgated in subpart B of this part does not meet the mandatory conditions and requirements established in such regulation, he shall issue to such manufacturer, processor, or packer an order determining that a permit shall be required before the food may be introduced or delivered for introduction into interstate commerce by that person. The order shall specify the mandatory conditions and requirements with which there is a lack of compliance.

(1) The manufacturer, processor, or packer shall have 3 working days after receipt of such order within which to file objections. Such objections may be filed by telegram, telex, or any other mode of written communication addressed to the Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-605), 5100 Paint Branch Pkwy., College Park, MD 20740. If such objections are filed, the determination is stayed pending a hearing to be held within 5 working days after the filing of objections on the issues involved unless the Commissioner determines that the objections raise no genuine and substantial issue of fact to justify a hearing.

(2) If the Commissioner finds that there is an imminent hazard to health, the order shall contain this finding and the reasons therefor, and shall state that the determination of the need for a permit is effective immediately pending an expedited hearing.

(b) A hearing under this section shall be conducted by the Commissioner or his designee at a location agreed upon by the objector and the Commissioner or, if such agreement cannot be reached, at a location designated by the Commissioner. The manufacturer, processor, or packer shall have the right to cross-examine the Food and

Drug Administration's witnesses and to present witnesses on his own behalf.

(c) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether a permit is required and shall so inform the manufacturer, processor, or packer in writing, with the reasons for his decision.

(d) The Commissioner's determination of the need for a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay a determination of the need for a permit pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

[42 FR 14334, Mar. 15, 1977, as amended at 54 FR 24891, June 12, 1989; 61 FR 14479, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

§ 108.6 Revocation of determination of need for permit.

(a) A permit shall be required only during such temporary period as is necessary to protect the public health.

(b) Whenever the Commissioner has reason to believe that a permit holder is in compliance with the mandatory requirements and conditions established in subpart B of this part and is likely to remain in compliance, he shall, on his own initiative or on the application of the permit holder, revoke both the determination of need for a permit and the permit that had been issued. If denied, the applicant shall, upon request, be afforded a hearing conducted in accordance with § 108.5 (b) and (c) as soon as practicable. Such revocation is without prejudice to the initiation of further permit proceedings with respect to the same manufacturer, processor, or packer should later information again show the need for a permit.

§ 108.7 Issuance or denial of permit.

(a) After a determination and notification by the Commissioner in accordance with the provisions of § 108.5 that a manufacturer, processor, or packer requires a permit, such manufacturer, processor, or packer may not thereafter introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or