DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

March 22, 2010

Gary Burin
Senior Managing Toxicologist
Technology Sciences Group Inc.
1150 18th Street, N.W.
Suite 1000
Washington, DC 20036

RE: Food Contact Substance Notification (FCN) 001052

Dear Dr. Burin:

This letter is in reference to the notification for the food contact substance and use described as follows:

Food Contact Substance (FCS)
An aqueous solution of chlorine dioxide (CAS Reg. No. 10049-04-4).)

Notifier
CDG Environmental, LLC

Manufacturer/Supplier
CDG Environmental, LLC

Intended Use
As an antimicrobial agent to be applied to red meat (including meat parts and organs), raw agricultural commodities, processed, comminuted or formed meat products, and seafood.

Limitations/Specifications
The chlorine dioxide is manufactured by passing a mixture of chlorine gas and air, or chlorine gas and nitrogen gas, through a column of granules composed of sodium chlorite and other salts that are generally recognized as safe.

The FCS will be applied to food commodities in accordance with current industry GMPs, in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-C102-E in the "Standard Methods for the examination of Water and Wastewater 20th ed. 1998", or an equivalent method. The following conditions apply according to use:

Food Commodity Type	Conditions of Use
Red meat (Including meat parts and organs)	The FCS will be applied as a spray to red meat, meat parts and organs, or as a dip to red meat parts and organs
Processed, comminuted, or formed meat products	The FCS will be applied as a spray or dip, unless precluded by standards of identity in 9 CFR 319, prior to the packaging of food for commercial purposes. The FCS will not be used on ready-to-eat meats.
Raw agricultural commodities	The FCS will be applied as a spray or dip in the preparing, packaging of holding of food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i) but not applied under 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the FD&C Act. Treatment of raw agricultural commodities shall be followed by a potable water rinse or by blanching, cooking or canning.
Seafood	The FCS will be used in water and ice that are used to rinse, wash, thaw, transport, or store seafood. Treatment of seafood products that will be consumed raw shall be subjected to a potable water rinse prior to consumption.

This is to inform you that as of March 23, 2011, FCN 001052 will become effective. It will be added to the list of effective notifications which is available in the Food Ingredients and Packaging section under the Food topic on the Agency's internet site at http://www.fda.gov. The Agency has determined, based upon evidence supporting this finding contained in the environmental assessment for FCN 001052, that the intended use of the FCS will not have a significant impact on the quality of the human environment. As such, an environmental impact statement is not required. The Agency's finding of no significant impact, and the evidence supporting that finding contained in the environmental assessment for FCN 001052, will be made publically available in the Food Ingredients and Packaging section under the Food topic on the Agency's internet site at http://www.fda.gov.

This effective notification is applicable only to aqueous chlorine dioxide, manufactured by CDG Environmental, LLC, and is limited to the use identified above. You should inform the Agency of any modification to the FCS limitations/ specifications given in the notification or of any alteration in the manufacturing process that would result in a change in the impurities or impurity level in the FCS. Such changes may require the submission of a new notification.

FDA's review of this notification was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The existence of an effective notification for a FCS does not relieve use of the subject substance from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act or with 21 CFR 174.5 (General provisions applicable to indirect food additives). For example, in

accordance with section 402(a)(3) of the Act, use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(ll) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(ll) or any of its exemptions apply to the intended use of the FCS. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the FCS would not violate section 301(ll).

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the Agency will inform you of its determination that the intended use of the FCS is unsafe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the Agency immediately and be prepared to supply the necessary data to resolve any questions.

In accordance with the procedures outlined in the Memorandum of Understanding between FDA and the Food Safety and Inspection Service (FSIS), FDA has provided FSIS with the information contained in FCN 001052 for review (FSIS Log No. 11-ING-0721-N-A). FSIS' letter of March 1, 2011, documenting their review is provided as an attachment[1] to this letter.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Paul Honigfort, Ph.D.
Consumer Safety Officer
Division of Food Contact Notifications HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

[1] 3-1-2011, W. Shaw Jr. to P. Honigfort.

USDA United States Department of Agriculture
Food Safety and Inspection Service

Office of Policy and Program Development

Risk, Innovations, and Management Division
George Washington Carver Center
5601 Sunnyside Ave: STOP 5271
Beltsville, MD 20705-5271

MAR 0 1 2011

Paul Honigfort, Ph.D.
Consumer Safety Officer
Division of Food Contact Notification
Office of Food Additive Safety
Center for Food Safety & Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, HFS-275
College Park, MD 20740

Dear Dr. Honigfort:

In accordance with the procedures outlined in the Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS), you requested comments from FSIS regarding the use of chlorine dioxide on meat products (FCN 1052). Specifically, CDG Environmental, LLC is requesting permission to use an aqueous solution of chlorine dioxide as an antimicrobial agent applied as a spray or dip at a level not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-ClO2 E in the "Standard Methods for the Examination of Water and Wastewater," 20th ed., 1998, or an equivalent method to red meat, red meat parts and organs, processed, comminuted, or formed meat food products. (FSIS Log No. 11-ING-0721-N-A).

Under the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), FSIS is responsible for determining the efficacy and suitability of food ingredients in meat, poultry, and egg products. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product, or one that misleads the consumer.

FSIS has completed its review of the FCN 1052 information. FSIS agrees with FDA's conclusion that the technical effect of chlorine dioxide as an antimicrobial agent at the concentration specified in FCN 1052 has been adequately demonstrated in numerous previous submissions to FDA and FSIS. Thus, regarding suitability, FSIS has no objection to the use of an aqueous solution of chlorine dioxide as an antimicrobial agent applied as a spray or dip at a level not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-ClO2 E in the "Standard Methods for the Examination of Water and Wastewater," 20th ed., 1998, or an equivalent method to red meat, red meat parts and organs, processed, comminuted, or formed meat food products. This would not include ready-to-eat (RTE) meat and meats precluded by the standards of 9 CFR 319.

FSIS requests that FDA advise CDG Environmental, LLC to seek regulatory guidance from the FSIS' Risk, Innovations, and Management Division (RIMD) about any further use of chlorine dioxide in meat, poultry, and egg products. Such an inquiry should be directed to William Shaw, Jr., Director, RIMD, Office of Policy and Program Development, Food Safety and Inspection Service, 5601 Sunnyside Ave., Mailstop 5271, Beltsville, MD 20705-5271.

Sincerely,

William K. Shaw, Jr., Ph.D.
Director
Risk, Innovations, and Management Division
Office of Policy and Program Development