petition on thiobarbituric acid (TBA) values of raw and cooked poultry exposed to chlorine dioxide-containing process water. A TBA test is commonly used as an indicator of oxidative decomposition (and of rancidity) of meat and fat. The more oxidative decomposition, the higher the TBA values. The agency determined that the TBA values for both raw and cooked poultry exposed to chlorine dioxidecontaining process water did not significantly differ from that for poultry exposed to tap water. Thus, the agency concludes that no significant oxidation of poultry exposed to chlorine dioxidecontaining process water occurs under the prescribed conditions of use.

FDA also evaluated information in the petition on the levels of oxidationsensitive fatty acids (e.g., oleic, linoleic, linolenic, and arachidonic acid) in raw untreated poultry and in poultry exposed to chlorine dioxide-containing process water. Fatty acid profiles were comparable for treated and untreated poultry when analyzed by gas chromatography. FDA concludes that exposure to chlorine dioxide at levels 7 to 10 times higher than that prescribed in the proposed regulation does not result in appreciable loss of these fatty acids from poultry.

Based on the above findings, the agency concludes that 3 ppm of residual chlorine dioxide in poultry process water will not result in a measurable increase in oxidation of poultry as compared with poultry exposed to tap water.

The agency also considered the possibility of formation of mutagenic compounds in poultry and poultry process water treated with chlorine dioxide. Ames test information presented in the petition showed no evidence of mutagenic activity in poultry process water treated with chlorine dioxide. Thus, the agency concludes that the use of chlorine dioxide in poultry process water under the conditions prescribed in the regulation should not pose a significant health concern from the formation of mutagenic substances.

IV. Conclusions

FDA has evaluated the data in the petition and other relevant material and has consulted with scientists in the Food Safety and Inspection Service in the U. S. Department of Agriculture concerning the technological and practical aspects of the proposed use of chlorine dioxide. Based upon this evaluation, the agency concludes that the proposed use of the additive is safe and will have the intended technical effect. The agency also concludes that a specification for minimum purity of chlorine dioxide should be included in the regulation to reflect the purity of the chlorine dioxide that it evaluated. Therefore, 21 CFR part 173 is amended as set forth below.

V. Inspection of Documents

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Imapct

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before April 3, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this

document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Kirk-Othmer Encyclopedia of Chemical Technology, Vol. 5, pp. 612–632.

2. Letter dated July 30, 1991, to Dr. Richard Higby from J. W. Salminen, Health Protection Branch, Health and Welfare Canada.

3. Lillard, H. S., "Levels of Chlorine and Chlorine Dioxide of Equivalent Bactericidal Effect in Poultry Processing Water," *Journal of Food Science*, 44:1594–1597, 1979.

4. Lillard, H. S., "Effect on Broiler Carcasses and Water of Treating Chiller Water with Chlorine or Chlorine Dioxide," *Poultry Science*, 59:1761–1766, 1980.

5. Thiesson, G. P., W. R. Usborne, and H. L. Orr, "The Efficacy of Chlorine Dioxide in Controlling Salmonella Contamination and Its Effect on Product Quality of Chicken Broiler Carcasses," *Poultry Science* 63:647– 653, 1984.

6. Gordon, G., R. G. Kieffer, and D. H. Rosenblatt, "The Chemistry of Chlorine Dioxide" in *Progress in Inorganic Chemistry*, Vol. 15, pp. 201–286, S. J. Lippard, ed., Wiley-Interscience, New York, 1972.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

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: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. New section 173.69 is added to read as follows:

§173.69 Chlorine dioxide.

Chlorine dioxide (CAS Reg. No. 10049–04–4) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is generated by treating an aqueous solution of sodium chlorite with either chlorine gas or a mixture of sodium hypochlorite and hydrochloric acid. The generator effluent contains at least 90 percent (by weight) of chlorine dioxide with respect