

TECHNICAL DATA SHEET

TECHNICAL & ENVIRONMENTAL SERVICES

Regulatory Issues Regarding Food Application of Sodium Chlorite and Chlorine Dioxide

Introduction

The application of sodium chlorite and chlorine dioxide to human food is a complex issue. To the layperson, it is difficult to identify the regulatory agency that is responsible for overseeing the use of sodium chlorite and/or chlorine dioxide in a particular segment of the food processing industry. This Technical Data Sheet attempts to provide a history of Agency opinions, policies, and regulations regarding food processing applications.

As we review the different types of Food and Drug Administration (FDA) communications it is important to understand the relative value of each type of document. A good understanding of the following terms will also be helpful: Indirect Food Additive, GRAS and GRAS Affirmation. These topics are covered in detail under the next two headings.

Indirect Food Additive:

"Indirect food additives are not directly and intentionally added to a food for some functional purpose.

"Two important threshold factors are: First, an additive must be a 'substance.' Second, the substance must become a component or otherwise affect the characteristics of the food as a result of its intended use.

"If a substance is an added substance in food, a more stringent measure of harm is applicable than if the substance were a naturally occurring component in food.

"It is important to distinguish between 'food additive' and 'food.' Food is an extremely broad term that includes food components and raw materials as well as food additives. All food additives must be approved prior to use; food does not have to be. The fact that food does not require prior approval is not as big a loophole as may first appear, since food becomes a food additive if it is used as a component in another food (e.g., a potato in stew), unless it is excluded from the food additive definition because it is GRAS--as in the case with potatoes."¹

GRAS and GRAS Affirmation:

"Food which is generally recognized as safe (GRAS) is excluded from the food additive definition and its accompanying strict standards. To achieve GRAS status, several requirements must be met. First, there must be a general recognition of safety. To prove this, the proponent of the substance must introduce testimony regarding the state of scientific knowledge. [21 CFR 170.30(a)]. Second, it must be established that the GRAS supporting experts are qualified to evaluate the substances by virtue of their scientific training and experience. And third, for pre-1958 substances, general recognition of safety may be established through experience based on common use in food.

"GRAS status is a question of fact that exists independent of whether FDA has considered the issue. However, manufacturers that wish to claim GRAS status are in a much better regulatory position with the FDA's endorsement of GRAS status."¹

FDA Advisory Opinions, Information Statements or Letters by Agency Personnel:

"There are many questions for which no adequate rule or precedent exists. In such a case, you may wish to obtain an opinion from the Food and Drug Administration. Using the form specified in the regulation, the request must indicate the issue involved together with a full statement of the facts and legal points relative to the request. [21 CFR 10.85]. The request may be denied if, in the view of the Commissioner, the request: is incomplete, 'cannot reasonably be given on the matter involved,' a prior advisory opinion or regulation adequately covers the matter, the request does not raise a policy issue of broad applicability, or the 'Commissioner otherwise concludes that an advisory opinion would not be in the public interest.' [21 CFR 10.85(a)].

"Formerly, advisory opinions were binding. In 1992, however, FDA proposed to revise its advisory opinion rules, [57 FR 47314, October 15, 1992, listed at 21 CFR 10.85 and 10.90], to indicate that advisory opinions would no longer be binding but 'simply represent the Agency's best advice on the matter at issue at the time they are rendered.' Guidelines

would have the same status as opinions, providing 'useful information' about Agency practices and procedures. The proposal includes in its definition of an advisory opinion which would not be binding not only statements in preambles to proposed regulations but also preambles to final regulations. **The only documents that would not be deemed advisory opinions would be codified regulations and final orders issued through formal rulemaking procedures.**

"The Agency proposed taking these steps on grounds that: (1) the courts have found that advisory opinions are not generally binding; (2) obliging FDA to follow advisory opinions and guidelines may limit the Agency's ability to respond to specific situations; (3) finally, the proposed regulations respond to the case *Community Nutrition Institute v. Young* 818 F.2d 943 (D.C. Cir. 1987) which called into question FDA's procedures for issuing advisory opinions and guidelines that purported to be binding.

"Industry groups have opposed this change on the grounds that good faith efforts to comply with what appears to be regulatory requirements in formal opinions and guidelines might not be accepted by the Agency. Such opinions, they argue, are intended to help industry to comply, and preambles to proposed rules are an important vehicle for announcing Agency policies. A question of fairness is raised if the Agency seeks to make advisory opinions immune from judicial review. The Agency has yet to issue a final rule on this subject.

"An advisory opinion represents FDA's formal position. It obligates the Agency to act in conformity until the opinion is amended or revoked. Except in unusual situations involving an immediate and significant danger to health, FDA may not recommend legal action against a person or product with respect to an action taken in conformity with an unrevoked advisory opinion.

"Amendment or revocation of an advisory opinion may be affected at any time. *Federal Register* publication is adequate notice of the revocation or amendment of an advisory opinion. As an alternative to the *Federal Register* publication, the regulations provide for amendment or revocation 'in the same manner as the notice of the advisory opinion was originally given.' [21 CFR 10.85(g)].

"Care should be taken to distinguish between formal advisory opinions and informal statements or letters by Agency personnel. An informal opinion, whether written or oral, **does not bind the Agency.** (FDA letter to the contrary does not bar enforcement proceedings.)

"Advisory opinions often take a year or more from the time the opinion is initially requested. Often the

Agency's decision does not provide the clear-cut guidance the request sought to evoke.

"The majority of FDA advisory opinions are not denominated as such. Trade Correspondence (only issued between 1938 and 1946), compliance policy guides, and guidelines (relating to test procedures, protocols, ingredient specifications, labeling or other technical or policy criteria) are advisory opinions. Any portion of the *Federal Register* notice -- other than the text of a final rule -- is also an advisory opinion. These opinions are readily revoked or amended by inconsistent statements in later *Federal Register* issues, so extreme caution must be exercised in relying upon a statement in the preamble of a proposed or final rule as an advisory opinion."¹

The following is a chronological summary of available industry correspondence, FDA Advisory Opinions, Pending Amendments and Regulations relating to the status of different applications of sodium chlorite and chlorine dioxide in the food processing industry:

1. **Patent on Treating Shrimp**

Woodward, E. R. *US Patent 2,451,897* (1943)
Method of Treating Shrimp.

2. **Icing Fish in the "Round"**

International Dioxide, Inc., correspondence dated November 13, 1967 ... "[FDA] would not object to the use of ice containing 20 parts per million of stabilized chlorine dioxide on fish in the round, where such use does not result in residues in the fish or products prepared from them, and does not otherwise affect their nutritional or other characteristics." This opinion letter was later withdrawn ostensibly because of a lack of efficacy and safety data.

3. **Olin Chemical GRAS Petition**

Olin Chemical submitted a GRAS Petition to the FDA on March 23, 1973. However, Olin did not continue to pursue the petition and it was never granted. If that petition would have been approved, chlorine dioxide would have been affirmed generally recognized as safe (GRAS) status for the treatment of potable water and the washing of fruits and vegetables.

4. **ClO₂ Residue on Washed Fruits and Vegetables**

FDA wrote on June 24, 1977 ... "Until such time as a petition is approved and a regulation is established prescribing the conditions under which the particular substance may be used, the use of that substance would be illegal if its use results in residues in food. There is no authority under the provisions of the Federal Food, Drug, and Cosmetic Act to grant any exemption for the illegal use of a food additive. However, the use of chlorine dioxide under conditions where **no residue will remain** on the washed fruits and

vegetables would not be considered a food additive use.

"If you have determined by appropriate testing that, under the conditions of use described in your mailgram, **no residues of chlorine dioxide will remain** on the washed fruits and vegetables, you are free to conclude that chlorine dioxide would not be considered a food additive as that term is defined in section 201(s) of the Act."

5. Red Meat GRAS Petition Denied

General Bioscience GRAS Petition, as amended Oct. 3, 1980, was denied without prejudice by the FDA on May 31, 1988. If approved, that petition would have affirmed GRAS status for chlorine dioxide in the use of water at a level of 0.05 - 5.0 p.p.m. to disinfect freshly slaughtered red meat carcasses.

6. ClO₂ as a Flour Bleaching Substance

Chlorine dioxide has been granted prior sanction via clearance for optional use as a bleaching substance for flour under food standards 21 CFR 137.105, Flour.

"Unless such addition conceals damage or inferiority or makes the flour appear to be better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching or, in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect:

- (1) Oxides of nitrogen
- (2) Chlorine
- (3) Nitrosyl chloride
- (4) **Chlorine dioxide**
- (5) Benzoyl peroxide
- (6) Acetone peroxide
- (7) Azodicarbonamide

7. Cherry Bleaching GRAS

FDA wrote on June 24, 1982 ... "Sodium chlorite, as I was informed by the Bureau of Foods, is affirmed as an unlisted Generally Recognized as Safe (GRAS) substance and **may be used for bleaching cherries** provided the following conditions are met: it must be used in accordance with current good manufacturing practices for human food and the application must be at a minimum level needed to accomplish its intended effects. Its condition of use cannot be significantly different from those reported in the regulation as the basis on which the GRAS status was affirmed.

"Although sodium chlorite is not in the Food Chemicals Codex, the purity and quality must be food grade."

8. Sanitizing Solution Approval

FDA, 21 CFR 178.1010, Sanitizing solution Aug. 12, 1987 ... "Sanitizing solution **may be safely used** on food processing equipment and utensils, and on other food-contact articles as specified in this section within the following prescribed conditions:

(a) Such sanitizing solutions are used, followed by adequate draining, before contact with food.

(b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval ...

(b)(34) An aqueous solution of an equilibrium mixture of oxychloro species (predominantly chlorite, chlorate, and chlorine dioxide) generated either (i) by directly metering a concentrated chlorine dioxide solution, prepared just prior to use, into potable water to provide the concentration of available chlorine dioxide stated in paragraph (c)(29) of this section, or (ii) by acidification of an aqueous alkaline solution of oxychloro species (predominantly chlorite and chlorate) followed by dilution with potable water to provide the concentration of available chlorine dioxide described in paragraph (c)(29) of this section.

(c)(29) Solutions identified in paragraph (b)(34) of this section should provide, when ready to use, at least 100 parts per million and not more than 200 parts per million available chlorine dioxide as determined by the method titled 'Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available ClO₂),' which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC."

9. **ClO₂/NFPA and Process Water for Uncut, Unpeeled Fruits, and Vegetables**

National Food Processors Association correspondence, March 11, 1992: "The Food and Drug Administration (FDA) has written that it has no objections 'to the use of chlorine dioxide at up to 5 ppm in process water for washing uncut, unpeeled fruits and vegetables ... provided this is followed by a potable water rinse' (emphasis added).

"There has never been a question that whole carrots can be washed with water containing chlorine dioxide. However, peeled, sliced, and/or diced carrots cannot be washed with water containing chlorine dioxide."

"The status of peas, lima beans, and husked corn relative to the FDA position of permitted uses has been ascertained via a telephone conversation with Mr. Raymond Newbury, Deputy Director of FDA's Office of regulatory Compliance in Washington, DC. His verbal opinion is that peas and lima beans, whether fresh or blanched, are considered to be uncut and unpeeled. Therefore, water containing chlorine dioxide can be used to wash these commodities.

"Husked corn on uncut cobs is also considered to be uncut and unpeeled by the FDA and may be washed with water containing chlorine dioxide. However, corn-on-the-cob (where the cobs have been cut) and whole kernel core that has been removed from the cob are considered to be cut and cannot be washed with water containing chlorine dioxide."

10. **EPA/FDA Meat & Poultry Memorandum of Understanding**

United States Department of Agriculture to Olin, April 16, 1992: "We cannot authorize your product for the treatment of potable water in federally inspected meat and poultry plants because of the Memorandum of Understanding between FDA and EPA published in the July 20, 1979 Federal Register. The Memorandum of Understanding gives FDA jurisdiction over the water and substances in water within the boundaries of food processing establishments. Therefore, substances intended for addition to process water in meat and poultry plants must have appropriate food additive status. Neither sodium chlorite nor chlorine dioxide has been cleared by FDA for treating potable water in these food processing establishments."

11. **ClO₂/NFPA and Processing Fruits and Vegetables**

National Food Processors Association correspondence, July, 30, 1992. "Pending publication of a regulation on the use of chlorine dioxide in processing fruits and vegetables, FDA is not objecting to the use of chlorine dioxide at up to 5 ppm in process water for washing uncut, unpeeled fruits and vegetables, providing this is followed by a potable water rinse (1990).

12. **Sanitizing Solution Approval Amendment**

Rio Linda Chemical Co. FDA Petition Sept. 22, 1992, would amend 21 CFR 178.1010 (Sanitizing Solution) to clear an aqueous solution of chlorine dioxide and related oxychloro species, generated by acidification of an aqueous solution of sodium chlorite with sodium gluconate, citric acid, phosphoric acid, and sodium alkylphenoxybenzenedisulfonate, for use on food-contact surfaces, food-processing equipment, and utensils.

13. **ClO₂/NFPA Beans, Peas, and Potatoes**

National Food Processors Association correspondence, December 1992. "NFPA believes that for shelled beans and peas with intact cuticles, treatment with water containing up to 5 ppm chlorine dioxide is unlikely to result in appreciable permeation of chlorine dioxide or its reaction products and little or no residue is expected to remain following the potable water wash. However, please note that this applies to unblanched peas and beans with intact cuticles only. We believe that blanching may change the permeability of the cuticle, thereby rendering it no longer an effective barrier to chlorine dioxide and its reaction products. Unless we are provided with information to the contrary, we cannot agree that the use of 5 ppm chlorine dioxide on blanched peas and beans would leave no residue after washing.

"Additionally we would like to correct one misstatement in your letter. You stated that current FDA policy also permits up to 5 ppm chlorine dioxide in water for washing cut or peeled potatoes provided this is followed by a potable water rinse. While some letters have stated this position, we know of no basis for using a chlorine dioxide solution above 1 ppm for use when processing cut and peeled potatoes followed by a potable water rinse. This concentration has been shown to be sufficient to achieve the intended effect. The use of 5 ppm chlorine dioxide in water to process cut or peeled potatoes is greater than needed to accomplish its effect and, therefore, is not in accordance with good manufacturing practice."

14. Cut/Peeled Fruits and Vegetables

National Food Processors Association food additive petition for the use of chlorine dioxide in water contacting cut and peeled fruits and vegetables filed February 1994.

15. Poultry

Food and Drug Administration issued a final rule approving up to 3 parts per million (ppm) residual chlorine dioxide in process water contacting whole fresh poultry carcasses. FDA regulation was effective March 3, 1995. This application is currently under review by USDA.

On April 23, 1996, the Food and Drug Administration issued a final food additive rule approving the use of acidified solutions of sodium chlorite as an antimicrobial agent in poultry processing water. Under this rule, sodium chlorite may be used as a component of a carcass spray or dip solution prior to immersion of the carcass in a prechiller or chiller tank, or in the prechiller or chiller solution.

16. Seafood

Bio-Cide International, Inc. filed a food additive petition May 9, 1996 proposing the use of acidified solutions of sodium chlorite in processing water and ice in direct contact with seafood.

References

1. Federal Publications Inc., *Practical Food Law*, Course Manual, 44, 50, 55-56, 83, 356-358, 1993.

**Food Application Summary Sheet
Sodium Chlorite And Chlorine Dioxide**

Application	Chemical	Status	Reference	Limits
Red Meat (Carcass Disinfection)	Chlorine Dioxide	Approval denied	Food and Drug Administration (FDA) May 31, 1988	0.05 - 5.0 ppm
Flour Bleaching	Chlorine Dioxide	Approval	21 CFR Ch. 1 (4-1-92 Edition) Subpart-B 137.105	Minimum level needed
Cherry Bleaching	Sodium Chlorite	Generally Recognized As Safe (GRAS)	FDA Correspondence	Minimum level needed
Sanitizing Solution	Chlorine Dioxide	Approval	21 CFR Ch. 1 (4-1-92 Edition) Subpart B 178.1010	100 - 200 ppm
Sanitizing Solution	Aqueous solution of Chlorine Dioxide and related oxychloro species	Pending	Amendment request 21 CFR Ch. 1 Subpart B 178.1010	Not specified
Carrots (Whole)	Chlorine Dioxide	Approval	National Food Processors Association and FDA Correspondence March 11, 1992	Up to 5 ppm, followed by potable water rinse
Carrots (Peeled, sliced, and diced)	Chlorine Dioxide	Not Approved	National Food Processors Association and FDA Correspondence March 11, 1992	N.A.
Peas (Unblanched with intact cuticles)	Chlorine Dioxide	Approval	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be uncut and unpeeled)	Up to 5 ppm, followed by potable water rinse
Peas (Blanched with intact cuticles)	Chlorine Dioxide	Approval Questionable	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be uncut and unpeeled)	N.F.P.A. can not agree with 5 ppm Chlorine Dioxide
Lima Beans (Unbalanced with intact cuticles)	Chlorine Dioxide	Approval	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be uncut and unpeeled)	Up to 5 ppm, followed by potable water rinse
Lima Beans (Blanched with intact cuticles)	Chlorine Dioxide	Approval Questionable	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be uncut and unpeeled)	N.F.P.A. can not agree with 5 ppm Chlorine Dioxide
Corn (Husked on uncut cob)	Chlorine Dioxide	Approval	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be uncut and unpeeled)	Up to 5 ppm, followed by potable water rinse
Corn (Husked on cut cob)	Chlorine Dioxide	Not Approved	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be cut vegetables)	N.A.
Corn (Whole Kernel corn removed from cob)	Chlorine Dioxide	Not Approved	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be cut vegetables)	N.A.
Potatoes (Cut and peeled)	Chlorine Dioxide	Approval	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be cut vegetables)	1 ppm, followed by potable water rinse (N.F.P.A. knows of no basis for using Chlorine Dioxide solution above 1 ppm)
Potatoes (Fresh cut french-fry)	Chlorine Dioxide	Not Approved	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be cut vegetables)	N.A.

**Food Application Summary Sheet
Sodium Chlorite And Chlorine Dioxide**

Application	Chemical	Status	Reference	Limits
Cabbage (Used for cole slaw)	Chlorine Dioxide	Not Approved	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be cut vegetables)	N.A.
Tomatoes	Chlorine Dioxide	Approval	National Food Processors Association and FDA Correspondence March 11, 1992 (Considered to be uncut and unpeeled vegetables)	Up to 5 ppm, followed by potable water rinse
Poultry	Chlorine Dioxide	Approval	Rio Linda Chemical Co., Inc. Food Additive Petition	Residual concentration up to 3 ppm
Sanitation	Chlorine Dioxide Foam	Pending	Rio Linda Chemical Co., Inc., Food Additive Petition 2B4334 filed 06/12/92	—
Whole or cut and peeled or unpeeled fruits and vegetables	Chlorine Dioxide	Pending	National Food Processors Association Food Additive Petition 4R4415 filed 02/04/94	—
Poultry (Process water contacting whole fresh poultry carcasses)	Chlorine Dioxide	Approval	Food and Drug Administration, Federal Register, March 3, 1995. Final rule added as 21 CFR 173.69.	Up to 3 ppm residual chlorine dioxide in process water contacting whole fresh poultry carcasses.
Poultry Process Water	Acidified Sodium Chlorite Solution	Approval	Food and Drug Administration, Federal Register, April 23, 1996. Final rule added as 21 CFR 173.325	500-1200 ppm in carcass spray or dip solution. 50-150 ppm in prechiller or chiller solution
Seafood	Acidified Sodium Chlorite Solution	Pending	Bio-Cide International Food Additive Petition filed 5/9/96	—