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PART 173-SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.368 is added to subpart D to read as follows:

Sec. 173.368 Ozone.

Ozone (CAS Reg. No. 10028-15-6) may be safely used in the treatment, storage, and processing of foods, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR part 319), in accordance with the following prescribed conditions:

(a) The additive is an unstable, colorless gas with a pungent, characteristic odor, which occurs freely in nature. It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.

(b) The additive is used as an antimicrobial agent as defined in Sec. 170.3(o)(2) of this chapter.

(c) The additive meets the specifications for ozone in the Food Chemicals Codex, 4th ed. (1996), p. 277, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20055, or may be examined at the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(d) The additive is used in contact with food, including meat and poultry (unless such use is precluded by standards of identity in 9 CFR part 319 or 9 CFR part 381, subpart P), in the gaseous or aqueous phase in accordance with current industry standards of good manufacturing practice.

(e) When used on raw agricultural commodities, the use is consistent with section 201(q)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act.

[66 FR 33830, June 26, 2001; 67 FR 271, Jan. 3, 2002]

National Organic Rule 2000 Excerpt

The National List of Allowed and Prohibited Substances

205.600 Allowed and prohibited substances and ingredients in organic production and handling.

To be sold or labeled as "organic," or "made with organic (specified ingredients)," the product must be produced and handled without the use of:

- (a) Synthetic substances and ingredients, except as provided in §205.601 and § 205.603.
- (b) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
- (c) Nonsynthetic substances prohibited in § 205.602 or § 205.604; and
- (d) Materials, processes, or techniques prohibited in § 205.301.

205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section and § 205.102 and § 205.200 through § 205.207, the following synthetic substances may be used:

2) Chlorine Materials - Except, That, residual chlorine levels in the water

shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium Hypochlorite
- (ii) Chlorine Dioxide
- (iii) Sodium Hypochlorite

205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients)."

The following nonagricultural substances may be used only in accordance with any restrictions specified in this section and § 205.102, § 205.270, and § 205.300 through § 205.310.

9) Chlorine Materials - disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

- (i) Calcium Hypochlorite
 - (ii) Chlorine Dioxide
 - (iii) Sodium Hypochlorite
- (21) Ozone