# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 173

[Docket No. 93F-0483]

## Secondary Direct Food Additives Permitted in Food for Human Consumption

**AGENCY:** Food and Drug Administration,

11115.

**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of chlorine dioxide to control the microbial population in poultry process water. This action is in response to a petition filed by Rio Linda Chemical Co., Inc.

**DATES:** The regulation is effective March 3, 1995; written objections and requests for a hearing by April 3, 1995. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in new § 173.69, effective March 3, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA– 305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

## FOR FURTHER INFORMATION CONTACT:

Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

## SUPPLEMENTARY INFORMATION:

## I. Background

In a notice published in the Federal Register of February 2, 1994 (59 FR 4924), FDA announced that a food additive petition (FAP 4A4408) had been filed by Rio Linda Chemical Co., Inc., 410 North 10th St., Sacramento, CA 95814, proposing that the food additive regulations be amended to provide for the safe use of chlorine dioxide to disinfect waters contacting fresh meat, fresh poultry, processed meat, and processed poultry. Since filing the petition, the agency has concluded that it is more appropriate to replace the term "disinfect" with "control the microbial population" because "disinfect" implies total eradication of microbial contamination.

FDA has completed its review of the use of up to 3 parts per million (ppm) residual chlorine dioxide in process

water contacting whole fresh poultry carcasses. The agency is issuing this regulation to permit this use while its review of the other proposed uses of chlorine dioxide continues.

#### II. Chlorine Dioxide

Chlorine dioxide (CAS Reg. No. 10049-04-4) is a yellow to reddishyellow gas with a pungent odor similar to that of chlorine. Because chlorine dioxide is explosive when concentrated, it is usually generated at the site where it is used. Chlorine dioxide can be prepared by reaction of chlorine with sodium chlorite, reduction of sodium chlorate, or acidification of sodium chlorite. High yield production of chlorine dioxide (greater than 90 percent) is accomplished by reaction of sodium chlorite with chlorine or by reaction of an acid, sodium hypochlorite, and sodium chlorite (Ref.

Chlorine dioxide is a strong oxidant which is expected to react with microbial contaminants and other organic material present in poultry process water. Oxidation of chlorine dioxide results in the formation of chlorite ion, which is an oxidant that is capable of reacting with organic material in poultry process water. Residual chlorate present as an impurity in chlorine dioxide solutions can also act as an oxidant.

Chlorine dioxide is currently listed in 21 CFR 178.1010(b)(34) as a component of a sanitizer solution. Chlorine dioxide is also listed in 21 CFR 137.105 for use as a bleaching agent for flour and is also approved by the Environmental Protection Agency (EPA) for use in potable water treatment plants (40 CFR part 141, subpart H). The Health Protection Branch of Health and Welfare Canada has stated in a letter to the petitioner that chlorine dioxide is permitted for use in poultry chiller water in Canada (Ref. 2).

Chlorine dioxide is a potential substitute for chlorine, which is currently commonly used in poultry processing. Published studies that were included in the petition show that chlorine dioxide is four to seven times more effective than an equal concentration of chlorine as a bactericide in poultry chiller water (Refs. 3, 4, and 5). Thus, chlorine dioxide can be used at considerably lower levels than chlorine without compromising bactericidal effects. Most of the studies conducted by the petitioner were with residual chlorine dioxide levels in the process water of 3 ppm.

## III. Safety

Data from the gas chromatographicmass spectroscopic analysis of poultry process water containing 3 ppm of chlorine dioxide were provided in the petition. These data show that organic reaction byproducts, such as the potentially toxic trihalomethanes (e.g., chloroform), are not present in poultry process water at the 0.2 parts per billion (ppb) limit of detection when the method for detecting chloroform is used. (EPA proposed a drinking water standard (59 FR 38668 at 38670, July 29, 1994) that permits a maximum contaminant level of up to 80 ppb (400 times the amount detectable by the analytical method) of "total trihalomethanes" (chloroform, bromoform, dibromochloromethane and bromodichloromethane) in drinking water.) Moreover, FDA's review of the results of an Ames test on poultry process water that was treated with 20 ppm chlorine dioxide revealed no mutagenic activity. The Ames test results support the conclusion that significant levels of harmful organic reactions byproducts will not be formed when chlorine dioxide, at a residual level of 3 ppm, is used as the bacteriocidal agent in poultry process water.

In addition to evaluating the probable formation of organic reaction byproducts from the use of chlorine dioxide in poultry process water, FDA has also evaluated the possible presence of residual chlorine dioxide, chlorite, and chlorate on treated poultry carcasses; the potential for the oxidation of poultry tissue, including sensitive fatty acids; and data from mutagenicity tests.

Based on its evaluation of the information in the petition, the agency has concluded that no detectable residues of chlorine dioxide would remain on poultry carcasses, and that exposure to chlorite and chlorate as a result of this use of chlorine dioxide would be virtually nil. (No chlorite or chlorate could be detected on poultry (raw or cooked) at the limit of detection (50 ppb) for the method used.) The agency also concluded that the very low levels of chlorite and chlorate that may be retained on poultry carcasses as a result of exposure to chlorine dioxidecontaining process water would be converted to correspondingly low levels of chloride (a relatively innocuous substance, e.g., chloride in table salt) during cooking (Ref. 6).

FDA also considered potential oxidative effects of chlorine dioxide, chlorite, and chlorate on poultry. The agency reviewed information in the