

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

IN THE MATTER OF

CDG Technology, Inc.
759 Roble Road
Allentown, PA 18109

Respondent

DOCKET NO: FIFRA-03-2008-0147

ADMINISTRATIVE COMPLAINT
AND NOTICE OF
OPPORTUNITY FOR HEARING

CERTIFICATE OF SERVICE

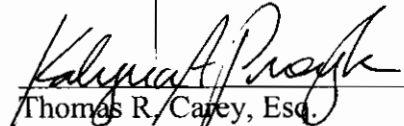
I hereby certify that I caused the original and two (2) copies of the foregoing Answer and Additional Appearance of Kalyna A. Procyk to be delivered by overnight mail, postage prepaid, to:

Lydia Guy
Regional Hearing Clerk
Mail Code 3RC00
U.S. EPA – Region III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

and a true and correct copy to be mailed via overnight mail, postage prepaid, to the following person(s) at the following address(es);

Jennifer M. Abramson (3WC32)
Assistant regional Counsel
Mail Code 3RC00
U.S. EPA – Region III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029

Date: May 30, 2008


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ENTRY OF ADDITIONAL APPEARANCE OF KALYNA A. PROCYK

Now comes Kalyna A. Procyk of BELL, BOYD & LLOYD LLP, and hereby enters her additional appearance as one of the attorneys for the Respondent, CDG TECHNOLOGIES, INC. in the above-captioned matter.

Respectfully submitted,
CDG TECHNOLOGIES, INC.

By: 

Kalyna A. Procyk

Date: May 30, 2008

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I. ANSWER AND REQUEST FOR A HEARING

NOW COMES the Respondent, CDG TECHNOLOGY, INC. ("CDG" or "Respondent"), by and through its attorneys, Bell, Boyd and Lloyd LLP, and in response to the Complaint and Notice of Opportunity for Hearing ("Complaint") instituted by the United States Environmental Protection Agency ("EPA" or "Complainant"), and brought pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act as Amended ("FIFRA" or "the Act"), 7 U.S.C. § 136l(a), and associated regulations promulgated at 40 C.F.R. §§ 150-189, and in accordance with the Consolidated Rules of Practice Governing Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules of Practice"), hereby states its Answer and Request for an Opportunity for Hearing and Informal Settlement Conference thereto as follows:

II. GENERAL ALLEGATIONS

1. Section II, paragraph 1 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

2. Respondent denies that EPA has accurately described the nature of Respondent's products and services at Section II, paragraph 2, of EPA's Complaint. The Respondent's *Saf-T-Chlor*TM ("Saf-T-Chlor") product that is the subject of EPA's Complaint contains sodium chlorite as its active ingredient, which is intended solely for use in Respondent's "Gas: Solid System" to generate pure chlorine dioxide gas at the location of use (*e.g.* water treatment plants). The Saf-T-Chlor product remains in factory-sealed containers that serve as a fixed-bed reactor; it is never added directly to the water being treated. Respondent admits that it is a Delaware corporation that operated out of an establishment located at 140 Webster Street in Bethlehem, Pennsylvania.

3. Section II, paragraph 3 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

4. Section II, paragraph 4 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

5. Section II, paragraph 5 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

6. Section II, paragraph 6 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

7. Section II, paragraph 7 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

8. Section II, paragraph 8 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

9. Section II, paragraph 9 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

10. Respondent admits the factual allegation in Section II, paragraph 10 of the Complaint.

11. Respondent denies the allegations contained in Section II, paragraph 11 of the Complaint in that they do not accurately reflect the labeling history of Respondent's Saf-T-Chlor product during the period alleged therein. Respondent admits that prior to June 6, 2006 containers of sodium chlorite sold or distributed to Respondent's Gas: Solid System customers were labeled with "Technical Sodium Chlorite" labels prepared by or based upon EPA-approved labels for Energia Aragonesas, S.A. ("Aragonesas"), the company that supplies sodium chlorite to Respondent. Respondent admits that the allegations in Section II, paragraphs 11 a., b., and c. reflect information on the "Technical Sodium Chlorite" labels. Respondent denies any remaining allegations in Section II, paragraph 11 of the Complaint.

12. Section II, paragraph 12 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

III. VIOLATIONS

COUNT 1 – SALES/DISTRIBUTIONS OF UNREGISTERED PESTICIDES

13. Respondent's answers to EPA's allegations contained in Paragraphs 1 through 12 of the Complaint are incorporated herein by reference.

14. Section III, paragraph 14 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

15. Section III, paragraph 15 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

16. Section III, paragraph 16 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

17. Respondent admits that between April 2003 and June 2006 it distributed or sold containers of granulated sodium chlorite made from EPA-registered technical grade sodium chlorite powder pesticide product Sodium Chlorite Technical, 80 percent, EPA No. 52564-1. There was no chemical difference between the products, except a difference in water content. The directions for use on the Aragonesas product include “add water.”

18. Respondent admits the allegations in Section III, paragraph 18 of the Complaint.

19. Section III, paragraph 16 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

20. Respondent admits that its granulated Saf-T-Chlor product did not have a separate and individual registration from EPA pursuant to Section 3 of FIFRA, § 7 U.S.C. 136a between April 2003 and June 2006. Respondent denies the remaining allegations in Section III, paragraph 20 of the Complaint.

21. Respondent denies that the sale and distribution of its Saf-T-Chlor product between April of 2003 and June of 2006 constituted the distribution or sale of an unregistered pesticide product in violation of Section 3(a) of FIFRA, 7 U.S.C. § 136a(a).

22. Respondent denies that each sale or distribution of Saf-T-Chlor during the time period between April 2003 and June 2006 constitutes a separate unlawful act under Section 12(a)(1)(A) of FIFRA, 7 U.S.C. 136j(a)(1)(A), for which penalties may be assessed pursuant to Section 14(a) of FIFRA, 7 U.S.C. 136l(a).

COUNT II – SALES/DISTRIBUTIONS OF MISBRANDED PESTICIDES

23. Respondent’s answers to EPA’s allegations contained in Paragraphs 1 through 22 of the Complaint are incorporated herein by reference.

24. Section III, paragraph 24 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

25. Section III, paragraph 25 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

26. Respondent admits that drums of sodium chlorite sold or distributed to its customers during the time period between April 2003 and June 2006 were labeled "Technical Sodium Chlorite" and that the labels included, in part, the following statements:

- a. EPA Reg. No. 52564-1
- b. Active Ingredient
 - Sodium Chlorite 80%
 - Inert Ingredients 20%

Respondent denies that containers of Saf-T-Chlor sold or distributed between April of 2003 and June of 2006 were intended to reflect that Saf-T-Chlor had received a separate and individual pesticide registration from EPA pursuant to Section 3 of FIFRA, § 7 U.S.C. 136a. Respondent denies any additional allegations, if any, intended by EPA in Section III, paragraph 26 of the Complaint.

27. Respondent denies the allegations in Section III, paragraph 27 of the Complaint that the Technical Sodium Chlorite labels affixed to containers of Saf-T-Chlor sold or distributed between April 2003 and June 2006 implied that the Saf-T-Chlor product had a separate and individual pesticide registration, or that such separate and individual pesticide registration was in fact required to support such sale and distribution. Respondent further denies that the labels affixed to containers of Saf-T-Chlor sold or distributed between April 2003 and June 2006 were false or misleading. Respondent admits that EPA registration Number 52564-1 was received by

Aragonesas in May of 2002, but denies that use of this EPA registration number on Technical Sodium Chlorite labels was false and misleading as to the identity of the product.

28. Respondent denies that any alleged “discrepancy” between the Material Safety Data Sheet for Saf-T-Chlor and label statements described in Section III, paragraph 26 b of EPA’s Complaint demonstrates that the Technical Sodium Chlorite labels on containers of Sodium Chlorite sold or distributed between April of 2003 June of 2006 were false or misleading as to the efficacy of the granulated sodium chlorite used in Gas: Solid Systems to generate chlorine dioxide gas.

29. Respondent denies that the sale or distribution of granulated sodium chlorite between April 2003 and June 2006 was false or misleading as to the registration status of the product, and/or concentrations of the active ingredient constituted misbranding as defined by Section 2(q)(1) of FIFRA, 7 U.S.C. 136(q)(1).

30. Respondent denies EPA’s allegations in Section III, paragraph 30 of the Complaint.

31. Respondent denies EPA’s allegations in Section III, paragraph 31 of the Complaint.

32. Section III, paragraph 32 of the Complaint alleges a proposition of law for which no response is necessary pursuant to the Consolidated Rules of Practice.

IV. PROPOSED CIVIL PENALTY

The paragraphs under Section IV of the EPA’s Complaint are not numbered. Accordingly, it is questionable whether this section of the Complaint contains factual allegations which require specific responses in this Answer pursuant to the Consolidated Rules of Practice. Nevertheless, in response to Section IV of the Complaint, Respondent states as follows:

Respondent reserves the right to contest the nature, number, and severity of individual alleged FIFRA violations in a more detailed fashion after receipt of responses to Respondent’s

Freedom of Information Act (“FOIA”) requests made to EPA and EPA’s Office of Prevention, Pesticides and Toxic Substances, which were submitted electronically through EPA’s web-based FOIA system on May 9, 2008.

Respondent reserves the right to contest the nature, number, and severity of the individual alleged FIFRA violations in a more detailed fashion after receipt of EPA’s prehearing information exchange pursuant to 40 CFR § 22.19.

Respondent reserves the right to contest EPA’s purported application of EPA’s *Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act* dated July 2, 1990 in terms of the nature, extent, or seriousness of the alleged FIFRA violations.

Respondent has no knowledge of the nature or extent of the “specific evidence” that EPA references in Section IV of the Complaint that purportedly supports EPA’s allegations contained therein. Respondent requests that such specific evidence be produced as part of EPA’s prehearing information exchange.

Respondent disputes the statements in Section IV of the Complaint that characterizes Respondent’s alleged violations as “very serious” or which otherwise characterize various allegations as being established from an administrative standpoint in accordance with the Consolidated Rules of Practice (e.g. “The false or misleading statement on Saf-T-Chlor label regarding its registration status deceive consumers by implying the product has been approved by EPA as being effective and safe.) As stated in this Answer, Respondent denies such allegations, and each and every one of them.

Respondent further believes that the recital of EPA’s duties vis-à-vis the purposes of FIFRA are self-serving and are inappropriate for inclusion in EPA’s Complaint under the Consolidated Rules of Practice; especially in light of the sophistication of CDG’s municipal water

treatment and other customers, as well as the fact that the Aragonese Technical Sodium Chlorite has already been vetted with EPA as part of the FIFRA registration process. Such customers routinely track water quality of their treatment facilities. CDG believes that this is the true measure of the effectiveness of Respondent's Saf-T-Chlor product from an objective standpoint.

Respondent also vigorously denies the bald allegation alleged in the last paragraph of Section IV of EPA's Complaint that "the violations alleged in this Complaint created a substantial risk to human health and the environment and substantial harm to the FIFRA registration program." As indicated to EPA on several occasions in the past, it is not the concentration of the sodium chlorite active ingredient in Saf-T-Chlor that is the measure of its success in treating water, it is the level of pure chlorine dioxide generated by the Gas: Solid System using sodium chlorite is what really matters from an efficacy standpoint. Indeed, this efficacy was born out during the FIFRA registration process for Saf-T-Chlor that was expedited by EPA's Office of Pesticide Programs in order to resolve the Stop Sale, Use or Removal Order ("Stop Sale Order") issued on May 24, 2007. It is also why EPA, the U.S. Department of Defense, and others sponsored research using the CDG Gas: Solid System during the same period of the alleged violations.

V. REQUEST FOR HEARING

Respondent hereby makes a formal request for hearing as provided for in Section 14 of FIFRA, 7 U.S.C. §1361(a)(3), and in accordance with the Administrative Procedure Act, 5 U.S.C. §551 *et seq.* and 40 CFR § 22.15(c) regarding the Complaint, the material facts alleged therein, and to contest the amount of any proposed penalty.

VI. DEFENSES

A. Sale & Distribution of Saf-T-Chlor Was Conducted Pursuant to FIFRA Repackaging Requirements

Respondent's intent during the time period between April of 2003 and June of 2006 was to repack Aragonesas Technical Sodium Chlorite into containers in accordance with 40 CFR §165, Subpart D. In this regard, Respondent utilized the information from the FIFRA-registered label for Aragonesas Technical Sodium Chlorite with EPA Registration No. 52564-I in developing labels for Saf-T-Chlor containers. During the time period in question, it was not Respondent's intent to sell or distribute an unregistered pesticide, as alleged by EPA. The granulation process used to form granular sodium chlorite from powdered Aragonesas sodium chlorite did not change the formulation of the Aragonesas powdered sodium chlorite or impact the efficacy of Saf-T-Chlor's use in generating chlorine dioxide using the Gas: Solid System.

B. Granulation Process Does Not Constitute "Misbranding"

Respondent's Saf-T-Chlor product is a granulated form of Aragonesas Technical Sodium Chlorite. The FIFRA approved label for Aragonesas lists the active ingredient as sodium chlorite at 80%. The sodium chlorite "active ingredient" in both the Aragonesas and Saf-T-Chlor products are a misnomer in the sense that the sodium chlorite itself does not render the desired pesticidal effect. Instead, the sodium chlorite is the chemical precursor that, when combined with water and dilute chlorine gas in the container, form pure chlorine dioxide gas, which is what renders the desired pesticidal effect. Indeed, the approved label for Aragonesas sodium chlorite states, in part, as follows: "[f]or use as a precursor in the generation of chlorine dioxide as a disinfectant, sanitizer, and to control."

The granulation process to manufacture Saf-T-Chlor does not alter the desired pesticidal effect of the chlorine dioxide gas that is generated using the Gas: Solid System. While the wet

weight verses dry wet concentrations of powdered Aragonese sodium chlorite verses Saf-T-Chlor are slightly different, the final chlorine dioxide concentrations – the true measure of product efficacy – are the same.

Furthermore, Saf-T-Chlor is intended for use solely in a specialized CDG Gas: Solid System, and only by a relatively small market of sophisticated municipal drinking water treatment plants, municipal wastewater treatment plants, industrial wastewater treatment facilities, and cooling towers at petrochemical facilities. Saf-T-Chlor is not marketed for use by the general public. Accordingly, any allegation that the product was “misbranded” should be gauged by the market in which the product is used.

In this case, EPA is basing its misbranding allegations on a bald percent active ingredient concentration comparison between dry weight of powdered sodium chlorite verses wet weight of granular sodium chlorite. This comparison is too rigid in regard to gauging the true measure of each product’s actual efficacy. Indeed, the Saf-T-Chlor registration process that Respondent undertook to help resolve EPA’s Stop Sale Order essentially supports Respondent’s original position on the efficacy of Saf-T-Chlor. Accordingly, EPA’s allegations that Saf-T-Chlor was “misbranded” in violation of FIFRA are without merit.

C. EPA’s Civil Administrative Complaint and Stop Sale Order Violate Respondent’s Due Process Rights

The Fifth Amendment of the United States Constitution requires that regulations and administrative determinations be facially clear enough to be understood by impacted persons so that they can know what conduct is prohibited. EPA’s allegations in its Stop Sale Order and Complaint that Saf-T-Chlor required a separate FIFRA registration and was “misbranded” constitute a violation of Respondent’s due process rights under the Fifth Amendment because historic contacts between Respondent, EPA, and other U.S. Government officials – that

Respondent relied upon – led Respondent to conclude that the efficacy of granulated Saf-T-Chlor sodium chlorite was established to EPA’s satisfaction. Specifically, this defense is predicated upon Respondent’s historic, pre-2007 dealings with agencies of the United States, including EPA, regarding the efficacy of the Gas: Solid System and Saf-T-Chlor technologies. These dealings included, in part, the following:

- Respondent has had an open dialog with EPA Office of Drinking Water since approximately 1996, when Respondent started working with municipal drinking water utilities;
- Since developing Saf-T-Chlor in 2001, CDG has held in-depth briefings on its Gas: Solid System and Saf-T-Chlor technologies with EPA officials, including senior personnel in the EPA’s Office of Pesticide Programs;
- Since 2001, CDG has performed contract research for the US Government in connection with the use of high-purity chlorine dioxide gas for destruction of biological warfare agents (e.g. *Anthrax*), using the Gas: Solid System and Saf-T-Chlor technology. Funding agencies included EPA and the US Department of Homeland Security; and
- In 2004, CDG participated in EPA’s Environmental Technology Verification program. The subject of this program was the destruction of biological agents with high-purity chlorine dioxide using the Gas: Solid System and Saf-T-Chlor.

At no time during its previous dealings with EPA (and other US Government officials) was the efficacy of the Gas: Solid System and Saf-T-Chlor called into question. Indeed, the efficacy of Respondent’s technologies was in fact proven. For EPA to now claim that Saf-T-Chlor was misbranded is a clear violation of Respondent’s due process rights.

D. Collateral Estoppel

As stated above, both EPA and other U.S. Government officials were appraised of both the Saf-T-Chlor and Gas: Solid System technologies well in advance of EPA's issuance of its Stop Sale Order and the Complaint. Both EPA and other U.S. Government officials were satisfied with the efficacy of granulated Saf-T-Chlor sodium chlorite. Respondent relied upon these federal government representations in its Saf-T-Chlor marketing efforts. EPA, therefore, is estopped from asserting that Saf-T-Chlor is "misbranded" in violation of FIFRA, as well as now asserting that it is entitled to seek penalties for such alleged FIFRA violations.

E. Doctrine of Laches

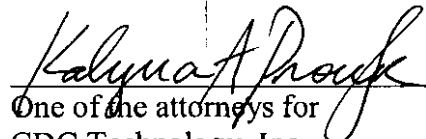
EPA's original Stop Sale Order was issued on May 24, 2007. Thereafter, the Stop Sale Order was vacated by EPA on July 17, 2007. Respondent believed at that time that the EPA's enforcement action in regard to Saf-T-Chlor was resolved. EPA subsequently filed its Complaint on March 27, 2008 – over eight (8) months following the vacature of the Stop Sale Order. This long delay in filing its Complaint after the vacature of the Stop Sale Order constitutes laches. Accordingly, under the doctrine of laches, it is inequitable for EPA to assert FIFRA-related violations concerning Saf-T-Chlor at this time, or to recover any associated penalties.

VII. REQUEST FOR SETTLEMENT CONFERENCE

Respondent hereby requests an informal settlement conference with EPA representatives to discuss the allegations contained within EPA's Complaint, a proposed penalty assessment, if any, the impacts of any proposed penalties to Respondent's business operations, and to discuss resolution of the matter.

May 30, 2008

Respectfully submitted,


One of the attorneys for
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