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September 18, 2008

Congressman John Dingell, Chairman
Committee on Energy and Commerce
316 Ford Office Building
Washington, DC 20515

Re: Testimony concerning the investigation into *Regulatory Toxicology and Pharmacology*, and impact of this publication on Brunswick, Georgia.

Honorable John Dingell,

The Committee's February 5, 2008 letter to the Weinberg Group and its April 2, 2008 letter to the American Chemistry Council concerning the journal *Regulatory Toxicology and Pharmacology* (RTP) was of great interest to the Glynn Environmental Coalition (GEC) since this journal has been used to deny our community basic protections that most Americans take for granted.

Summary

Our community has a very simple request of EPA Region 4: test areas contaminated by toxaphene pesticide and report all the chemicals present.

Toxaphene, a now banned pesticide, was manufactured in Brunswick, Georgia, from 1948 to 1980 and disposed of in several landfills, and in our estuary; now this toxic waste is spread throughout our community, including two Superfund Sites, one of which is located next to an elementary school. In 1991, the U.S. Environmental Protection Agency (EPA), the State of Georgia, and the Hercules Corporation, which manufactured the pesticide, met and agreed to change the analytical method for toxaphene to one that reported toxaphene and "some other product". Our Coalition's efforts resulted in the EPA Office of Inspector General (OIG) finding that the analytical method developed was inappropriate, and that it under-reported the amount of chemicals present; the OIG ordered a new and appropriate analytical method be developed. In response to the EPA OIG, EPA Region 4 and Georgia Environmental Protection Division published a paper in *Regulatory Toxicology and Pharmacology* advocating the reporting of only

3 of the 670+ chemicals in the toxaphene mixture. Even though the EPA OIG found the EPA Region 4 method would under-report the amount of chemicals present, EPA Region 4 has continued to advocate for methods that will either under-quantify or not report toxaphene chemicals present. The GEC asked EPA Region 4 to retest, by an appropriate analytical method, Altama Elementary School, which abuts a Superfund Site with toxaphene manufacturing wastes and has known releases to school property. Instead of testing by an appropriate method, EPA Region 4 did a presentation to the Board of Education that used the article from *Regulatory Toxicology and Pharmacology* to conclude that even if toxaphene was present on school property, the chemicals are not a human health risk.

Documents obtained from EPA Region 4 indicate that, in cooperation with Hercules Incorporated, efforts continue to develop and implement another analytical method that will only report a few of the chemicals present. We want appropriate testing conducted and all the chemicals present reported. Meanwhile, the risk to our school children and others exposed to toxaphene-contaminated soil, air, water, and seafood will remain undetermined.

Background and Discussion of Issues

Toxaphene, a now banned pesticide, was manufactured in our community from 1948 to 1980. Pesticide manufacturing wastes were disposed of in several landfills, estuary, and two Superfund Sites, one of which is located next to Altama Elementary School. Toxaphene migrated from the Hercules Plant site into surrounding neighborhoods, and from the Hercules 009 Landfill Superfund Site to Altama Elementary School. An estimated 2 to 3 million pound of toxaphene manufacturing wastes were released into the estuary.

In 1991, the U.S. Environmental Protection Agency (EPA), the State of Georgia, and Hercules met and agreed to change the analysis and quantification method for toxaphene to one that reported toxaphene and “some other product”. The Toxaphene Task Force (TTF) was formed and was composed of chemists from EPA Region 4, Georgia Environmental Protection Division, and Hercules Incorporated. As a result of this change in how toxaphene was quantified by the TTF, none was reported when actually present above levels set to protect human health and the

environment. [1] (Attachment A) When an analytical method fails to detect or report chemicals present, public health is jeopardized by the false belief that the seafood, soil, water, or sediments are safe to consume or to be exposed. Furthermore, the integrity of the nation's food basket is compromised when flawed analysis allows contaminated seafood to be harvested and sold.

The GEC brought our concerns about the under-quantification of toxaphene to the attention of EPA Region 4 throughout the 1990's without satisfactory results. The GEC submitted our concerns to the EPA OIG, which became a formal audit that culminated with the EPA OIG releasing *Appropriate testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site Brunswick, Georgia* (Report 2005-P-00022, September 26, 2005, Assignment 2004-124).

Dr. R. Kevin Pegg, in his capacity as our community's technical advisor under an EPA Technical Assistance Grant for the Hercules 009 Landfill Superfund Site, reviewed and commented upon the EPA OIG report. [2] (Attachment B) Dr. Pegg wrote an in-depth discussion of the toxaphene analysis and quantification issues covered by the EPA OIG, and the uncertainty caused by Toxaphene Task Force analytical method.

Simon and Manning - EPA Region 4 Response to the EPA Office of Inspector General

In response to the EPA OIG Report, EPA Region 4 and the State of Georgia produced the article, *Development of a reference dose for the persistent congeners of weathered toxaphene based on vivo and in vitro effects related to tumor promotion*, which was published in *Regulatory Toxicology and Pharmacology*, by Ted Simon, EPA Region 4; Randall Manning, Georgia Environmental Protection Division, hereafter referred to as Simon and Manning. [3] Noteworthy is that the article did not present any new data, but rather was a creative reinterpretation of existing scientific studies that came to a radically different conclusion about the toxicological properties of toxaphene, and advocated testing for only three of the 670+ chemicals in the

[1] Under Quantification of Polychlorinated Camphene (Toxaphene) in Brunswick, Glynn County, Georgia. January 2001. http://www.glynnenvironmental.org/ToxapheneAnalysis.htm
[2] EPA Toxaphene Testing Method Found Inappropriate, October 2005. http://www.glynnenvironmental.org/009TAR10-05.htm
[3] Ted Simon, T, R. Manning. Development of a reference dose for the persistent congeners of weathered toxaphene based on in vivo and in vitro effects related to tumor promotion. Regulatory Toxicology and Pharmacology, Volume 44, Issue 3, April 2006, Pages 268-281

toxaphene mixture, which would not be present or only in very small amounts. The EPA OIG found the article interesting but noted that the method proposed would underestimate the amount of toxaphene chemicals present, and would exclude the toxaphene chemicals present in the largest amounts. Furthermore, the OIG accepted the report under the condition that the authors produce the calculations used to reach the conclusions. Neither EPA Region 4 nor the authors have been able to produce the calculations used to reach the conclusion presented in the article.

The Simon and Manning article published in *Regulatory Toxicology and Pharmacology* has been extensively commented upon by the GEC. [4] (Attachment C) Simon and Manning argued for using only three of the 670+ chemicals in the toxaphene pesticide mixture for quantification and human health risk analysis, which are referred to as p-26, p-50 and p-62 congeners (a congener is a single chemical from the toxaphene mixture). The premise of their reasoning was from a study of toxaphene in fish from the North Atlantic Ocean, Investigation into the Monitoring, Analysis and Toxicity of Toxaphene in Marine Foodstuffs study (MATT).[5] The MATT study selected the p-26, p-50 and p-62 congeners for analysis because it had previously been determined that they were the most prominent in the seafood from the area being studied. The prominent chlorinated camphene congeners in manufacturing wastes in Glynn County are very different, with Hx-Sed and Hp-Sed being the most prominent. Simon and Manning fails to conduct any analysis of what congeners are appropriate for areas contaminated by toxaphene manufacturing wastes.

The premise of the Simon and Manning article was fatally flawed for several reasons.

1. The selection of p-26, p-50 and p-62 congeners is used as an indicator of toxaphene in areas where they are the primary congeners, such as northern latitudes, and is inappropriate for southern latitudes such as Brunswick, Georgia. The primary analytical use of p-26, p-50 and p-62 congeners is as an indicator of toxaphene and not as a quantification or risk assessment tool.[6] The MATT study found relevance in the p-26, p-50 and p-62 congeners only because exposure is

[4] Comment from the Glynn Environmental Coalition on the June 20, 2006, EPA Region 4, Final Response to the Recommendations and Final Report for the Hercules 009 Landfill OIG/Ombudsman Report *Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site Brunswick, Georgia* (Report 2005-P-00022, September 26, 2005); Assignment 2004-124. September 7, 2006. http://www.glynnenvironmental.org/009IG-comments-09-06.htm

[5] MATT, 2000. Final Report, Investigation into the Monitoring, Analysis and Toxicity of Toxaphene in Marine Foodstuffs FAIR CT PL.96.3131.

[6] Oetjen, K., H. Karl, Levels of toxaphene indicator compounds in fish meal, fish oil, and fish feed. Chemosphere. July, 1998.

exclusively from North Atlantic Ocean seafood exposed to atmospheric distilled chlorinated camphene, which results in higher percentages and ratios of the three congeners.

2. The range of p-26, p-50 and p-62 congeners vary widely in seafood so total chlorinated camphene, or total toxaphene, is measured for toxicological evaluations. The range of toxaphene congeners can range widely, but as a rule, the higher in the northern latitudes the seafood was obtained, the greater the percentage of p-26, p-50 and p-62 congeners. The use of p-26, p-50 and p-62 congeners is less useful as an indicator for seafood from southern latitudes. Total toxaphene is measured when a risk assessment is being conducted.[7] Tables 6 and 7 in the Simon and Manning paper demonstrate the significant decrease in p-26, p-50 and p-62 congeners in Glynn County, which has been noted in other studies.

3. The comparison of seafood exposed to dumped toxaphene manufacturing wastes versus atmospherically distilled chlorinated camphene is inappropriate. Simon and Manning violate the basic principles of scientific investigation by drawing conclusions between dissimilar data sets, and failed to report that the routes of exposure of the marine organisms in the data sets were vastly different. This omission invalidates all conclusions derived. The injection of so many variables, and the failure to report these variables, draws into questions the conclusions reached by Simon and Manning. A review of literature would have revealed that use of p-26, p-50 and p-62 congeners is inappropriate for southern latitudes.

4. Dioxin is a component of toxaphene manufacturing wastes and must be taken into consideration when planning sampling, analysis, and risk assessments. Simon and Manning ignore the known additional toxicological properties of toxaphene manufacturing wastes. Toxaphene manufacturing wastes contain their own unique composition of congeners, compounds, and contaminants that must be considered when evaluating risk to human health and the environment. The simplistic approach to toxaphene identification, quantification, and risk assessment presented by Simon and Manning will pose a significant threat to human health and the environment.

[7] Chan, H. M., F. Yeboah. Total toxaphene and specific congeners in fish from the Yukon, Canada. Chemosphere. August 2000.

5. When p-26, p-50 and p-62 toxaphene congeners were measured in seafood from Brunswick, Georgia, they ranged from 1.56% to 8.69%, and the average was 4.80%. The p-26, p-50 and p-62 congeners are not the most prevalent in Brunswick, Georgia, and are inappropriate for use as chlorinated camphene indicators. The MATT study found the range of p-26, p-50 and p-62 toxaphene congeners in fish exposed via atmospherically distilled toxaphene in the Northern Atlantic Ocean ranged from 8.02% to 58.05%, and averaged 22.45%.

Dr. R. Kevin Pegg, in his capacity as our community's technical advisor under an EPA Technical Assistance Grant, reviewed and commented upon the Simon and Manning article and noted many deficiencies and scientific inaccuracies.[8] (Attachment D) Significant flaws were found in the conclusions concerning toxaphene's carcinogenic and genotoxic properties. Furthermore, it was noted that the authors generalized, speculated, and infer to such a degree that meaningful conclusions cannot be drawn.

Dr. Kathy Burns reviewed and commented upon the Simon and Manning article and found many scientific inaccuracies concerning the arguments presented concerning carcinogenicity and a lack of adherence to EPA policy and procedures.[9] (Attachment E)

Dr. Jennifer Sass, Natural Resource Defense Council, also provided comments concerning the Simon and Manning article and noted the bias of *Regulatory Toxicology and Pharmacology* towards industry perspectives, which was supported by 18 additional organizations knowledgeable about the issue. [10]

> It should be extremely concerning to taxpayers that a scientific article that proposes to disregard all but a handful of PCC congeners is co-authored by scientists from EPA Region 4 and the Georgia Environmental Protection Division (Simon and Manning, 2006). Though no source of funding is disclosed, it is published in a journal, *Regulatory Toxicology and Pharmacology*, well-known to be biased towards industry perspectives.

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[8] Review and Comments on the paper "Development of a Reference Dose for the Persistent Congeners of Weathered Toxaphene based on In Vivo and In Vitro Effects Related to Tumor Promotion" by Simon and Manning. August 2006. http://www.glynnenvironmental.org/ToxapheneAnalysis08-06.htm

[9] Comments on the Reliance of USEPA Region 4 on Simon and Manning, 2005 in Decisions Regarding the Hercules 009 Landfill Superfund Site in Brunswick, Georgia. September 7, 2006.

[10] Public Interest Comments on the Office of Inspector General Reports: Appropriate Testing and Timely Reporting are Needed at the Hercules 009 Landfill Superfund Site, Brunswick, Georgia, Report 2005-P-00022; September 26, 2005. Report Report 2005-P-00022 (Addendum); September 13, 2005, and
More Information is Needed on Toxaphene Degradation Products, Report No. 2006-P-00007, December 16, 2005. October 2006. http://www.glynnenvironmental.org/009IG-comments-10-06.htm

> In fact, in 2002 the journal was targeted in a letter by over forty scientists, including noted international experts and journal editors, citing concerns about, "apparent conflicts of interest, lack of transparency, and the absence of editorial independence".[i] Specifically, their letter cites, "the journal's apparent bias in favor of industries that are subject to governmental health and environmental regulations". The letter goes on to identify financial supporters of the journal sponsor, including, the American Chemistry Council, Dow AgroSciences, R.J. Reynolds Tobacco Co., and others. Moreover, the letter identified a "significant percentage" of the editorial board with financial ties to companies whose products are the subjects of studies published in the journal. Is it any wonder, then, that this article advocating a weakening of cancer potency of toxaphene found its way to this journal? But, the fact that the authors are public employees suggests a concerning level of partnership between Hercules and the regulatory agencies.

All parties that reviewed and commented upon the Simon and Manning article found deficiencies and inaccuracies in the scientific argument presented.

EPA Region 4 Refusal to Report All Toxaphene Chemicals Present and Other Deficiencies

The EPA OIG noted in the audit closeout letter that EPA Region 4 remained steadfast in their refusal to test for and report all toxaphene chemicals present, and noted the calculations for the Simon and Manning article were not provided. [11] (Attachment G)

The EPA OIG's audit close-out letter was commented upon by Dr. R. Kevin Pegg. The lack of any supporting documentation for the Simon and Manning article was noted. (Attachment H)

The EPA Office of Inspector General made an error when asking for groundwater to be analyzed and risk assessed by the scheme presented in the Simon and Manning paper. Utilizing data from fish tissue, which metabolize and selectively bioaccumulate specific toxaphene chemical components, is inappropriate for soil, air, or groundwater. Furthermore, the OIG failed to recognize or address the source of contamination, which are toxaphene manufacturing wastes. Toxaphene manufacturing wastes contain additional contaminants such as dioxin that warrant consideration during testing and assessment of human health risks.

EPA Region 4 Refusal to Test Altama Elementary School

[11] Memorandum: OIG Ombudsman Report 2005-P-00022, Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site, Brunswick, Georgia. October 31, 2006.

After the EPA OIG found the method to test for toxaphene in our community inappropriate, the GEC requested that EPA Region 4 re-sample Altama Elementary School that abuts the Hercules 009 Landfill Superfund Site, which has documented releases to the school property from the Superfund Site and has only received testing by the method found to be inappropriate and known to under-quantify toxaphene. Further requests to test the school were made by the Glynn County Board of Education. Instead of testing the school, the EPA Region 4 made a presentation to the Board of Education on January 29, 2008. In this EPA Region 4 presentation, based upon the Simon and Manning article, the EPA concluded that even if chemicals were present, they were not harmful to the elementary school students, and refused to re-test a school known to be contaminated and only tested by an inappropriate method.

Both the GEC (Attachment I) and Dr. R. Kevin Pegg (Attachment J) commented on the January 29, 2008, EPA Region 4 presentation to the Board of Education and provided comments and examples specific inaccuracies to the school system's attorney.

EPA Region 4 Implementation of Simon and Manning Risk Assessment Method Instead of the EPA Integrated Risk Information System (IRIS)

According to EPA Region 4 documents, the Simon and Manning risk assessment scheme has been used to the exclusion of the body of scientific knowledge and the EPA IRIS database to rewrite documents for Superfund Sites contaminated with toxaphene. After the EPA Office of Inspector General October 31, 2006, close-out letter was received by EPA Region 4; efforts were made to implement the Simon and Manning risk assessment method at Superfund sites. The Terry Creek Dredge Spoils National Priorities List (NPL) Site Remedial Investigation/Feasibility Study documents were identified for revision to reflect the risk assessment scheme presented in Simon and Manning instead of using the EPA Integrated Risk Information System (IRIS) established for this purpose. [12] EPA Region 4 defined the best available science as Simon and Manning for toxicity. The next step identified was for the EPA Technical Services Section to develop Remedial Goal Options for soil and sediment based upon the risk assessment scheme in Simon and Manning. [13] The EPA IRIS database has been effectively been eliminated by EPA Region 4 as the risk assessment tool for toxaphene contaminated sites in Brunswick, Georgia.

[12] EPA Region 4 Briefing Summary, Terry Creek Dredge Spoils, Brunswick, Georgia. July 31, 2007
[13] EPA Region 4, Path Forward, Terry Creek Dredge Spoils, Brunswick, Georgia. August 13, 2007

EPA Region 4 Implementation of the Hercules Analytical Method Instead of EPA Office of Inspector General Ordered EPA Office of Solid Waste Method

As the EPA Office of Inspector General (OIG) noted, EPA Region 4 resisted testing for and identifying all toxaphene chemicals, and advocated for reporting only the three toxaphene chemicals identified by Simon and Manning. EPA Region 4 noted that the national effort to incorporate the Gas Chromatography-Negative Ion Mass Spectroscopy (GC-NIMS) into SW-846, ordered by the OIG, is on a separate path and inconsistent with the Hercules method. Still, one of EPA Region 4's next steps was to prioritize their laboratory workload to incorporate the ability to perform Hercules' GC-NIMS.[14] This action strongly implies that EPA Region 4 was working in conjunction with Hercules to implement an analytical method other than the OIG ordered method under development by EPA Office of Solid Waste.

EPA Region 4 and Hercules Meet with EPA Office of Solid Waste to Advocate for Limited Toxaphene Chemicals Testing

On February 19, 2008, EPA Region 4 met with Shen-Yi Yang, of the EPA Office of Solid Waste, Arlington, Virginia, who is developing a formalized GC-NIMS toxaphene analysis and quantification method as the EPA OIG instructed. At this meeting, EPA Region 4 inappropriately pressured Ms. Yang to change the analytical method under development to one that would only measure the three chemicals identified in the Simon and Manning paper, which the EPA OIG already found to be a method that would under-report the amounts of chemicals present, and specifically exclude the chemicals present in the largest quantities (personal communication).

EPA Region 4 Information Withheld

Information has not been forthcoming from EPA Region 4. An effort was made to obtain additional information through a Freedom of Information Act request, but EPA Region 4 is withholding ~400 documents from 2006 forward that would shed further light on how the Simon

[14] EPA Region 4, Path Forward, Terry Creek Dredge Spoils, Brunswick, Georgia. August 13, 2007

and Manning article is being used, and on the Weinberg Group re-assessment of the toxicity of toxaphene.

The Weinberg Group Hired by Hercules to Perform Toxicological Studies on Toxaphene

The Weinberg Group was hired by Hercules to re-assess toxaphene's toxicity. Tactics noted by the Committee have been put in motion, including a Scientific Advisory Panel to design two studies. According to EPA documents, the first study will be used to design the second study to determine toxicity of only a few chemicals in the toxaphene mixture. Included on this panel is Dr. James Klaunig, a person of interest to the House Energy and Commerce Committee for his past activities. The comments of the Scientific Advisory Panel were incorporated into the testing plan, according to the August 21, 2007, presentation by the Weinberg Group.[15] Notable is that only a few of the chemicals from the toxaphene mixture will be used in the risk assessment.

In closing, The Glynn Environmental Coalition is grateful for your attention to the abuses being perpetrated under the guise of science through the journal *Regulatory Toxicology and Pharmacology*. We have tried to briefly outline how this journal has been used to argue for continued biased analysis and quantification of toxaphene in our community. Do we ask too much when we ask for our elementary school, and other areas tested by the method the EPA OIG found inappropriate, to be tested by an appropriate method and all the chemicals present be reported? Until appropriate testing is conducted, and all chemicals present are reported, toxicologists and health professional will not be able to assess the risk nor make recommendations to protect human health and the environment.

[15] Toxaphene Risk Assessment: Re-evaluation and Data Development, James C. Lamb, Ph.D., DABT, FATS. The Weinberg Group Inc. Washington, DC. August 21, 2007.

[i] Axelson O, Balbus JM, Castleman B, Cohen G, Davis D, Donnay A, Doolittle R, Duran BM, Egilman D, Epstein SS, Goldman L, Grandjean P, Hansen ES, Heltne P, Huff J, Infante P, Jacobson MF, Joshi TK, Ladou J, Landrigan PJ, Lee PR, Lockwood AH, MacGregor G, Melnick R, Messing K, Needleman H, Ozonoff D, Ravanesi B, Richter ED, Sass J, Schubert D, Sharpe VA, Socha A, Suzuki D, Teitelbaum D, Temple NJ, Terracini B, Thompson A, Tickner J, Tomatis L, Upton AC, Wyatt RM, Wigmore D, Wilson T, Wing SB. Letter to Academic Press and Elsevier Sciences, Inc. Re: Regulatory Toxicology and Pharmacology. November 19, 2002.

Attachment A

Under-Quantification of Polychlorinated Camphene (Toxaphene) in Brunswick, Glynn County, Georgia.
January 2001

Summary

The U.S. EPA, Georgia EPD, and Hercules Inc. met as the "Toxaphene Task Force" (TTF) and developed a method for identifying and quantifying the pesticide toxaphene in Brunswick, Georgia. The TTF method has threatened human health by failing to detect or significantly under quantifying toxaphene levels present in the environment. U. S. EPA and the Agency for Toxic Substance and Disease Registry toxicologist have documented why the TTF method fails to produce data that is useful in making their decisions and recommendations to protect human health. Analysis for toxaphene by gas chromatography with electron capture negative ionization mass spectrometric detection (GC-ECD and GC-ECNI-MS) has produced the data needed for toxicologist to make decisions protective of human health.

Background

The Glynn Environmental Coalition (GEC) is located in Brunswick, Glynn County, Georgia, where an insecticide mixture of polychlorinated camphene (PCC), commonly called toxaphene, was manufactured by Hercules Incorporated. Manufacturing of PCC took place at Hercules Incorporated, Brunswick, Georgia, from 1948 to 1980.[1] PCC is defined as camphene with 67% to 69% chlorine by weight, and is a complex mixture of over 670 separate chemicals.[2],[3],[4] During the period PCC was manufactured, PCC manufacturing wastes and PCC was discharged into the estuary by way of Dupree and Terry Creek at a rate of 250 to 300 pounds of PCC per day.[5] Fugitive emissions of PCC contaminated wind-blown dust, water runoff, and vehicle traffic distributed PCC throughout the neighborhoods around the Hercules Plant site. [6] In addition, significant amounts of PCC were deposited into at least four landfills and dumps in Glynn County.[7], [8]

In 1991, chemists from the EPA, EPD, and Hercules Inc., performed a limited study and developed a set of guiding principles for the determination of PCC in groundwater, soil, and manufacturing waste sludge samples from the Brunswick, Georgia, area.[9], [10] The results of this limited study was the development of the "Toxaphene Task Force" (TTF) methodology for the identification and quantification of PCC. The TTF methodology was further modified in

August 1997. [11] Even though the August 1997 modifications were proposed for only specified areas and only for soil and groundwater, the method has been used at Sites throughout Glynn County and has been used to determine PCC's in fish tissue for human health determinations.[12] The August 1997 method is also referred to as the "Hercules Protocol".[13]

The ability of the agreed upon TTF method to accurately identify and quantify PCC has been questioned by the Agency for Toxic Substance and Disease Registry (ATSDR) and the EPA.

Statement of the Problem

The method developed by the TTF for the identification and quantification of PCC in Brunswick, Georgia, seriously underestimates the true amount present, and excludes the PCC chemicals that health officials are most concerned about. Specifically, the TTF method fails to report the "total toxaphene" and "apparent toxaphene" that are the basis of recommendations by the EPA, Food and Drug Administration (FDA), and ATSDR toxicologist to protect human health and establish cleanup levels at PCC contaminated sites.

Local, State and Federal health officials rely upon the accuracy of data gathered on PCC levels to make recommendations to minimize or eliminate exposure of citizens through consumption of contaminated seafood, water, or contact with contaminated soil, sediments, and sludge. Based on PCC data collected, interim actions are recommended to protect the public in the form of seafood consumption advisories, and emergency removal actions, while long-term remedies are developed. High quality and accurate data is crucial in taking short-term actions and recommendations, and developing long term remedial plans.

Health officials from the EPA and ATSDR have identified the TTF method as seriously flawed in providing data meaningful to their deliberations on the potential health ramifications from the consumption of PCC contaminated seafood, and exposure to PCC contaminated air, soil, sludge, sediments, and water. The EPA and ATSDR are specific in the type and quality of data needed to make decisions protective of human health and the environment. Likewise, the EPA and ATSDR have been specific in the ways the TTF method has threatened human health by failing to detect and understating actual PCC levels present. Most notable is that the TTF method excludes the fraction of the 670+ PCC chemicals that are of concern in making health based recommendations. Recent re-analysis of samples has shown that the TTF method failed to

identify the presence of PCC in seafood at levels 52 times the EPA "do not eat" recommendation. The TTF method has failed to accurately identify PCC in many other samples, or to significantly understate actual levels of PCC present.

Discussion

Formation of the Toxaphene Task Force began at meeting on September 30, 1991, at the Georgia EPD. It was agreed that previously the regulatory agencies and Hercules had used a procedure that identified "apparent toxaphene" when analyzing environmental samples.[14] Analysis for "apparent toxaphene" is the criteria used by the U.S. Food and Drug Administration (FDA) to make health based recommendations for maximum levels of PCC in food.[15] It was agreed that if the U.S. EPA, Georgia EPD, and Hercules agreed upon the method and the findings of the task force, it would be used by the EPA for any work relating to the Superfund Site[16] or any RCRA matters pertaining to the Hercules facility involving toxaphene. It was proposed that those in attendance meet again to review the work of the task force and to discuss whether the samples do, in fact, reflect toxaphene or some other product. Clearly, a decision was made at the meeting to develop a PCC analytical method different from the health-based method currently in use.

The report of TTF, released June 4, 1993, was described as a very limited study of toxaphene analysis of real samples collected at the Hercules facility in Brunswick, Georgia.[17] The TTF method was designed to identify and quantify "technical toxaphene", instead of the "total toxaphene" or "apparent toxaphene" used by toxicologist in determining the potential risk to human health and the environment.

The TTF made specific changes in the identification and quantification of PCC that result in a significant reduction of "total toxaphene" and "apparent toxaphene". Quantification was limited to the 4-6 major peaks on the "back half" of the toxaphene chromatogram while many of the prominent PCC's found in the "front half" are associated with unmodified technical toxaphene.[18],[19],[20],[21] The TTF further excluded PCC from the quantification process by eliminating any peak which is larger in proportion to the other component peaks in the sample than in the toxaphene standard.[22] The U.S. Food and Drug Administration, in the "apparent toxaphene" method, instructs to include all peaks, and notes that relative heights and widths of matching peaks in the residue and reference standard will probably differ. [23]

One chemist from the U.S. EPA noted that the "latter peaks" in samples were decreased and the "early peaks" were increased in environmental samples from Brunswick, and that the TTF method may seriously underestimate the true concentration of toxaphene.[24],[25] Because early and disproportionate peaks are eliminated from the quantification in the TTF method, it produces much lower PCC quantification results than those found using the U.S EPA approved Contract Laboratory Program (CLP) analytical method. The U.S. EPA Region 4 Environmental Services Division Laboratory analyzed split samples by the TTF method and a contracted laboratory by the U.S. EPA approved CLP method. Results showed that the TTF method either failed to detect PCC or only identified as little as 3.2% of the PCC present.[26]

Seafood samples collected in 1997 by the Georgia Department of Natural Resources, and analyzed by the Georgia Environmental Protection Division using the TTF method, were re-analyzed by the Skidaway Institute.[27] While PCC was not detected in any sample (n=56) using the TTF method, Skidaway detected PCC in every sample up to 26 parts per million (PPM). Even when the EPA "do not eat" levels of 0.5 PPM was exceeded by 52 times, PCC was reported as "not detectable" in fish by the TTF method.[28] The Food and Drug Administration (FDA) has a maximum allowable PCC level of 5 PPM in commercially caught seafood sold in the United States, until revoked in 1993.[29] In addition, in setting the FDA level, it makes the assumption that the seafood will be diluted in the Nation's food basket. The FDA also explicitly states that FDA maximum allowable levels are not to be applied to a seafood source consumed by the local population. The TTF method failed to find PCC at over five-times the FDA commercial level, yet commercial seafood harvest continues within the areas. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), food tolerance restrictions for toxaphene (PCC) range from 0.1 to 7 ppm. Therefore, the failure of the TTF method to detect toxaphene at levels meaningful to the protection of human health and the environment presents local health threats and may have national significance.

ATSDR evaluated the data produced by the TTF method and found many concerns over it use.[30] The TTF method failed to accurately identify and quantify a known amount of the PCC in the calibration standard. They found that the composition of the weathered PCC in fish differs from that in the technical-grade PCC, and the PCC adsorbed on soil may have a different bioavailability than technical-grade PCC. In addition, the TTF method seems to eliminate the option to conduct a total area method that estimates the PCC concentration from all peaks in the

chromatogram.[31] The ATSDR concluded that the use of the "back half" peak method (TTF method) is likely to result in significant underestimation of PCC concentration, and the estimated dose could be 10 times higher if historical data are taken into account for dose estimation.[32] ATSDR recommended that sensitive and specific methods, such as electron capture negative ion mass spectrometry (GC-ECNIMS) be used for the evaluation of toxaphene in fish and sediment.

Local, State, and Federal health officials depend on PCC data from the EPA, EPD, and Hercules Incorporated, in preparing remedial plans and making recommendations to potentially exposed citizens around contaminated areas. In addition, the Georgia EPD will NOT make a consumption recommendation without data.[33] An analytical method that fails to find the chemical of concern or that seriously understates the actual levels present fails to protect human health. Bad data leads to bad decisions and recommendations by local, State, and Federal officials that result in health threatening exposure of the citizenry. The integrity of the Nations food basket is compromised by flawed analysis that allows contaminated seafood to be harvested and sold.

Corrective action plans required by the EPA and EPD are promulgated on protection of human health and the environment. Remedial actions that are based upon faulty or inaccurate data will fail to fulfill the intent of the law, which is to protect human health. Any analytical method that fails to find the chemical(s) of concern (COC) at levels meaningful to the protection of public health is a threat to public health. When a method is represented to be accurate at levels meaningful to public health and fails to detect COC's, and the COC is reported as not present, public health is jeopardized by the false belief that the seafood, soil, water, or sediments are safe to consume or be exposed.

Conclusions

The Glynn Environmental Coalition (GEC) believes that the U.S. EPA, Georgia EPD, and Hercules have entered into an agreement that failed to identify and under reported PCC levels present. This agreement has led to data that is a threat to human health and the environment because health agencies are making seafood consumption and soil, sediment, and sludge exposure recommendations based upon flawed data. In addition, remedial actions by the U.S. EPA and Georgia EPD will not be protective of human health and the environment because cleanup levels will not accurately reflect true levels of PCC present.

Recommendations

The GEC is seeking the following remedy for PCC sampling that has not produced data meaningful to the protection human health .

1.) Order that all future PCC analysis and quantification be done using Gas Chromatography with Electron Capture and Electron Capture Negative Ionization Mass Spectrometric Detection (GC-ECD and GC-ECNI-MS) for environmental samples such as fin- and shellfish or other biota, soil, sediment, sludge, and water.

2.) Order that all analysis and quantification report "total" PCC levels present.

3.) Order sampling, analysis, and quantification of PCC by GC-ECNI-MS in all areas and media previously analyzed and quantified by the TTF method in Brunswick, Glynn County, Georgia.

Prepared by Daniel Parshley, Project Manager

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Attachment B

EPA Toxaphene Testing Method Found Inappropriate

Overview

The Environmental Protection Agency's Office of Inspector General recently issued a report entitled "Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site, Brunswick, Georgia" dated September 26, 2005. This document, developed by EPA's Ombudsman, refutes Region 4 EPA's methods for analyzing toxaphene at the 009 Superfund Site and the Terry Creek Disposal Superfund Site, and at other areas around Glynn County, Georgia. Nearly 15 years of data collected on soil, air, water and biological samples tested in Brunswick are now in doubt.

Each department in the United Sates administration has an Inspector General office to provide oversight for the agency. Several years ago the Glynn Environmental Coalition formally requested an investigation on items ranging from toxaphene testing in Glynn County to questions regarding lack of compliance in the cleanups in Brunswick. This first report mainly investigates the issue of toxaphene analysis. The Office of Inspector General has concluded that the methods used by Region 4 have not and could not precisely determine the form of toxaphene found in Glynn County.

Background

The 009 Superfund Site is a former road construction borrow pit refilled with waste from pesticide manufacturing at Hercules Inc. Toxic sludge, off-grade product, and contaminated soil were deposited into the pit, some of which was below the water table at least part of the year. Although the Record of Decision—the legally mandated cleanup goals for the site--stated that all contaminated soils above 76 parts per million (ppm) would be stabilized *in situ*, the EPA allowed a much simpler cleanup of merely covering the waste with a soil/cement mixture using above-ground mixing techniques. At question are the legalities of changing cleanup plans without seeking community input, and whether or not the cleanup achieved any of the goals of the original Record of Decision.

The Terry Creek Disposal area is a marshy region at the confluence of Terry and Dupree Creeks in Glynn County that receives industrial runoff from the Hercules plant. Decades of dumping into the creek system and a series of dredging operations widely distributed toxaphene within the marshes. The main issue at this site is if toxaphene is accurately measured in seafood since the area is part of the local fishery.

In addition to the EPA regulated sites, "toxaphene-like" substances were found in the soils of local public schools and other public and private properties. Based on this Report by the EPA Ombudsman, these "toxaphene-like" materials are toxaphene congeners subject to EPA regulation. Overall, there is the major question of whether or not the EPA permitted testing giving false data on toxaphene. There are many scientific studies showing toxaphene can be measured more accurately than the techniques used by EPA in Glynn County.

Toxaphene and its breakdown products are poisons, mutagens, possible cancer agents and they do bioaccumulate.

Toxaphene

Internationally recognized scientific studies show there are usually three different types of toxaphene: technical, weathered and biological. Technical toxaphene is the type made at the factory and sold worldwide for agricultural pest control. Technical toxaphene is not one chemical, it is a mixture of about 200 different chemicals produced by adding chlorine to camphene, a chemical made from tree resin. Different manufacturing processes produce slightly different mixtures. Although the chlorination of camphene can produce any of about 600+ different chemicals (called congeners) most technical grades have about 200 chemical congeners. Weathered toxaphene occurs after toxaphene is used. Environmental processes such as air drying, sunlight and bacteria degrade toxaphene. Since each of the more than 200 chemicals in technical toxaphene breaks down differently, weathered toxaphene varies in the types of chemicals present. Some chemicals appearing in weathered toxaphene are not found in the original technical grade of toxaphene, but they are still some of the 600+ different types of chlorinated camphenes, they are just produced from technical toxaphene by environmental processes. Biological toxaphene occurs when plants and animals absorb toxaphene from the environment. Every bacteria, plant, or animal has a different ability to absorb toxaphene congeners. Fish tissues have a different set of toxaphene chemicals from humans. Some toxaphene congeners are found often and in high concentrations (a process known as bioaccumulation), other congeners rarely occur in animal tissues. Biological toxaphene is very different from technical toxaphene, but all of the compounds found in biological toxaphene are still members of the same set of 600+ congeners found in toxaphene.

Note that Glynn County, Georgia has a fourth and fifth type of toxaphene. Off-grade product, material that was not toxic enough to sell, and residue from manufacturing, were dumped locally both in the 009 landfill and into Terry Creek. This material was not the same as technical toxaphene, but was still toxic, mutagenic and potentially carcinogenic. It is only found near the sites of manufacture, such as Brunswick, Georgia. Off-grade product toxaphene and manufacturing residue toxaphene will still weather and bioaccumulate, just like technical toxaphene.

Types of toxaphene measurements

All of the methods for analyzing toxaphene use gas chromatography or “GC.” GC separates all 600+ possible toxaphene compounds so that they can be seen and measured. There are several different measurement methods and technologies.

Total Area Method

This is the basic method required by the US EPA for chemicals with multiple congeners. It detects technical, weathered and biological grades of toxaphene, as well as the off-grade product and manufacturing residue forms. Basically, all of the possible toxaphene chemicals are detected and added together to quantify total toxaphene. This method was not used by the EPA in Brunswick, Georgia, but is used at other EPA sites in the United States and by other governments and researchers around the world.

Toxaphene Task Force Method

This method was developed by EPA Region 4 in Atlanta, Georgia, with Hercules Inc., and the State of Georgia. While gas chromatography is still used, only a few of the chemicals specific for

technical toxaphene are used in the analysis. Even if other toxaphene chemical congeners are present, they are ignored. The toxaphene task force method (known as EPA Method 8081) detects technical grade toxaphene as well as the total area method; however 8081 does not detect all off-grade products, does not detect some forms of manufacturing residue toxaphene, and can only detect weathered toxaphene in the first few years after placing in the environment. The TTF method does not detect toxaphene after it has been in the environment for several years, and it does not detect biological toxaphene. The TTF method is apparently used only in Glynn County Georgia and nowhere else in the world. The method is not recognized by other governments or by researchers as a useful method because it under-reports the actual toxaphene concentration.

GC negative ion mass spectroscopy

This technique, called the NIMS method, can detect all forms of toxaphene and is a widely respected method with a high degree of scientific merit regarding interpretation of results. It is especially useful for detecting biological forms of toxaphene accumulation. This is the method favored by the EPA Inspector General. NIMS is still not approved by the EPA.

Discussion

Quoting from page 5 of the Ombudsman's report section titled **"EPA's Method Fails to Identify Toxaphene Breakdown Products in Groundwater"**: *"… the groundwater monitoring data collected at the site, using EPA's method, only identified the original toxaphene mixture in the groundwater."* Further, same page: *"When the OIG looked at the groundwater monitoring data for evidence of toxaphene breakdown products, the OIG found some evidence suggesting toxaphene breakdown products may be in the groundwater surrounding the Hercules 009 Landfill Site."*

In Appendix A of the report the OIG shows by example chromatograms and states, in the section titled **"EPA Method 8081 Does Not Identify Toxaphene Degradation Products"**: *"…EPA Method 8081 fails to detect toxaphene degradation products (i.e., "weathered" toxaphene or individual toxaphene congeners) in environmental samples."* Method 8081 is the method produced by Region 4 EPA's Toxaphene Task Force using the subset of toxaphene congeners.

The Ombudsman report also notes that EPA is required to monitor toxaphene degradation products. On page 21 in the section titled **"Superfund's Remedy Requires the Evaluation of Toxic Degradation Products"**: *"Therefore, the Superfund's MNA [Monitored Natural Attenuation] guidance requires EPA to anticipate and to test for the presence of potentially toxic degradation products at hazardous waste sites. Since toxaphene is known to degrade in the environment and these degradation products are thought to be toxic, EPA must evaluate the groundwater at the Hercules 009 Landfill site for toxaphene's degradation products…"*

The Ombudsman report noted other problems with the conduct of sampling by the EPA in Brunswick. An addendum to the report discussed potential problems with the cleanup of environmental samples using sulfur, and a second problem with heat settings on the instrument. Sulfur can interfere with the analysis, some instrument temperature settings fail to detect toxaphene. In combination with the inability of methods used by EPA to quantify weathered toxaphene, the potential biases of the cleanup and column temperature means that much of the data used by EPA to design and verify Superfund cleanups are doubtful.

The Report also cites comprehensive toxicology and body burden studies on toxaphene congeners conducted at a variety of laboratories. Notable among these is the MATT study (Investigation into the Monitoring, Analysis and Toxicity of Toxaphene in Marine Foodstuffs, 2000) describing the bioaccumulation of specific toxaphene environmental end-products in commercial fish species. EPA Region 4 should have been aware of these studies—it is their responsibility to follow the scientific literature. Region 4 should have responded to the growing body of literature regarding toxaphene years ago. In addition to criticizing toxaphene analysis the OIG report also faults EPA on lack of timely reporting, failure to make key decisions, and notes unacceptable modifications to "independent" third-party reviews before release to the public.

Concluding Remarks

For more than a decade EPA Region 4 used the toxaphene task force method (EPA Method 8081) in Glynn County despite research showing the method does not give valid data on environmental toxaphene. At this point it is not clear if cleanups at the 009 landfill and Terry Creek Outfall meet the legal remediation goals. It is not clear because EPA has used an unreliable method that cannot measure the types of toxaphene found in water and soil.

It is fair to say much of the data on toxaphene occurrence and exposure is "inconclusive" for samples taken in Brunswick and tested by method 8081. Not all of the thousands of samples examined so far are in error—obviously many observed both technical toxaphene and some forms of weathered toxaphene. However, virtually all of the groundwater and soil samples need retesting to verify the presence or absence of weathered toxaphene.

EPA is proposing developing new methods using the NIMS method advocated by the Inspector General. While there may be some debate over methods, one thing is crystal clear: EPA Region 4 should not be the agency to produce and validate any new toxaphene method. The Atlanta, Georgia EPA office is far too biased to be trusted with developing toxaphene methods.

Written by R. Kevin Pegg, Ph.D.; edited by Dr. Mary S. Saunders. Copies of the newsletter are available from the GEC, at the Glynn County library, or at **www.enviro-issues.net** on the Internet.

HERCULES LANDFILL SUPERFUND SITE
TECHNICAL ASSISTANCE REPORT

"This project has been funded wholly or partly by the U.S. Environmental Protection Agency under Assistance Agreement Number V994050-92-0 to The Glynn Environmental Coalition, Inc. The contents of this document do not necessarily reflect the views and policies of the U.S. Environmental Protection agency, nor does mention of trade names or commercial products constitute endorsement or recommendation for use."

Volume 14, Number 1, October 2005

Attachment C

September 7, 2006

Glynn Environmental Coalition
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Paul D. McKechnie, Director Public Liaison/Acting Ombudsman
U.S. EPA, Office of Inspector General
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Boston Sub Office
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Boston, Massachusetts 02114-2023

Re: Comment from the Glynn Environmental Coalition on the June 20, 2006, EPA Region 4, Final Response to the Recommendations and Final Report for the Hercules 009 Landfill OIG/Ombudsman Report *Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site Brunswick, Georgia* (Report 2005-P-00022, September 26, 2005); Assignment 2004-124.

Mr. McKechnie,

Enclosed, please find comments from the Glynn Environmental Coalition (GEC) on the June 20, 2006, Environmental Protection Agency (EPA) Region 4, Final Response to the Recommendations and Final Report for the Hercules 009 Landfill OIG/Ombudsman Report *Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site Brunswick, Georgia* (Report 2005-P-00022, September 26, 2005); Assignment 2004-124. We trust the EPA Office of Inspector General will take the following comments into consideration in formulating the final OIG response to EPA Region 4.

The enclosed comments include reviews of the EPA Region 4 Response by R. Kevin Pegg, Ph.D., and Kathleen Burns Ph.D., and are included in the GEC comments by reference.

Sincerely,

Bill Owens, President

CC: Chris Baughman

Enclosures

Comments from the Glynn Environmental Coalition on the June 20, 2006, Environmental Protection Agency Region 4, Final Response to the Recommendations and Final Report for

the Hercules 009 Landfill OIG/Ombudsman Report *Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site Brunswick, Georgia* (Report 2005-P-00022, September 26, 2005)

September 7, 2006

1. The OIG identified under quantification of chlorinated camphene as a problem at the Hercules 009 Landfill Superfund Site, and numerous other sites across the nation. Even when chlorinated camphene was present, the TTF method either reported none present or only quantified a small amount of the chlorinated camphene compounds indicated by the chromatogram. The question that MUST be answered is, "Will all chlorinated camphene present in environmental samples be identified and quantified?

Environmental sampling and analysis data is used to protect human health and the environment, and the same data will be used by several different scientific disciplines. Toxicologist produce health and risk assessments, biologists evaluate environmental risk to micro to macro biota, and remedial plans are developed to protect human health and natural resources. At a minimum, all chlorinated camphene MUST be reported in environmental samples. Neither the OIG nor the EPA Region 4 Response evaluated their recommendations and conclusions against the scientific disciplines that will be utilizing the data set from sites contaminated by chlorinated camphene or toxaphene manufacturing wastes.

2. The EPA Region 4, Final Response to the Recommendations and Final Report for the Hercules 009 Landfill OIG/Ombudsman Report (Response) *Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site Brunswick, Georgia* (OIG Audit) constitutes a refusal to implement the recommendations in the OIG Audit, and misrepresents the finding of the OIG.

In the OIG Audit, specific recommendations were made for the quantification of chlorinated camphene.

> *"The OIG believes that spiked sample recoveries of the individual toxaphene congeners of interest, such as Hx-Sed, Hp-Sed, p26, p50, and p62, should be incorporated into any NIMS method considered by the EPA for developing and validating."*
>
> *"EPA needs to use a congener-specific analytical method (e.g., GC/NIMS) to positively identify and quantify toxaphene degradation products in the environment. The OIG highly recommends standardizing and validating the GC/NIMS method and inserting a EPA GC/NIMS method into SW-846."*

Contrary to the OIG Audit recommendations, EPA Region 4 has proposed chlorinated camphene quantification and risk assessments be based solely on p-26, p-50 and p-62 congeners and that all other compounds be excluded from the quantification and risk assessment process. As the OIG noted, Hx-Sep and Hp-Sed congeners account for the majority of chlorinated camphene found in Glynn County, Georgia. Even though the OIG identified the need for more toxicological data on the Hx-Sep and Hp-Sed congeners, EPA Region 4 has proposed elimination of these from the quantification and risk assessment process without presenting data in support of this conclusion. To the contrary, Hx-Sep and Hp-Sed congeners are the most prominent and represent a significant risk to citizens of Glynn County due to the chronic exposure via seafood, soil, and air.

The OIG noted that there are deficiencies in the studies used to determine the toxicity of chlorinated camphene, in that the exposure periods were short and did not represent the extended period of exposure (1948 to 2006) of those living in Glynn County. Further complicating the reaching of any conclusions is the lack of data about the chronic exposure to metabolites produced during human elimination of chlorinated camphene over the duration of exposure experienced in Glynn County, which is where chlorinated camphene was manufactured from 1948 to 1980. In addition, the majority of the data relied upon by the OIG and EPA Region 4 was from populations and food stuffs that derived chlorinated camphene levels from atmospherically distilled chlorinated camphene, which does not contain the same ratio of congeners as in Glynn County. Atmospherically distilled chlorinated camphene is very different than Glynn County where manufacturing wastes, off-grade product, and product were dumped into Glynn County estuaries, landfills, dumps, and fugitive emissions from the Hercules Plant into surrounding neighborhoods.

3. EPA Region 4 has structured their entire Response to the OIG Audit around the Simon and Manning article to the exclusion of the many studies about chlorinated camphene and its toxicological effects. EPA Region 4 contends: *"The OIG introduced the Region to the MATT report as the sole information on the toxicity of weathered toxaphene."*
For EPA-Region 4 to represent that the OIG did an exhaustive search of the scientific articles published concerning the toxicological properties of chlorinated camphene is a gross misrepresentation. Even more egregious is for EPA Region 4 to represent that the OIG stated there is only one scientific article concerning weathered toxaphene. Still, EPA Region 4 has claimed that the MATT study is the toxicology model, and used it as their rationale for their Response and the Simon and Manning study.

4. The proposed toxaphene quantification method using only p-26, p-50 and p-62 congeners that is proposed by EPA Region 4 is a re-packaging of the Toxaphene Task Force (TTF) method and will result in a larger under quantification of chlorinated camphene than the TTF method.
The OIG identified the TTF as an inappropriate analytical method since it failed to identify and quantify chlorinated camphene. The OIG found the TTF method was estimated to report as little as 10% of the actual levels of chlorinated camphene present, failed to identify or report Hx-Sed and Hp-Sed chlorinated camphene, and relied only on the latter peaks for quantification, which resulted in a gross underreporting of the actual levels of chlorinated camphene present. The toxicologist with the Agency for Toxic Substance and Disease Registry (ATSDR) noted that use of the "back half" peak method (TTF method) is likely to result in significant underestimation of PCC concentration, and the estimated dose could be 10 times higher if historical data are taken into account for dose estimation. [i] The OIG interview with Dr. Keith Maruya for the Hercules 009 Landfill Superfund Site Five-Year Review resulted in an estimation of toxaphene levels up to 10 times higher than reported by the TTF analytical method. The three congeners proposed for quantification use - p-26, p-50 and p-62 - are located in the latter area, or back-half, of the chromatogram and will exclude Hx-Sep and Hp-Sed chlorinated camphene, which the OIG identified as being important to quantify.

5. Neither the OIG or EPA Region 4 provide toxicological data in support of excluding all chlorinated camphene congeners, other than p-26, p-50 and p-62, from consideration in risk assessments. Sites in Glynn County contain chlorinated camphene manufacturing wastes, off-grade product, and decades of releases into the estuary, landfills, dumps, in

addition to fugitive emissions from the Hercules Plant into nearby neighborhoods. The arguments presented by the OIG and EPA Region 4, that are based upon seafood data, are not relevant when the underlying data is examined and compared to actual conditions present in Brunswick, Glynn County, Georgia. The following comments explore the inconsistencies in the OIG and EPA Region 4 reasoning that led to the conclusion that only p-26, p-50 and p-62 congeners are relevant to the protection of human health and environmental resources in Glynn County.

6. EPA Region 4 stated in their Response, "At this time, the Region considers Simon/Manning as the authoritative article on the toxicity of the degradation products. It focuses on p26, 50, and 62."
Since EPA Region 4 has declared the "…Simon/Manning as the authoritative piece on the toxicity of the degradation products," the article should be closely examined for its adherence to the principals of scientific investigation and reporting. The GEC also asked for other recognized authorities on chlorinated camphene to review and comment on the arguments presented, data and studies used to construct arguments and conclusions, and the quality of the scientific investigation conducted by the authors. The GEC submits the following comments concerning the Simon and Manning article as additional comments to those solicited from experts in their field.

7. The quantification method proposed by EPA Region 4 will report between 1.56% and 8.69% of the chlorinated camphene present, according to the Simon and Manning article.
Failing to quantify between 91% and 99% of the chlorinated camphene present in environmental samples results in a significant and unacceptable degree of uncertainty for any risk assessments produced with the data. Simon and Manning quantified chlorinated camphene congeners p-26, p-50 and p-62 in fish that were exposed by two very different routes, which resulted in very different ratios of congeners, and therefore, very different risk potentials.

8. Dumped Chlorinated Camphene Exposure Route (Simon and Manning, Table 7)
In the seafood samples from the Terry Creek Dredge Spoil Areas/Hercules Outfall Site in Brunswick, Georgia, exposure was from chlorinated camphene manufacturing wastes and chlorinated camphene that was dumped directly to Terry Creek from 1948 to 1970, and additional discharges from residual chlorinated camphene in the Hercules Plant soils, in excess of 8%, continue in 2006. When p-26, p-50 and p-62 congeners were measured in seafood, they ranged from 1.56% to 8.69%, and the average was 4.80%. The p-26, p-50 and p-62 congeners are not the most prevalent in Brunswick, Georgia, and are inappropriate for use as chlorinated camphene indicators.

9. Atmospherically Distilled Chlorinated Camphene Exposure Route (Simon and Manning, Table 6)
Both the OIG and EPA Region 4 relied heavily on the MATT Report[i] for their reasoning and conclusions regarding toxicity. The MATT study investigated levels of chlorinated camphene congeners in seafood exposed by chlorinated camphene that had been atmospherically distilled and transported, which resulted in a very different ratio of chlorinated camphene congeners with very different risk potentials than the ratio of congeners found in Glynn County, Georgia. Individual chlorinated camphene congeners will volatilize and precipitate differently, depending upon the congener's specific chemical properties and atmospheric variables. The result of this atmospheric distillation is selective transport and selective precipitation of individual congeners.

The range of p-26, p-50 and p-62 congeners found in fish exposed via atmospherically distilled chlorinated camphene ranged from 8.02% to 58.05%, and averaged 22.45%.

The MATT study selected the -26, p-50 and p-62 congeners for analysis because it had previously been determined that they were the most prominent in the seafood from the area being studied. The prominent chlorinated camphene congeners in manufacturing wastes in Glynn County are very different, with Hx-Sed and Hp-Sed being the most prominent. Simon and Manning fails to conduct any analysis of what congeners are appropriate for areas contaminated by manufacturing wastes.

10. Dioxin is a component of chlorinated camphene manufacturing wastes and must be taken into consideration when planning sampling, analysis, and risk assessments. Simon and Manning ignores the known additional toxicological properties of chlorinated camphene manufacturing wastes. Chlorinated camphene manufacturing wastes contain their own unique composition of congeners, compounds, and contaminants that must be considered when evaluating risk to human health and the environment. The simplistic approach to chlorinated camphene identification, quantification, and risk assessment presented by Simon and Manning will pose a significant threat to human health and the environment.

11. The use of p-26, p-50 and p-62 congeners is used as an indicator of chlorinated camphene in areas where they are the primary congeners. The primary analytical use of p-26, p-50 and p-62 congeners is as an indicator of chlorinated camphene and not as an quantification or risk assessment tool. [i] The MATT study found relevance in the p-26, p-50 and p-62 congeners only because exposure is exclusively from seafood exposed to atmospheric distilled chlorinated camphene, which results in higher percentages and ratios of the three congeners in northern climates.

12. The range of p-26, p-50 and p-62 congeners vary widely in seafood so total chlorinated camphene is measured for toxicological evaluations. The range of chlorinated camphene congeners can range widely, but as a rule, the higher in the northern latitudes the seafood was obtained, the greater the percentage of p-26, p-50 and p-62 congeners. The use of p-26, p-50 and p-62 congeners is less useful as an indicator for seafood from southern latitudes. [i] Total toxaphene is measured when a risk assessment is being conducted. [i] Tables 6 and 7 in the Simon and Manning paper demonstrate the significant decrease in p-26, p-50 and p-62 congeners in Glynn County, which has been noted in other studies.

13. The comparison of seafood exposed to dumped versus atmospherically distilled chlorinated camphene is inappropriate. Simon and Manning violate the basic principles of scientific investigation by drawing conclusions between dissimilar data sets, and failed to report that the route of exposure of the seafood in the data sets were vastly different. This omission invalidates all conclusions derived. The injection of so many variables, and the failure to report these variables, draws into questions the conclusions reached by Simon and Manning. A review of literature would have revealed that use of p-26, p-50 and p-62 congeners is inappropriate for southern latitudes.

14. Failure of Simon and Manning to report variables such as mode of exposure in the data sets that were compared, and failure to report the ratio of all chlorinated camphene congeners present in seafood Tables 6 and 7 undermines the article to the point that no

conclusions can be reached, nor should the premise presented for risk assessments be utilized. The failure to follow basic scientific investigative techniques and report variables in the data set renders the conclusions and recommendations unusable. If the Simon and Manning method of chlorinated camphene quantification and risk assessment is implemented, it would present significant risks to human health and the environment.

15. As manufactured, chlorinated camphene contains over 800 different chemicals that are found in different ratios depending on the source, latitude, and other environmental factors. Reducing toxaphene quantification and risk assessment to only p-26, p-50 and p-62 congeners ignore these environmental factors and the variables that need to be taken into consideration when conducting human and environmental risks assessments, and remedial decision-making. Environmental sampling should, at a minimum, report all chemical compounds present in the environment. There is no scientifically sound reason for not reporting chemicals present in the environment.

16. Simon and Manning appears to be written as an advocacy of limited testing at the other Sites in County that received chlorinated camphene manufacturing wastes, off-grade product, and other residues of the manufacturing process. These Sites represent significant exposure routes via air, soil, and different congener ratios that are not normally encountered outside of communities where chlorinated camphene was manufactured. All major exposure pathways and sources need to be identified, but the OIG failed to do so in the Audit, and incorrectly speculates that air and soil exposure are practically negligible when stating:

> *"In general, a major factor needed to evaluate the level of risk to human health is to determine the major exposure pathways to toxaphene's degradation products and to determine all potential sources. The Hercules 009 Landfill site is just one off the potential exposure routes. …The remaining exposure routes (i.e. air and soil are practically negligible)."*

While local fish consumption is a very significant risk factor, chlorinated camphene levels higher than at the 009 Site are spread throughout the community. The following sources of chlorinated camphene should be considered by the OIG before discounting other significant chronic exposure routes and considering the implication presented in the EPA Region 4 Response:

- Hercules Plant: chlorinated camphene levels in the plant site soils exceed 8% and are a significant air and soil exposure risk, via wind blown dust and erosion.
- Areas surrounding the Hercules Plant: chlorinated camphene was found above 64 ppm on an elementary school playground. Significant source areas are suspected to be present in neighborhoods surrounding the Hercules plant site.
- Terry Creek Site: Between 2 and 3 million pounds of chlorinated camphene manufacturing wastes are estimated to have been released into the estuary, some of which is in dredge spoil areas that are a potential air exposure source.
- Chlorinated camphene was reported to be disposed of in the T Street Dump that is located in the estuary, 4th Street Landfill next to the Glynn Schools Stadium, and Old Sterling Landfill.
- Hercules has taken depositions from workers concerning distribution of toxaphene to employees, purchase by Glynn County Parks and Recreation, and Glynn County Schools for use throughout the community.

17. The GEC agrees that compounds that bioaccumulate need to be identified, but applying chlorinated camphene congeners relevant in Europe and northern latitudes to Glynn County that is located in a southern latitude is inappropriate. The OIG and EPA Region 4 erred by focusing on congeners in fish from northern latitudes that are not relevant to the chemicals of concern at chlorinated camphene contaminated Sites in Glynn County. The OIG took an inappropriate leap of logic when writing:

> *"However, five toxaphene congeners (i.e. p26, p50, p40, p41, and p44) are not readily metabolized and excreted and, thus, can accumulate in the human body. … To evaluate the level of risk to human health, EPA needs to know the concentration of these five congeners and their metabolite precursors in the environment."*
>
> *"Since these five toxaphene congeners represent the long-term chronic toxaphene exposure problem to humans, the toxicity of these five individual congeners and/or mixture of these five congeners needs to be determined in more detail than is currently available in the scientific literature"*

Even though the conclusion of the OIG might be appropriate in another situation, the basis of the logic and underlying data from a dissimilar area that formed the rationale is not appropriate for chlorinated camphene manufacturing sites and areas that received the wastes.

The GEC agrees that there should be concern about these five congeners and more information would be desirable, but the entire chlorinated camphene manufacturing waste mixture is of concern for long-term chronic exposure in Glynn County. As the OIG noted, the toxicology of chlorinated camphene is not well understood, and even less so for manufacturing wastes . The OIG presents no data in support of ignoring the other 800-plus compounds in the chlorinated camphene mixture manufactured by Hercules, or the manufacturing wastes.

The inherent weakness of considering only persistent congeners found in fish from northern latitudes, as borne out in the discussion of Dr. Olson's study, is that short term exposures can have profound effects on offspring. The exposure duration during the study was not long enough to produce effects attributable to bioaccumulation. Potential endocrine disruption by chlorinated camphene compounds or metabolites must remain under consideration as toxic components, as well as other potential adverse health effects noted in the ATSDR Toxicological Profile for Toxaphene. Synergistic effects of the chlorinated camphene compound in Glynn County could be much different than those noted in studies since both chlorinated camphene and manufacturing wastes are the chemicals of concern. Dioxin produced during chlorinated camphene production could significantly increase the cancer potential of the chemicals present in Glynn County toxic sites.

18. Dr. Gill's and Dr. Barr's studies discussed by the OIG are interesting, but the OIG failed to note that the source was airborne chlorinated camphene transported to Canada in Dr. Gill's study and the general population in Dr. Barr's study, and not exposure to PCC and manufacturing waste products. The same mistake was repeated in the EPA Region 4 Response and by Simon and Manning. Sampling of the local Glynn County population will be needed to confirm any applicability between the results Dr. Gill and Dr. Barr presented and the very different situation that exists in Glynn County. By no means should the need for additional

studies or information be used as an excuse not to take action to protect the citizenry of Glynn County from widely distributed chlorinated camphene and manufacturing wastes.

19. The OIG made specific recommendations about which chlorinated camphene congeners should be identified and quantified. The EPA Response limits the selection of congeners to only those in the back-half of the chromatogram window, which is a repackaged version of the Toxaphene Task Force method that will quantify even less of the chlorinated camphene present. Interestingly, and borne out in the OIG audit and the Simon and Manning paper, the p-26, p-50 and p-62 congeners are not prevalent in Glynn County. The OIG's report recommended the following, which includes the prominent congeners, in addition to identification of all chlorinated camphene in the environment.

> *"Since toxaphene is known to degrade in the environment and these degradation products are thought to be toxic, EPA must evaluate the groundwater at the Hercules 009 Landfill site for toxaphene's degradation products, specifically, the Hx-Sed and Hp Sed congeners, but also the p26, p50, p40, p41, and p44 congeners."*

20. The OIG made sweeping conclusions about which compounds in the chlorinated camphene mixture manufactured by Hercules are of toxicological concern based upon data from fish from northern latitudes, and made inappropriate recommendations concerning chlorinated camphene analysis to a few selected compounds. The EPA Response seized upon the congeners and studies identified by the OIG to craft a more limited chlorinated camphene congener quantification and analysis presented in the Simon and Manning paper.
The OIG previously stated:

> "*Conducting a detailed and comprehensive risk assessment for the potential exposure to toxaphene from the Hercules 009 Landfill site is a complex task that is beyond the scope of this OIG review."*

The sweeping recommendations for limited congener analysis do require a comprehensive health assessment and evaluation of literature far greater in scope than presented in the OIG Report or the Simon and Manning paper. At a minimum, ATSDR and natural resource trustees should review any proposed analysis, quantification, and risk assessment procedures for chlorinated camphene. The OIG should clearly recommend that all chlorinated camphene and degradation products will analyzed, identified, and reported in samples from Sites in Glynn County.

21. The OIG identified the need for further research into carcinogenicity and embryotoxicity, but the scope of the research should not be limited to congeners that are not relevant to the chlorinated camphene and manufacturing wastes present in Glynn County. The toxicology of chlorinated camphene is not well enough understood to limit the scope of research at this time, and the toxicology of chlorinated camphene degradation products is even less understood. Regardless of any recommendations for further research, measures should be taken to determine the current human health risks through appropriate testing and the precautionary principle applied until research results are produced, reviewed, and published in a recognized peer reviewed scientific journal that are relevant to the chlorinated camphene congeners and manufacturing wastes present in Glynn County.

22. Glynn County has been identified by the Georgia Department of Human Resources, Division of Public Health, as an area with an incidence of disease above the State of Georgia and National averages, which is noteworthy. Glynn County demographics indicate that the majority of African Americans live in the areas most contaminated by chlorinated camphene and subsistence fish in areas conatminated by chlorinated camphene. The following health facts should be considered when evaluating chlorinated camphene exposure in Glynn County:

- Childhood leukemia mortality rate in all black males is twice the Georgia average, 14.1769 in Glynn County, compared to 7.6755 in Georgia per 100,000. Childhood leukemia rates are higher in Glynn County for all demographic groups than the Georgia Average.
- Adult lymphoma rates in Glynn County are higher for all demographic groups, except white females.
- All cancers, chronic obstructive pulmonary disease, and liver disease in Glynn County are higher than the national averages. **The liver is a known target organ of chlorinated camphene.**
- Infant mortality and low birth weight rates are higher in Glynn County than national rates.
- The Georgia Department of Human Resources, Division of Public Health has identified Glynn County as having a significantly higher incidence of cancer than the state rate.

23. Children attending schools located next to chlorinated camphene contaminated areas show decreased IQ scores that increase with age. As noted in animal studies, chlorinated camphene has been demonstrated to cause developmental delays. School children attending schools near chlorinated camphene contaminated sites in Glynn County scored lower than children attending other schools. IQ should remain a constant, but as the children grew older the IQ scores rose, which indicates an environmental factor delaying learning potential. Further study is needed of the population that has been chronically exposed for several generations to chlorinated camphene and manufacturing wastes, including impacts to offspring and learning potential.

[1] Health Consultation - Terry Creek Dredge Spoils Areas/Hercules Outfall Brunswick, Glynn County, Georgia. Agency for Toxic Substance and Disease Registry. December 7, 1999.
[2] MATT, 2000. Final Report, Investigation into the Monitoring, Analysis and Toxicity of Toxaphene in Marine Foodstuffs FAIR CT PL.96.3131.
[3] Oetjen, K., H. Karl, Levels of toxaphene indicator compounds in fish meal, fish oil, and fish feed. Chemosphere. July, 1998.
[4] Oetjen, K., H. Karl, Levels of toxaphene indicator compounds in fish meal, fish oil, and fish feed. Chemosphere. July, 1998.
5 Chan, H. M., F. Yeboah. Total toxaphene and specific congeners in fish from the Yukon, Canada. Chemosphere. August 2000.

Attachment D

Review and Comments on the paper "Development of a reference dose for the persistent congeners of weathered toxaphene based on in vivo and in vitro effects related to tumor promotion" by Simon and Manning[i]

This article seeks to redefine environmental toxaphene monitoring by using only tumor promotion as the effect of toxaphene exposure. Further, the authors propose using only three of the several hundred compounds that make up toxaphene as indicators of toxaphene in all media. The paper provides no new experimental observations, no new survey data, and no new calculation algorithms. Instead, the authors use a subset of toxaphene publications to support their views.

The Simon and Manning paper defines toxaphene as all of 800 different chemicals possible for the chlorination of camphene. We concur with this description, as Hercules Incorporated, the manufacturer of toxaphene, stated in their original patent that toxaphene is random chlorination of a nonspecific mixture of camphenes derived from pine stump tar. None of the toxaphene in the environment was ever produced from site specific chlorination of a defined organic carbon skeleton. In just the sixth line of the first paragraph of this paper the authors clearly state that Technical Toxaphene (or "TT") "…consists of a mixture of up to 800 different chemicals…" In the third paragraph the authors offer definitions for Technical Toxaphene (TT) and weathered toxaphene (WT), with weathered defined as degraded Technical Toxaphene. Since there are only about 800 possibilities for toxaphene congeners (the individual chemicals in toxaphene), and the authors have already stated that these make up TT, weathered toxaphene is just a form of technical toxaphene by their own definition. Their descriptions of TT and WT by no means form an inclusive list of the potential forms of toxaphene that may be encountered in the environment. Toxaphene manufacturing waste dumped in streams and borrow pits in Brunswick, Georgia, for example, is toxaphene by the definition in the sixth line of Simon and Manning. Further, the "toxaphene-like" compounds found on schoolyards and in neighborhoods throughout Glynn County, Georgia, also meet the definition of technical toxaphene as defined by Simon and Manning. Essentially, with this definition there is no need for any definition other than "TT" for toxaphene found anywhere on earth; and we concur with their definition.

Simon and Manning Model based on Tumor Promotion

Simon and Manning argue that toxaphene monitoring should be based solely on tumor promotion. The authors provided three arguments in support of their logic: lack of mutagenicity; lack of significant developmental defects; and, carcinogenicity.

Mutagenicity of Toxaphene

The authors' statements regarding toxaphene genotoxicity—the ability to cause genetic damage--in humans are confused and uncompelling. Two points in this regard: it is well-known that microbial studies on mutagenicity, chemically induced damage to DNA, are not directly transferable to humans; and animal exposure studies for lethal doses and minimal effects dose may not produce death or tumors in a manner similar to human physiology. Carcinogenicity, the formation of tumors, is a complex subject, typically, the process requires damage to cellular DNA, but not always, and some chemicals that participate in this process are promoters, not initiators, in the sequence of tumor formation. Since science cannot, at this time, always predict a chemicals' carcinogenicity, best practices require that, if any type of study points to potential

genotoxicity, then the material is presumed genotoxic until proven otherwise. The requirement for solid and substantial proof of the absence of a human effect is not found within the arguments of Simon and Manning.

The science proving that toxaphene is genotoxic in bacterial systems is compelling. TT is mutagenic in the Ames test, a widely-accepted bacterial test for quantifying DNA damage. Additionally, there are numerous other bacterial systems where toxaphene is proven to damage DNA. These studies have been reproduced in many laboratories. There is no ambiguity that toxaphene causes DNA damage.
There are two studies regarding chromosomal aberrations in humans cited by Simon and Manning. One was a study of eight field workers accidentally exposed to airborne toxaphene[i] from a spraying incident that found evidence of genotoxicity. A second study[i], examining agricultural workers who may or may not have been exposed from working around toxaphene, did not find evidence of genetic damage.

Visual damage to chromosomes, the organized complex of DNA and proteins within each cell visible during cellular division, is a good indicator of genotoxicity. Simon and Manning correctly note that toxaphene induces sister chromatid exchanges, one form of genetic damage. These studies have been repeated in numerous laboratories and show unequivocally that toxaphene is genetically active in mammalian cells. In reference to the agricultural workers, in both studies potentially exposed workers were monitored by drawing blood samples, separating the white blood cells into culture medium, and examining the rapidly dividing cells. Typically though, any damage or "aberrations" occur from acute injury at high chemical doses and only appear in blood cells for a brief period after exposure. Simon and Manning cite the inconsistency between the two field studies as proof there is ambiguity over toxaphene and chromosome damage. However, field studies of accidentally exposed workers are independent studies, not laboratory controlled studies, and each exists separate from the other. There are no correlations within the studies between toxin dosages; cohorts (age, sex, size, diet, etc.); there are unequal sample sizes; and no control on when and how chromosomes are derived from blood cells. Under these conditions the parameters are all variables; thus, one study cannot be used to refute the other as Simon and Manning have done. The absence of gross chromosomal aberrations in one field study cannot be used to refute the evidence of chromosome damage in other field workers exposed to high levels of toxaphene. Nor does the absence of gross chromosome aberrations in some exposed workers refute, disclaim, or render ambiguous the numerous SCE laboratory studies. Scientists have rules for comparing data sets; Simon and Manning ignored those rules to reach the conclusion they preferred.

Developmental Effects of Toxaphene
Both in *vitro* and *in vivo* (laboratory studies using isolated cells or whole animals respectively) show that toxaphene, and individual congers, cause developmental effects. There is no dispute among scientists that toxaphene changes the way organ systems develop in growing animals. Simon and Manning argue in section 2.1.2 of their paper that doses that induce developmental effects can be used as a not-to-exceed level for toxaphene in the environment. The authors did not provide a predictive model or calculation for this approach. Simon and Manning cite four references, two laboratory studies on toxaphene exposure in rats, and two studies on toxaphene levels in the blood plasma of Inuit women, in support of their dosages. We could not figure out, from the information provided, how they calculated safe dosages for toxaphene from the combination of these four monographs. That 100 ng/ml is useful as a reference for toxaphene in

the environment is a highly ambiguous claim by these authors, and it should be ignored without greater support from the literature.

Toxaphene and Cancer

Toxaphene is carcinogenic. In vivo studies show toxaphene causes cancer in laboratory animals. It is interesting and significant that Simon and Manning do not cite studies that show toxaphene is clearly carcinogenic. We restate these findings here:

"Two long-term carcinogenicity bioassays with toxaphene have been performed in rats and mice with both species showing a carcinogenic response."
"A statistically significant dose-related increased incidence of thyroid tumors (adenomas and carcinomas) was seen in both male and female rats."
"A statistically significantly increased incidence of liver cancer in treated animals was observed and was dose-related[i]*."*

The only question is whether or not toxaphene also causes cancer in humans. Simon and Manning offer no models or observations that disprove or prove a link between toxaphene and human cancer.

Existing models for cancer—including the types of carcinoma cited by Simon and Manning--involve a multi-step progression from normal cell to genetically damaged cell, followed by growth proliferation, followed by metastasis. The presumption is that carcinogenic compounds (mutagens and promoters) must be present at genotoxic levels at each stage of neoplasm initiation and promotion. There is also a presumption in cancer models that most cancer onset is a multi-year, and in many cases, multi-decade process. Further, it is a tenet of cancer modeling that there are genetic predilections for certain cancers within human subpopulations, and also genetic resistances to some cancers within racial and ethnic subgroups.

As already noted, toxaphene is mutagenic and, therefore, the potential to cause the mutations that lead to cancer is a possibility. Simon and Manning correctly note that toxaphene is a tumor promoter. Numerous studies using a variety of tools show that toxaphene acts to interrupt normal cellular communication, one definition of a tumor promoter.

After failing to cite data on mutagenesis and tumor production, Simon and Manning calculate an exposure value for tumor promotion based only studies in rats. They could only reach this point in their model by ignoring relevant science that refutes their hypothesis. The authors then further compound this error by citing toxaphene congener levels and the occurrence of breast cancer in Inuit women. The Inuit live in the circumpolar region and have a diet high in fish stocks.

Simon and Manning have incorrectly and unscientifically inferred that levels of toxaphene congeners observed in more recent times have always occurred. In fact, there is no data to indicate what toxaphene levels were in the past in the Inuit subpopulation, TT could have been higher or lower, historically. There is no way of determining present day TT-caused cancer levels based on initiation and promotion events in the past without knowing past exposure levels. For their model to have any relevance Simon and Manning must mistakenly presume the present levels occurred throughout recent history, and, further, there are implied assumptions in their argument that any model for human breast cancer would correlate with rodent models. Also,

Simon and Manning have tacitly argued that Inuit are as prone to any TT-induced tumors as the general population. That Inuit women have comparable rates of TT-induced cancers as compared to the general population is practically prophetic on the part of Simon and Manning. Inuits may be more at-risk, or less-at risk, based on dietary, environmental, or genetic factors. That the Inuits experience constitutes a proof of their model is an extraordinary claim that requires extraordinary proof, and Simon and Manning offer no proof.

∑3PC

Simon and Manning chose three of the several hundred toxaphene compounds to base testing for environmental toxaphene: p-26, p-50, and p-62. More data and field surveys are needed to determine if these three compounds are indicative of dietary fish residues. For aquatic food chain and rain deposition (atmospheric reflux) these compounds may indeed prove useful for monitoring food stocks, after more data has been collected and evaluated. However, to make the leap from blood plasma levels caused by eating contaminated fish caught near the Arctic Circle, to soil cleanups in the southeastern US, is scientifically invalid.

We concur that the logic of the approach has merit; there may be a set of TT congeners that are especially indicative of the presence of TT in both TT standards and weathered or off-grade materials that can be used. However, the three selected by Simon and Manning are arbitrary at this junction when applied to soil cleanups; the authors offer no data, nor is there any in the literature. More science is needed before any conclusions can be drawn.

Summary

The Simon and Manning paper raises several issues related to analysis of environmental toxaphene. Unfortunately, the authors generalize, speculate, and infer to such a degree that meaningful conclusions cannot be drawn. One of greatest dangers in research is to assume what one is trying to prove. Assuming at the outset, that a particular conclusion should result, inevitably introduces bias in the conclusions. The preference amongst researchers is for any conclusion to result independently from well-planned and well-controlled experiments. When one proceeds entirely from the basis of literature, from dogma, or experience there can be no such independent conclusion; since one has selected the literature, the dogma and only those experiences that are believed relevant to the desired conclusions.

Such bias is evident in the Simon and Manning paper. The authors state from the outset their intention to prove that just 3 of 800 toxaphene congeners can be used to determine the safety of soil at any cleanup site anywhere in the world. The authors argue that these three congeners are predictive regardless of the origin of the toxaphene, regardless of the form of environmental degradation, regardless of any extraction or instrument bias. In the process of selecting studies to support their view Simon and Manning ignored facts that disagree with their model.

Toxaphene is a highly toxic biocide. Toxicity is an endpoint that must be monitored in any cleanup. Scientifically valid and reproducible studies show wide-ranging mutagenicity in Ames test and cancer in rats. Other studies conclude it is at least likely TT causes chromosome damage in humans. The authors' tunnel vision on three congeners is inappropriate given the unlikelihood all of the toxic and genotoxic effects could be explained by just 3 of 800 congeners acting alone, or in concert. It is more logical to presume, in the absence of hard data, that these multiple effects occur from different isomers in the complex mixture, and that different compounds may affect different animals or plants.

Studies on the Inuit Indians do not exonerate TT as a potential source of carcinogenic chemicals. At this time, the numerous studies showing increases in breast cancer and other tumors in the Inuit have not been traced to a single source. Therefore, a contribution by TT to the overall cancer rate cannot be overruled. Further, this single endpoint cannot be the sole determining factor for soil cleanup in North America. Superfund law is based on multiple criteria: meets all laws; implementability; state acceptance, community acceptance; feasibility; reduction in toxicity, mobility, or volume; and, overall health of humans and the environment. Superfund criteria clearly state that is the overall health of humans and the environment, not just humans, that must be considered. The authors have not shown that cleanup endpoints derived from humans near the artic circle could be protective for other species in North America. Without more hard physical data there is little difference between using the Region 4 Environmental Protection Agency's discredited toxaphene task force (TTF) methodology and the model described in this paper.

Conclusions and Recommendations

At this point in time, it is very clear that lines are drawn between the Region 4 EPA and practically everyone else regarding toxaphene analysis for the purposes of cleaning sites in the southeastern USA. The EPA seems intent on using the toxaphene task force methodology, or its Simon and Manning clone. On the other side are numerous environmentalists and academic scientists, with similar credentials relative to the EPA, who argue current practices underreport toxaphene. Finally, there is the EPA's own Ombudsman who has tried to find the best available science and apply it to this case; however, in the years that the Office of Inspector General has been involved little progress has been made. It appears Region 4 will continue to use some variation of the discredited TTF method unless it can be shown, without equivocation, by some third party, neither EPA nor environmental, that the toxaphene measurement technology Region 4 is using cannot, and will not, work.

We note that the National Research Council of the National Academy of Sciences can undertake the studies needed to clarify toxaphene measurement in the environment. The NRC has undertaken chemical-specific studies on asbestos, dioxin, trichloroethylene (TCE), and on numerous other environmental issues. Progress on cleaning the environment of toxaphene will not be made until toxaphene is defined; debating that definition has become an endless process. A third-party should be consulted and there is none more accepted than the NRC. We recommend that the Glynn Environmental Coalition seek to have a thorough review of toxaphene by a committee of the National Academy of Sciences.

R. Kevin Pegg, Ph.D.

[1] Simon, T. and R. Manning. 2006. Regulatory Toxicology and Pharmacology.
[2] Samosh, 1974.Tsitol Geneti. 8, 24-27.
[3] USEPA, 1978. OPPTS.

[4] From: http://www.epa.gov/IRIS/subst/0346.htm

"This project has been funded wholly or partly by the U.S. Environmental Protection Agency under Assistance Agreement Number V994050-92-0 to The Glynn Environmental Coalition, Inc. The contents of this document do not necessarily reflect the views and policies of the U.S. Environmental Protection agency, nor does mention of trade names or commercial products constitute endorsement or recommendation for use."

Attachment E

Comments on the Reliance of USEPA Region 4 on Simon and Manning, 2005[i] in Decisions Regarding the Hercules 009 Landfill Superfund Site in Brunswick, Georgia

Kathleen Burns, Ph.D.[i]

The U. S. Environmental Protection Agency Region 4 responded in June 20, 2006 to the EPA Office of Inspector General report, "Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site, Brunswick, Georgia," Report 2005-P-00022, September 26, 2005. EPA relied upon the article, "Development of a reference dose for the persistent congeners of weathered toxaphene based on in vivo and in vitro effects related to tumor promotion," by Simon and Manning, to support their arguments regarding the management of the Hercules 009 Landfill Superfund Site.

The following comments on EPA Region 4's reliance on Simon and Manning, specific issues within the Simon and Manning article, and other issues addressed below were written and are being submitted to the Office of the Inspector General of the US EPA at the request of the Glynn Environmental Coalition (GEC). These comments are pertinent to consideration of some specific health impacts addressed in previous documents by Region 4 EPA, the cleanup of toxaphene from areas where public health or environmental damage may occur due to its presence, and the overall approach taken by US EPA in regions across the country with respect to consistent and reliable application of protective policies.

Topics included in these comments include: the use of epidemiological information in the Simon and Manning paper (and reliance on that information by Region 4 EPA), the apparent lack of adherence by Region 4 EPA to US EPA guidance regarding the exposure of children to mutagenic carcinogens, and the apparent inconsistency that the proposed actions may generate within the Agency with respect to toxaphene. I have also addressed the issue of considering all congeners of toxaphene because it is essential that the full spectrum of hazards and relevant materials be considered when evaluating the risks and establishing protective cleanup levels. This is not addressed in detail here due to the submissions anticipated by other parties and scientists on this issue.

I. The argument presented on using breast cancer rates among Inuits as a basis for establishing a frank effect level.

Relevant data on the increases in breast cancer among Inuits were not presented.

Simon and Manning use an association to address causality, which is never a legitimate use of epidemiological data, and is especially inappropriate for a multifactoral disease such as breast cancer. They note that Inuits are exposed to toxaphene at higher rates than the US population, (up to 4 ug/l in plasma), and conclude:" The Inuit have approximately twentyfold lower breast cancer rates than comparison population so clearly this concentration is less than a frank effect level."

No cancer researcher or epidemiologist would find that statement even plausibly relevant. There are known substantial differences in genetic susceptibility to breast cancer (and other cancers) and many of the risk factors for breast cancer that are present in the mainland US are not present in the Inuit occupied areas, including many air and water pollutants. The National Library of Medicine lists over 450 scientific journal articles on various breast cancer risk factors published within just the last five years (search conducted August, 2006).

I have summarized some relevant evidence demonstrating that the Simon-Manning claim is irrelevant, primarily addressing the fact that there have been increases in the rates of breast cancer among Inuit women subsequent to the introduction of toxaphene into their environment (though no causal argument is made here).

The increasing incidence of breast cancer in the second half of the 20th century among Inuits is of serious concern. "The incidence increased from 28.2 per 100 000 in 1969-1973 to 34.3 per 100 000 in 1984-1988." (Miller and Gaudette, 1996). Over a 15 year period, that is an increase in 22% in the rate of breast cancer among Inuits.

A subsequent study considered the breast cancer rates among Inuits moving forward into the late 1990s, comparing two periods: 1973-1987 and 1988-1997. Using gender specific age adjusted cancer rates, the researchers found: "The incidence of lung, stomach, breast and colon cancer increased" (Friborg et al, 2003).

Thus, there is clearly an increase in breast cancer rates among Inuit women and also increases in other potentially lethal cancers among the Inuit people. The importance of this is underscored when the relative isolation and past health of these people is considered. This is best illustrated by the following very disturbing statement made over 20 years ago on the situation with respect to Canadian Inuit women:

> Breast cancer was absent before 1966 and was found in only 2 of 107 Canadian Inuit women stricken with cancer from 1967 to 1980, whereas the recent rates in the longer-acculturated Inuit of Alaska and Greenland have approached those prevailing in modern Western women.

(Hildes and Schafer, 1984)

A spectrum of cancers are of concern with respect to toxaphene, not merely breast cancer.

The occurrence of breast cancer is not the primary focus of concern for human cancers as the following indicates:

"As mentioned previously, toxaphene is carcinogenic in rats and mice and also has been proven to be mutagenic (*1,178*). Such findings have led to the assumption that toxaphene poses a risk as a human carcinogen. Human exposure to toxaphene occurs mainly through the consumption of contaminated fish or by occupational exposure. Data are scarce on the risk to humans from toxaphene exposure (*1*). Brown et al. (*228*) and Cantor et al. (*229*) evaluated the association between elevated risk of leukemia and non-Hodgkin's lymphoma (NHL) among farmers and exposure to pesticides and other agricultural chemicals and concluded that there is an elevated risk of NHL among farmers. Risk increased in cases in which farmers personally handled, mixed, or applied pesticides, did not use protective clothing, and when more specific active

mixtures of pesticide exposure were used. Chemicals most strongly associated with risk of NHL were carbaryl, chlordane, DDT, diazinon, dichlorvos, lindane, malathion, nicotine, and *toxaphene*. " (de Geuss et al, 1999)

Evaluations of lymphomas and leukemias have not been extensively carried out among the Inuits, but there is some evidence available. Historically, Inuit peoples in have had a low risk for lymphatic and hematopoietic malignancies, including non-Hodgkin lymphoma, Hodgkin's disease, multiple myeloma and the combined leukaemias. However, Inuits women have had an increase in hematopoietic system cancer (leukemias) during the second half of this century (Lanier and Alberts, 1996). It is noted by this author that women typically have a higher body fat composition, and toxaphene congeners are lipophilic substances that seek, deposit in, and bioaccumulate in body fat. While no single cause can be identified as the reason for increase leukemia rates among women in this population, it is noted that the increase occurred during a period when levels of many persistent organic pollutants were increasing in the global environment.

Overall, the well documented and very troubling increases in cancer among Inuit and other polar communities prompt serious concerns about causality. It is notable that these increases correlate in time with increased Persistent Organic Pollutants (POPs) present in their food supply during the post-WWII period, including toxaphene. And although no causality can be implied from time correlations, they do raise public health concerns. The lower incidence of breast cancer among Inuits than among other women in the US in no way exonerates toxaphene as a causal agent in breast cancer in the US or among the Inuit population.

II. Requirement for applying an additional factor to consider early life exposures to mutagenic carcinogens

EPA now requires that risk assessments and the establishment of new standards, exposure limits, etc, take into account the increased susceptibility to cancer that is conferred when exposures occur early in life to mutagenic carcinogens. This is fully described with many relevant documents at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283

The EPA requires the use of factors that are expected to range from 3 to 10 and that reduce the amount of a toxic chemical that may be present in order to protect children during the pre and postnatal period. The use of a factor to address this area of health risk is relevant for toxaphene based on information provided below and in other sources.

Toxaphene it is not mutagenic in all test systems; however, it is mutagenic in many. There have been numerous genotoxicity studies conducted over decades by various groups, with tests sponsored by different groups, and it is therefore not surprising that the results are not consistent. De Geuss et al (1999) states, "Toxaphene is carcinogenic in rats and mice and also has been proven to be mutagenic." (excerpt from quote above).

Numerous summaries of the genotoxicity of toxaphene have been provided in journal articles, and in the ATSDR Toxicological Profile for Toxaphene. The following, from de Geuss et al (1999) is brief and relevant:

> "More recently, Steinberg et al. (*224*) tested toxaphene and four toxaphene congeners, B[12012]-(202), B[12012]-(212), B[30030]-(122), and B[30012]-(111),

for mutagenic activity in *Salmonella typhimurium* strains TA98 and TA100 using a validated microsuspension procedure instead of the usual plate-incorporated procedure. Toxaphene was mutagenic only in the TA100 strain at concentrations of 2,500, 5,000, and 10,000 µg ml^{-1}. In contrast, toxaphene was also mutagenic to strain TA98 at a concentration of 10,000 µg $plate^{-1}$ when using the plate-incorporated assay. Using the microsuspension method, none of the four tested toxaphene congeners showed mutagenic activity in strain TA100 at any of the concentrations tested (maximum concentration: 10,000 µg ml^{-1}). A dose-dependent (10-10,000 kg $plate^{-1}$) increase in His revertants was also observed in strains TA97, TA98, TA100, TA102, and TA104 by Schrader et al. (*225*) in the absence of S9 metabolic activation. Genotoxicity of the technical toxaphene, as well as B[30012]-(111), but not B[12012]-(202), B[12012]-(212), and B[30030]-(122), was also demonstrated by Boon et al. (*128*) using the Mutatox assay. Addition of rat S9 fraction or microsomes of harbor seal and albatross decreased the genotoxic potential of the tested congeners and toxaphene. More *in vitro* evidence for genotoxicity was found by Sobti et al. (*226*) showing toxaphene-induced sister-chromatid exchange (SCE) in cultured lymphoblasts. In contrast, Schrader et al. (*225*) could not demonstrate convincing evidence of a toxaphene-induced (1-10 µg ml^{-1}) dose-dependent SCE induction at the HGPRT gene locus in V79 cells.

Knowing that cell-cycle delay may interfere with the expression of genotoxicity, Steinel et al. (*220*) studied the effect of cell-cycle delay on the induction of SCE by toxaphene in Chinese hamster lung (Don) cells. They found that toxaphene exhibited a dose- and time-dependent decrease in cell-cycle progression. At similar concentrations of toxaphene, higher numbers of SCEs were observed and dose and treatment time relationships were demonstrated. Hence, SCE induced by toxaphene was not masked by mitotic delay and longer toxaphene treatment times were not necessary in Don Chinese hamster cells. Nevertheless, the authors support recommendations for prolonged incubation times in SCE assays affected by mitotic delay."

The assertion of genotoxicity is supported by the observation that studies show toxaphene is capable of causing multiple types of cancers in experimental systems (de Geuss et al, 1999). This finding indicates that it is possible that toxaphene induces cancer by more than one mode of action. While there may be some carcinogenic modes of action that do not involve mutations (e.g., promotion via other mechanisms), the evidence supports the use of the EPA-required default assumption regarding cancer induction (USEPA, 2005a, see USEPA Guidelines for Cancer Risk Assessment as summarized in Federal Register: April 7, 2005 (Volume 70, Number 66) Page 17765-17817 at: http://www.epa.gov/fedrgstr/EPA-TOX/2005/April/Day-07/t6642.htm). For mode of action discussions and related Agency risk assessment requirements see especially pages 17788 - 17817).

Industry has not disproven genotoxic mechanisms of cancer induction by toxaphene and EPA policy requires assumption of a mutagenic mode of action for carcinogens in the absence of evidence to the contrary. In fact, given the evidence of mutagenicity, it is unlikely that one could ever prove that toxaphene is incapable of inducing cancer via genotoxic mechanisms. Because the scientific evidence shows that toxaphene has genotoxic potential and is an established carcinogen, the EPA Risk Assessment Guidelines require that it the increased susceptibility that results from early life exposures to this chemical be considered. This is specified in "Guidelines for Carcinogen Risk Assessment and Supplemental Guidance for Assessing Susceptibility from

Early-Life Exposure to Carcinogens" (available at: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=116283 (USEPA, 2005b)

Additional information on this topic and the scientific concepts that support it have been discussed by Barton, Cogliano, Flowers, Valcovic, Setzer, Woodruff (2005), who have all contributed substantially to this EPA policy.

III. Consistency within the agency in the interpretation and use of scientific information in efforts to protect public health.

The information on cancer risk, and resulting guidelines on fish consumption for toxaphene based on its carcinogenic potential are relevant and are substantially different than those shown in the Simon-Manning paper. Internal inconsistencies in the evaluation of science and in the application of protective standards and policies are unacceptable within a federal agency. It is particularly important in areas where environmental justice issues have been raised that full attention be paid to using the protective and precautionary approaches specified in EPA's national policies, as posted in Federal Register notices. The decisions by EPA Region 4 must adhere to Agency policy and scientific consensus.

EPA guidance document on fish contamination concentrations and associated limits on intake when toxaphene is present as a contaminant in fish are provided in "Guidance for Assessing Chemical Contaminant Data for Use In Fish Advisories. Volume 2: Risk Assessment and Fish Consumption Limits - Third Edition at http://www.epa.gov/ost/fishadvice/volume2/v2ch4.pdf (USEPA, 2000). This document resulted from extensive internal and external peer review and represented the position of numerous scientists within the Agency. Volume 3, which addresses risk management for fish advisory programs, also prescribes some degree of precaution and preventative action and encourages local evaluation of exposures (see www.epa.gov for Volume 3).

IV. Consideration of all relevant components and breakdown products of toxaphene

Toxaphene is a complex mixture of chemicals with similar structures, as is the case for most organochlorine pesticides. There are standard approaches that have taken for these pesticides and for other mixtures of similarly structured chemicals (isomers, congeners, etc). These typically rely upon an evaluation of the relative toxicity of each of the components with respect to the full spectrum of potential health hazards (cancer, birth defects, neurotoxicity, immunotoxicity, nephrotoxicity, hepatoxicity, etc), or rely upon studies for each of these types of toxicity that evaluate the full mixture of similarly structured chemicals that comprises the named product.

In addition, US EPA typically requires that a risk assessment of a contaminated site include an evaluation of all of the breakdown products that will be produced under a variety of environmental conditions, and that the toxicity of these breakdown products be fully explored. Thus, the objective is to fully characterize the potential harm that may result from all plausible chemicals formed from the original group of contaminants, as well as from the original contaminant group itself.

US EPA also specifies that mixtures containing chemicals with similar structures and mechanisms of action be considered together in evaluating risk and in determining adequately protective actions. In the case of toxaphene within Glynn County, this should include all

manufacturing waste that falls within US EPA specified parameters for similar chemical structures and mechanisms of action. If this is not addressed in decisions made regarding cleanup for Glynn County, the potential risks may be unacceptably high.

There are extensive listed requirements, discussions of the rationale for the requirements, and examples of how all of the above listed issues have been addressed by the US EPA in the past within US EPA's website (www.epa.gov).

With respect to toxaphene, it is imperative that the full spectrum of chlorinated camphenes and the degradation products that occurred as a result of toxaphene be considered in any treatment of toxaphene (e.g., in cleanup levels, establishment of seafood advisories, evaluation of human body burden). The evaluation of the nature and amount of toxaphene present must be done in a scientifically defensible manner that addresses the actual conditions in Glynn County. This should include chemicals present as a result of local environmental circumstances (chemicals that result from disposal on land, releases into air and subsequent deposition, uptake and alterations within biota, interactions soils, air, or water that has specific properties - acidic, basic, etc).

There are straightforward and well established methods for evaluation of toxaphene's spectrum of chemical ingredients and breakdown products specified within US EPA's website and available through a variety of scientific papers. As one of the older pesticides used in the United States, methods that capture the spectrum of congeners comprising toxaphene are well known.

Considering US EPA's past actions on toxaphene and similar chemicals with respect to the protective stance taken, evaluation of the potential hazards, and the need to equitably manage the cleanup of contaminated sites, I urge the Office of the Inspector General to act on behalf of the public in affording the residents of Glynn County the full health and environmental protections to which they are entitled. While not underestimating the challenges this poses to all who are involved in this work, it is in the interests of the people of the County and future generations who will live there that the United States government insure that people will be able to live in a safe and healthy environment.

Respectfully submitted on September 7th, 2006 to Paul McKechnie, US EPA Office of Inspector General, Boston, Massachusetts by Kathleen Burns, Ph.D. of Lexington, Massachusetts via Glynn Environmental Coalition, Brunswick, Georgia.

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USEPA, 2005b. Guidelines for Carcinogen Risk Assessment and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens .

Attachment F

Comments to OIG on Hercules 009 Superfund Reports October, 2006

October 10, 2006
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Public Interest Comments on the Office of Inspector General Reports:
Appropriate Testing and Timely Reporting are Needed at the
Hercules 009 Landfill Superfund Site, Brunswick, Georgia[1]
Report 2005-P-00022; September 26, 2005
Report 2005-P-00022 (Addendum); September 13, 2005
and
More Information is Needed on Toxaphene Degradation Products[2]
Report No. 2006-P-00007, December 16, 2005

We, the supporters of this letter, advocate on behalf of our millions of members for regulations that provide protection to communities, workers, and wildlife. We do not have any financial interest in the subject of this letter.

Jennifer Sass, Ph.D., Natural Resources Defense Council (NRDC)[1]
Kathy Burns, Ph.D., ScienceCorps
Denny Larson, Director, Global Community Monitor
Kristin Schafer, Pesticide Action Network North America
Michelle Roberts, Beyond Pesticides
Joseph DiGangi, Ph.D., Environmental Health Fund
Ted Schettler MD, MPH Science and Environmental Health Network
Pam Miller, Alaska Community Action on Toxics
Rick Hind, Greenpeace, USA
Nathalie Walker & Monique Harden, Advocates for Environmental Human Rights
Lin Kaatz Chary, PhD, MPH, Indiana Toxics Action Project
Gregg Small, Washington Toxics
Mark A. Mitchell M.D., MPH, Connecticut Coalition for Environmental Justice
Kathleen Curtis and Roberta Chase Wilding, Clean New York
Amanda Hawes, Toxics Chair, WORKSAFE
Stephen Lester, MS, Center for Health, Environment, and Justice
Daryl Ditz, PhD, Center for International Environmental Law
Mary Brune, MOMS – Making Our Milk Safe

Jeanne Rizzo, Breast Cancer Fund

Summary

The Office of the Inspector General, at the request the Glynn Environmental Coalition, has reviewed claims that a Glynn County, GA Superfund site contaminated with Toxaphene is receiving inadequate clean up. At the heart of the dispute is a testing method that fails to detect most of the toxic congeners and degradation products of toxaphene, thus underestimating the extent of contamination. Use of the biased testing method was approved by a closed partnership between EPA Region 4, the Georgia Environmental Protection Division (GaEPD) and Hercules, Inc. that failed to include community representatives. Both the OIG and a previous review by the Agency for Toxic Substances and Disease Registry (2002), have recommended that EPA should discard this flawed method in favor of established tests that identify toxaphene degradation products.

We generally support the OIG reports, and encourage the OIG to issue a strong response to EPA to work with the community, apply appropriate scientific methods, and force the stringent clean up that was promised to the community over two decades ago when this site, predominately populated by low-income African-American families, was listed as a National Priority Superfund site.

[1] To whom correspondence should be sent. Full contact information at end of these comments.

History of the site [3]**:** ***twenty years is too long***

Hercules Inc., a former pesticide plant, manufactured toxaphene as an insecticide at its plant in the city of Brunswick, Glynn County, Georgia, from 1948 to 1980. In these comments, we will use the term "polychlorinated camphene" (PCC) to describe toxaphene, a mixture of over 670 chemicals of concern, and its residues and conversion products.

The Hercules 009 Landfill Superfund Site in the city of Brunswick, in Glynn County, Georgia operated from 1975 until 1980, and was listed on the National Priorities List (NPL) in 1984, over 20 years ago[4]. The Brunswick area has a commercial fishing port and a thriving seafood industry, as well as recreational fishing and crabbing.[9]

The Hercules 009 Landfill is described as a 16.5 acre property that is bordered by Georgia State Highway 25 on the west; an automobile dealership on the north; a juvenile slash pine forest on the east; and several homes, a church, a school, and a strip shopping center to the south/southeast of the property.[5]

Until required by the Clean Water Act to treat waste water in 1972, Hercules reportedly released up to 200-300 pounds of PCC per day as waste water,[6] ranged from 2,332 parts per billion (ppb) in 1970 to 6.4 ppb in 1974.[7] PCC has been reported at levels exceeding 15,000 parts per million (ppm) at the Hercules 009 Landfill Site.[8] In 1976 PCC discharge was restricted to a daily maximum of 1 pound per day and a daily average of 0.5 pounds per day. Subsequent discharge was limited to 0.00081 ppm, though violations were recorded.[9]

In July 1988, Hercules and EPA entered into an Administrative Order on Consent for conducting a remedial investigation/feasibility study (RI/FS)[10] to assess the risk to human and environmental health and evaluate treatment approaches.[11]

In 2002, the Agency for Toxic Substances and Disease Registry (ATSDR), an agency of the U.S. Department of Health and Human Services, conducted a public health assessment of some of the Hercules waste areas in Brunswick.[12] In that report, ATSDR recommended limiting consumption of fish from the contaminated areas.

Both the ATSDR and the Office of the Inspector General (OIG) specifically identified the method advocated by EPA Region 4 and Hercules as insensitive, inadequate, and likely to significantly underestimate contamination levels, and instead recommended the use of pre-validated and scientifically accepted measurement methods.[13] [14]

Current clean up issues: *intentionally insensitive methods fail to detect contamination*

The Hercules Landfill Superfund Site and five other sites contaminated by PCC in Glynn County, Georgia are slated for a sub-standard clean up that will leave at risk the community and the environment. This is being pushed through because of a closed

partnership between EPA Region 4 and Hercules that excluded community participation. This pairing of between state regulators and the regulated industry was self-titled the Toxaphene Task Force. Among numerous biased and discredited pronouncements of this task force was use of a measurement method that failed to detect most of the over 600 congeners, residues, and degradation products of PCC contamination. The Region 4 assessment, relying on the flawed method, was strongly criticized by the ATSDR in a 2002 report as underestimating the exposure.[15] The OIG specifically noted that the methods used by Region 4 and Hercules are not designed to measure toxaphene degradation products, and instead recommended established testing methods that specifically test for toxaphene degradates.[16]

The stubborn insistence by Region 4 to continue to rely on a biased and unscientific method that has been rejected by the ATSDR and the OIG can cynically be viewed as a blind, ideological adherence to fiction in the face of facts. The result of these actions, whether ignorant or intentional, is a failure to provide the protection for human and environmental health that is promised in the mission[17] of the EPA.

Hazard information: *Toxaphene is persistent, bioaccumulative, and banned*

Toxaphene is a toxic chlorinated-hydrocarbon persistent bioaccumulative banned pesticide. It is a mixture of over 670 chemicals of concern, and is approximately 40 to 75% chlorine by weight. In 1982 toxaphene was restricted in the US, and then fully banned in 1990. Although it has low solubility in water, it is readily adsorbed in soil and sediments, and bioconcentrates in aquatic organisms including fish. It is highly acutely toxic to fish, even at concentrations that are low parts per billion (ppb) or high parts per trillion (ppt).[18] [19] [20]

In its 2002 report of the Brunswick area, ATSDR described the relevant toxicity literature. Animal testing showed that pre-birth and post-natal exposure to toxaphene may interfere with normal development.[21] When pregnant rats were fed a diet contaminated with toxaphene, effects included poor righting ability and poor swimming ability, compared with healthy control animals.[22] The exposed rats eventually attained normal swimming ability. ATSDR also noted that, “when the rats took a maze test at the age of 70 days, those previously exposed to PCC components had difficulty remembering the path leading to the food”. ATSDR recommended that, “pregnant women and nursing mothers should avoid consuming large quantities of

contaminated fish and, obviously, avoid ingesting contaminated soil" to protect the developing fetus and child. ATSDR warned that exposure to PCC through contaminated fish and surface soils, should also be minimized in infants and young children.[23] Air exposures should also be considered hazardous; PCC is up to 8% in soils at the Hercules Plant.

National interest: ***a bad job here may lead to failed clean-ups nationally***

NPL sites are the most serious sites across the country, slated for possible long-term

cleanup by EPA's Superfund program. Altogether, there are 1,246 final sites across the country, of which 18 sites across 9 states include toxaphene as a contaminant.[24] Therefore, the level of clean up that EPA will require at this site is likely to impact requirements across the country.

The document record is clear that it is the intention of Hercules to submit its toxaphene review to the EPA database, the Integrated Risk Information System (IRIS), which contains EPA's scientific positions on potential human health effects from environmental contaminants. While not an enforceable regulatory standard *per se*, information on IRIS is considered by regulators at the state and federal level and others worldwide to set pollution cleanup standards and various exposure standards for air, water, and soil.

Hercules advocated a reduction in the cancer potency factor 10-fold on the IRIS database[25] from 1.1 per mg/kg/day to 0.11 per mg/kg/day, and stated that it has already gone so far as to submit its proposed factor to Office of Solid Waste and Emergency Response (USEPA/OSWER), based on "new information"[26] citing a 1998 report. This would likely severely impair clean-up action at contaminated sites all over the country.

In addition to weakening the cancer potency factor, Hercules also proposed to weaken the non-cancer "safe" level, known as a Reference Dose (RfD), posted on the IRIS database. In its comments to ATSDR, Hercules states that it has submitted an alternative RfD of 0.0007 mg/kg/day for the IRIS database.[27] This is approximately 3-fold more permissive than the old IRIS RfD of 0.00025 mg/kg/day (IRIS, 1993), which has now been removed from the IRIS database. Hercules specifically notes that use of its alternate RfD value would raise the screening level from 3 ppm to 7.5 ppm toxaphene in fish.[28]

It should be extremely concerning to taxpayers that a scientific article that proposes to disregard all but a handful of PCC congeners is co-authored by scientists from EPA Region 4 and the Georgia Environmental Protection Division (Simon and Manning, 2006). Though no source of funding is disclosed, it is published in a journal, *Regulatory Toxicology and Pharmacology*, well-known to be biased towards industry perspectives. In fact, in 2002 the journal was targeted in a letter by over forty scientists, including noted international experts and journal editors, citing concerns about, "apparent conflicts of interest, lack of transparency, and the absence of editorial independence".[29] Specifically, their letter cites, "the journal's apparent bias in favor of industries that are subject to governmental health and environmental regulations". The letter goes on to identify financial supporters of the journal sponsor, including, the American Chemistry Council, Dow AgroSciences, R.J. Reynolds Tobacco Co., and others. Moreover, the letter identified a "significant percentage" of the editorial board with financial ties to companies whose products are the subjects of studies published in the journal. Is it any wonder, then, that this article advocating a weakening of cancer potency of toxaphene found its way to this journal? But, the

fact that the authors are public employees suggests a concerning level of partnership between Hercules and the regulatory agencies.

Environmental Justice: ***EPA fails to act on Executive Order 12898***

The State and Federal agencies charged with the protection of human and environmental health are faced with a moral test of deciding whether to unfairly burden Glynn County families with health risks that they are not likely to bear themselves, and that are not shared equally across the nation.
Glynn County is comprised of 72% white population and 26.5% black population, more diverse than the National average of 80% white and 13% black (2004 Census data).[30] However, the Brunswick city has a total population of approximately 15,600 people, of which 36% are white and 60% are black (2000 Census data as reported by ATSDR).[31]

(data are rounded off)	Brunswick city (2000 data) [i]	Glynn County (2003/4 data)[i]	US (2003/4 data)[i]
White persons	36%	72%	80%
Black persons	60%	27%	13%
Median household income	$22,000 ($18,400 for black; $27,900 for white[i])	$38,000	$43,000
Persons living in poverty	30%	15%	12.5%

The county has approximately 27,000 households (2000 data), with a median household income of $38,600, less than the National median of $43,300 (2003 data). However, Brunswick City has a median household income of only $22,200 (2000 data), much lower than the county and national. This leaves 15% of Glynn County residents living below poverty (2003 data), more than the National average of 12.5%. However, 30% of Brunswick City residents live below poverty (2000 census data). In summary, Glynn County residents are more likely to be black and/or to be poor than the average American.

In addition to the Hercules 009 Superfund site, the Brunswick area is the site of two additional industrial facilities that have been classified as Superfund sites, and 17 other potentially hazardous waste sites.[36] Maybe the unfair distribution of toxic dump sites and other industrial facilities is a significant factor in the higher rate of cancer and other diseases among black residents compared with white residents of Glynn County. In the health service area that extends from Duval County (Jacksonville) FL to Glynn County GA, EPA reports that the overall cancer rate per 100,000 population is 177 for white males compared with 257.7 for black males.[37] The cancer rate for white females is 118.4, compared with 135.1 for black females. Childhood leukemia rates are almost 2-fold higher for black males (14.1 per 100,000), compared with white males (8.9 per 100,000);[38] data for females is similar for white (6.1) and black (4.9) populations.

The EPA provides a description of environmental justice on its website:

> Environmental Justice is the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. EPA has this goal for all communities and persons

across this Nation. It will be achieved when everyone enjoys the same degree of protection from environmental and health hazards and equal access to the decision-making process to have a healthy environment in which to live, learn, and work.[39] Despite this laudable and critical recognition of the unfair distribution of risk and disease across this country, a study just released in September 2006 by the Office of the Inspector General is highly critical of EPA's failed record on taking action to correct these injustices.[40] The IG recommended that EPA review its programs appropriately and take action consisted with Executive Order 12898 to address the unfair impact of industrial waste on communities.[41]

Take action now to protect human health

We generally support the OIG reports, and encourage the OIG to issue a strong response to EPA to work with the community, apply appropriate scientific methods, and force the stringent clean up that was promised to the community over two decades ago when this site, predominately populated by low-income African-American families, was listed as a National Priority Superfund site.

Thank you for your consideration of these comments.
Respectfully,

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[1] summary at http://www.epa.gov/oig/reports/2005/20050926-2005-P-00022-Gcopy.pdf full report at http://www.epa.gov/oig/reports/2005/20050926-2005-P-00022.pdf addendum at http://www.epa.gov/oig/reports/2005/20050926-2005-P-00022A.pdf

[2] summary at http://www.epa.gov/oig/reports/2006/20051216-2006-P-00007-Gcopy.pdf full report at http://www.epa.gov/oig/reports/2006/20051216-2006-P-00007.pdf

[3] EPA. Georgia NPL/NPL Caliber Cleanup Site Summaries. http://www.epa.gov/region4/waste/npl/nplga/herculga.htm

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[5] EPA. Georgia NPL/NPL Caliber Cleanup Site Summaries. http://www.epa.gov/region4/waste/npl/nplga/herculga.htm

[6] ATSDR. Public health assessment: Terry Creek dredge spoil areas/ Hercules outfall site, Brunswick, Glynn County, Georgia. 2002. http://www.atsdr.cdc.gov/hac/PHA/terrycreek/tcd_toc.html

[7] http://www.atsdr.cdc.gov/hac/PHA/terrycreek/tcd_p1.html#backa

[8] EPA. Georgia NPL/NPL Caliber Cleanup Site Summaries. http://www.epa.gov/region4/waste/npl/nplga/herculga.htm

[9] http://www.atsdr.cdc.gov/hac/PHA/terrycreek/tcd_p1.html#backa

[10] Definition of RI/FS http://www.epa.gov/superfund/whatissf/sfproces/rifs.htm

[11] EPA. Georgia NPL/NPL Caliber Cleanup Site Summaries. http://www.epa.gov/region4/waste/npl/nplga/herculga.htm

[12] http://www.atsdr.cdc.gov/hac/PHA/terrycreek/tcd_p1.html#backa

[13] summary at http://www.epa.gov/oig/reports/2006/20051216-2006-P-00007-Gcopy.pdf full report at http://www.epa.gov/oig/reports/2006/20051216-2006-P-00007.pdf

[14] ATSDR report (2002) Appendix F: Response to comments. ATSDR states, “On April 14, 2000, ATSDR formally received an analytical protocol from USEPA, Region IV describing the "Procedures for the Determination of Toxaphene," a three-page protocol dated August 14, 1997. This protocol, which was intended to be used by USEPA-Region IV and Hercules, employed "the last four to seven peaks in the 'back half' of the toxaphene chromatogram for calibration and quantification of toxaphene." The "four peak in the back half" methods dates to the packed column days, when there were only several usable peaks shown on the back half of toxaphene chromatogram (USEPA 1986 Method 8080). This "four-peaks-in-back- half" method was precise at that time... This method, however, has lost its precision now because the powerful capillary column in modern gas chromatography instruments generates dozens of peaks in the back half of the chromatogram of toxaphene standard... Although the Method 8081A of January 1995 kept this "four-peaks-in-back- half" method, the method was purged from the official December 1996 version of Method 8081 A, as well as the new Method 8081 B of January 1998. Recently, GA EPD repeated the analysis of 56 samples from the old April 1997 samples with the specific methodology of both GC-ECD and GC-MS at Skidaway Institute of Oceanography. On June 19, 2000, quantitative data for the 56 samples became available and the PCC concentrations up to 26 ppm was found in fin fish. This work was published in peer reviewed, open literature in September 2001.” http://www.atsdr.cdc.gov/hac/PHA/terrycreek/tcd_p3.html#appf

[15] http://www.atsdr.cdc.gov/hac/PHA/terrycreek/tcd_toc.html

[16] summary at http://www.epa.gov/oig/reports/2006/20051216-2006-P-00007-Gcopy.pdf full report at http://www.epa.gov/oig/reports/2006/20051216-2006-P-00007.pdf

[17] “The mission of the Environmental Protection Agency is to protect human health and the environment.” http://www.epa.gov/epahome/aboutepa.htm#mission

[18] Maruya KA and Lee RF. Arochlor 1268 and toxaphene in fish from a southern U.S. estuary. Environ Sci Technol 1998;32:1069-75.

[19] ATSDR report. 2002. http://www.atsdr.cdc.gov/hac/PHA/terrycreek/tcd_p1.html#sum

[20] The ATSDR report Appendix F reported that, “The acute LC50 values for other kinds of fish ranged from 2 ppb for basses to 18 ppb for bluegills. PCC in chronic exposure systems were one to three orders of magnitude more toxic to fish than were acute exposure systems. The chronically toxic effects of PCC were observed at 39 ppt in brook trout, and at 36.7 ppt in fathead minnow.” http://www.atsdr.cdc.gov/hac/PHA/terrycreek/tcd_p3.html#appf

[21] Agency for Toxic Substances and Disease Registry. Toxicological profile for toxaphene. Atlanta: US Department of Health and Human Services; August 1996.

[22] Olson KL, Matsumura F and Boush GM. Behavioral effects on juvenile rats from perinatal exposure to low levels of toxaphene, and its toxic components, toxicant A, and toxicant B. Arch Environ Contam Toxicol 1980; 9:247-57.

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Attachment G

EPA OIG Close Out Letter - October 31, 2006

Attachment H

009 Superfund Site - EPA OIG Close Out Letter
By Dr. R. Kevin Pegg

We received for review the response for the EPA's Office of Inspector General to EPA's Region 4 Administrator regarding the analysis of toxaphene at the 009 site. Previously the OIG had found that Region 4 was using methods that underestimated toxaphene in soils, groundwater and animal tissues. As part of that finding Region 4 was to utilize methods in keeping with the state-of-the-art in toxaphene testing, rather than decades-old methods that had been used. Region 4 provided a response to the OIG that raised a number of issues. Principally, Region 4 relied heavily on a position paper prepared by former Region 4 employees, Simon and Manning, on weathered toxaphene (we reviewed the S&M paper in a prior newsletter).

The OIG's response is complex and contradictory. The OIG continues to argue that more research is needed for the toxicology of toxaphene. The report states clearly that much more work on analysis is needed, and urges Region 4 to work directly with the EPA's Office of Research and Development to analyze toxaphene. And, the response urges transparency in the manner in which Region 4 calculates the remediation goals for the 009 site. Then again, the response states that they are dropping the matter as "…you [Region 4 EPA] have adequately addressed the recommendations we made."

The accompanying review by Michael Wilson, a former scientist with EPA that worked for the OIG, is not very detailed. It relies almost entirely on the documents provided by Region 4, and, according to the cover letter, was provided pro bono since the author is no longer at EPA. Regarding the Simon and Manning paper the author indicates it is the best science available because it is the only science available. Further, Wilson could also not calculate a reference dose using the Simon and Manning paper. Nonetheless, the author concludes that Region 4's burden-of-proof is met, despite the fact that he, like everyone else in the scientific community, is clueless as to the meaning and origin of the numbers cited by Region 4 in the S&M paper.

Essentially, one EPA employee has validated other EPA employees' unscientific and irreproducible work. The letters infer no additional effort will made on understanding toxaphene migration in Brunswick until after 2008. Note also, this marks the final report on the 009 Superfund site under the Technical Assistance Grant.

Attachment I

From: Glynn Environmental Coalition

To: Glynn County Board of Education

The Glynn Environmental Coalition (GEC) is providing the following information for your use when discussing the issues surrounding the testing of Altama Elementary School with the Board of Education (BOE). With your background in the environmental sciences, you should grasp the content and implications of the information provided. The EPA Region 4 presentation to the BOE on January 29, 2007, is a continuation of a decision made in 1991 to NOT report all chemicals present by development of an analytical method for toxaphene that is only used in Glynn County, which was found inappropriate by the EPA Office of Inspector General (OIG). The GEC trusts the following information will provide a firm basis for our concerns, which resulted in the EPA OIG agreeing that all chemicals present should be reported.

Summary of the issues:

In 1991, the EPA, Georgia EPD, and Hercules had a meeting in which they agreed to change the analytical method for toxaphene to report toxaphene and "some other product". The new method only reported toxaphene chemicals from the back half of the chromatogram. When toxaphene enters the environment as a mixture of over 670 chemicals, shifts in ratios of chemicals occurs by the most chlorinated loosing a chlorine atom or two and becoming the persistent form that appears in large quantities in the front half of the chromatogram. In 1997, the analytical method was changed further by eliminating any toxaphene chemicals not present in the same ratio as the calibration standard, further excluding toxaphene chemicals from quantification and reporting. The EPA OIG found these analytical method changes made by EPA Region 4 inappropriate. EPA Region 4 responded by developing another method that only measures 3 toxaphene chemicals (only found after people or fish metabolize the chemicals). This method would report none or ~3% of the toxaphene present. The EPA OIG said not to use the method and further stated that the Hp-Sed and Hx-Sed (toxaphene with 6 and 7 chlorines, which are the ones present in large amounts) should be reported. EPA Region 4 has steadfastly refused to report these toxaphene chemicals that are present in the largest amounts in defiance of the EPA OIG. (Under the Hercules Patent, toxaphene includes all chlorinated camphene with 3 to 10 chlorines attached)

At the Hercules 009 Landfill Superfund Site, a toxaphene cleanup level was set based upon the assumption that the other toxaphene manufacturing waste chemicals such as dioxin would be cleaned up to safe level. By not reporting all toxaphene present, other chemicals will not be cleaned up.

The EPA OIG use the example from our community where 56 fish samples from Terry Creek were analyzed by the inappropriate method and no toxaphene was reported in any sample. When re-analyzed by Negative Ion Mass Spectroscopy (NIMS), the fish had up to 26 ppm, or 56 times the EPA "Do Not Eat" level. Obviously, the inappropriate method is a health threat to all in our community and re-testing is needed. A similar situation could be occurring at Altama Elementary School, but like Terry Creek we will only know after appropriate testing is conducted.

EPA Region 4, Georgia EPD, and Hercules are united in their effort to keep all toxaphene chemicals being from being reported. The EPA's presentation to the Board of Education went one step further and declared, "...toxaphene breakdown products in soil do not pose a human

health risk." The EPA did not produce any studies or data to support their contention that a poison and carcinogen do not pose a human health risk, but there are numerous studies to the contrary that are discussed in the Agency for Toxic Substance and Disease Registry (ATSDR) Toxicological Profile for Toxaphene. Furthermore, the EPA OIG interviewed the ATSDR toxicologist whom estimated only 10% of the toxaphene present was being reported.

Toxaphene is present in our community up to 8% in soils (yes, that is percent, or 88,000 ppm). Around 2-3 million pounds of toxaphene were released into our estuary. Four toxic sites have not been investigated or cleaned up that contain toxaphene.

EPA Region 4 has made a decision to continue to NOT report all chemicals present and declare toxaphene does not pose a health risk, even when all the chemicals present has not been determined. The GEC would like to resolve this situation in cooperation with the Glynn County BOE in a manner that does not alarm parents or children.

The Glynn County BOE needs to be satisfied that chemicals have not been left on school property, sufficient information is available to conduct drainage ditch maintenance activities without recontamination, and school property is not encumbered by chemical contamination.

The GEC is providing the following information in the form of a rebuttal to the EPA's presentation to the BOE. Please do not hesitate to ask if you need clarification or documents cited.

- Slide: Removal and Testing… There were two removal actions on school property. The one that extended along the ditch and to the playground was not included by EPA Region 4. Contrary to the contentions of the EPA, toxaphene contamination was found in 1995 up to and abutting the school playground, which the GEC is cognoscente and a factor in our request for retesting the school (See Attachment A). School property was tested after the removal action and levels up to 84 ppm remained. Notable is that the EPA presentation excluded this area that extends to the playground from the removal action presented to the BOE, which further emphasizes the need for retesting the school. It is unknown why EPA Region 4 would withhold information about the removal action and the extent of contamination on school property.

- Slide: Sampling and Analysis… 1.) EPA claims sampling of the school yard is not part of Superfund or the Superfund Site, but the EPA has this data as part of the Site record, as indicated by being part of the presentation, and the EPA actually tested the soil (See Attachment B).

2.) The EPA contends that in 1993, there was no method for weathered toxaphene, which is incorrect. EPA Method 8080 at the time provided for reporting “total toxaphene” or "apparent toxaphene". EPA Region 4, Georgia EPD, and Hercules changed this analytical method through an agreement in 1991 to reporting toxaphene and "some other product". The analytical method developed was called the "Toxaphene Task Force" (TTF) method, and after further changes in 1997 called the "Hercules Protocol". The OIG called the method EPA (Region 4) Method 8081. At the meeting in 1991 where the agreement was struck between EPA Region 4, Georgia EPD, and Hercules, all parties agreed that they had previously tested for apparent toxaphene that reports all chlorinated camphene present, including what is now called "degraded" toxaphene, which is the same as toxaphene manufactured but now present in different amounts of the individual chemical components.

The EPA OIG discussed the changes made to EPA Method 8081 by EPA Region 4 and how toxaphene in soil was underestimated, and out rightly not reported when known to be present.

"However, EPA (Region 4) Method 8081 is not effective for detecting degraded toxaphene (i.e., “weathered” toxaphene) in environmental samples (e.g., soil, water, fish). For demonstration purposes, chromatogram 3A below is a known chromatogram of toxaphene degradation products in soils. When chromatogram 3A is compared by EPA Method 8081's identification criteria for technical toxaphene, chromatogram 3A obviously does not have the 22 same late eluding peak profile (i.e., the peaks after 29 minutes) as the technical toxaphene standard. **Therefore, a match is not made and the presence of toxaphene is not reported by the laboratory, even though specific toxaphene congeners (e.g., Hx-Sed and Hp-Sed) are <u>known to be present</u>.** This example demonstrates the manner in which EPA (Region 4) Method 8081 fails to detect toxaphene degradation products (i.e.,”weathered” toxaphene or individual toxaphene congeners) in environmental samples."

The OIG’s observation that toxaphene was present when none was reported by the TTF and Hercules Protocol methods is the same conclusion other studies have reached and confirmed though analysis. The OIG suggested that the observed compounds might be “toxaphene breakdown products", but many of the prominent chlorinated camphene (PCC) found in the front half of the chromatogram are associated with unmodified toxaphene or PCC as manufactured by Hercules.[i,i,i,i]

The EPA Region 4 chemist, who also participated in the development of the TTF method, noted that the "latter peaks" in samples were decreased and the "early peaks" were increased in environmental samples from Brunswick, and that the TTF method may seriously underestimate the true concentration of toxaphene.[i,i] The Georgia Environmental Protection Division chemist that participated in development of the TTF method noted that unknown peaks not quantified may have been toxaphene related and the total area method was not used when the TTF method was applied.[i] EPA Method 8081 requires that results report total toxaphene present, which was not done at Altama Elementary School. It is very unusual that analysis is conducted and chemical compounds present are not reported, as with the TTF method. Appropriate analytical methods, intended to protect human health and the environment, include the reporting of unidentified compounds when they are encountered.

Dr. R. Kevin Pegg, the community's Technical Advisor provided by an EPA Grant, summarized the analytical methods used in Glynn County, Georgia as follows:

Total Area Method

This is the basic method required by the US EPA for chemicals with multiple congeners. It detects technical, weathered and biological grades of toxaphene, as well as the off-grade product and manufacturing residue forms. Basically, all of the possible toxaphene chemicals are detected and added together to quantify total toxaphene. This method was not used by the EPA in Brunswick, Georgia, but is used at other EPA sites in the United States and by other governments and researchers around the world.

Toxaphene Task Force Method

This method was developed by EPA Region 4 in Atlanta, Georgia, with Hercules Inc., and the State of Georgia. While gas chromatography is still used, only a few of the chemicals specific for technical toxaphene are used in the analysis. Even if other toxaphene chemical congeners are present, they are ignored. The toxaphene task force method (referred to as EPA Method 8081) detects technical grade toxaphene as well as the total area method; however 8081 does not detect all off-grade products, does not detect some forms of manufacturing residue toxaphene, and can only detect weathered toxaphene in the first few years after placing in the environment. The TTF method does not detect toxaphene after it has been in the environment for

several years, and it does not detect biological toxaphene. The TTF method is apparently used only in Glynn County Georgia and nowhere else in the world. The method is not recognized by other governments or by researchers as a useful method because it under-reports the actual toxaphene concentration.

GC negative ion mass spectroscopy

This technique, called the NIMS method, can detect all forms of toxaphene and is a widely respected method with a high degree of scientific merit regarding the interpretation of results. It is especially useful for detecting biological forms of toxaphene accumulation.

- Slide: Altama Elementary Sampling Results... The three congener method the OIG warned not to use is presented under Simon/Manning. The EPA OIG noted:

> "The other toxaphene degradation congeners of principal concern for the human health evaluation (e-g., p26, p50, and p62) would only become the dominant congeners upon the subsequent metabolism of this microbially degraded toxaphene (e.g., Hx-Sed and Hp-Sed) by higher organisms (e.g., fish or humans). Therefore, if the EPA or PRP (Potentially Responsible Parties) test a site for only the p26, p50, and p62 congeners, the EPA or PRP will significantly under estimate the amount of contamination by toxaphene degradation products at the site."

It is notable that EPA Region 4 continues to advocate for toxaphene analytical methods that will underestimate or fail to detect the chemicals of concern present. Obviously, the toxaphene on school property and in the water has not been degraded by the metabolism of fish or humans. EPA Region 4's introduction of Simon and Manning PRGs is meaningless to the discussion and meant to confuse the BOE. This is EPA Region 4 implementing a method the OIG specifically said not to because it would under estimate the amount present.

- Slide: Drainage Ditch … The EPA has never explained how toxaphene crossed a 6 foot deep ditch and went hundreds of feet onto school property. As noted previously, there were two removal actions on school property. The one that extended along the ditch and to the playground was not included by the EPA. Contrary to the contentions of the EPA, toxaphene contamination was found in 1995 up to and abutting the school playground, which the GEC is cognoscente and a factor in our request for retesting the school (See Attachment A). School property was tested after the removal action and levels up to 84 ppm remained. Notable is that the EPA presentation excluded this area from the removal action presented to the BOE, which further emphasizes the need for retesting the school. It is unknown why EPA Region 4 would withhold information about the removal action and the extent of contamination on school property. The OIG interviewed two experts that independently estimated the inappropriate method used on school property would report around 10% of the toxaphene present, which leaves doubt about the protectiveness of the cleanup.

- Slide: 2005 Office of Inspector… EPA Region 4 made a gross misrepresentation of the OIG findings, and attempted to re-write history the way EPA Region 4 wants it to read. The GEC presented 128 concerns about the remediation of the Hercules 009 Landfill Superfund Site. The OIG addressed only 3 of the concerns. One of the 128 the GEC did raise concerns about was retesting areas previously tested by the inappropriate method. As noted previously, the EPA OIG advocated for testing soil when there were doubts about the testing conducted previously.

As EPA Region 4 noted, risks were to be evaluated, which cannot be completed without identifying chemicals of concern present.

The EPA OIG noted:

> "When toxaphene contamination is suspected, the groundwater and **soil** analyses should test for Hx-Sed and Hp-Sed because they would be the dominant toxaphene degradation products."
>
> "In my opinion, the published science is clear that the dominant congeners generated by the microbial breakdown of technical toxaphene in **soil** are Hx-Sed and Hp-Sed with the other toxaphene congeners being present at much lower levels. Therefore, if the EPA or the potentially responsible party (PRP) are testing to determine the nature and extent of the contamination at a site by toxaphene degradation products, the dominant toxaphene congeners in the **soil** or groundwater samples will be Hx-Sed and Hp-Sed."

EPA Region 4's contention that the OIG focused on only water appears to be intentionally misleading. The OIG noted extensively that EPA Region 4 was steadfast in their refusal to report all chemicals present and has engaged in reporting only some of the chemicals known to be present since 1993, which is prior to the testing of Altama Elementary school by the three parties (EPA Region 4, Georgia EPD, and Hercules) that developed the inappropriate method.

The OIG noted:

> "Unfortunately, EPA Region IV and I continue to disagree as to whether environmental testing for toxaphene degradation products by the GC/NIMS methodology should include Hx-Sed and Hp-Sed. Region IV does not agree with the OIG's stated opinion that Hp-Sed and Hx-Sed congeners need to be definitively determined in environmental testing for toxaphene degradation products."

- Slide: 2006 Groundwater… Again, EPA is implementing Simon & Manning, even though the OIG said it would underestimate amount present.

- Slide: Toxaphene Exposure… EPA Region 4 presented irrelevant information about toxaphene exposure in the Netherlands. Unlike the Netherlands, the school is sitting next to a Superfund Site containing the manufacturing wastes from the production of toxaphene with documented releases and failures to control migration to drainage ditches and school property. Furthermore Toxaphene was manufactured in Brunswick and the wastes, including dioxin, were disposed in the landfill. It is all the manufacturing waste chemicals that are a concern, and not just technical toxaphene. The landfill contains toxaphene manufacturing wastes and off-grade product that will have much different chemicals ratios and contaminants than the toxaphene pesticide sold for agricultural use. For these reasons, it is imperative to test for and report all chemicals present.

- Slide: Re-evaluation of Site Risks 1.) EPA Region 4 recalculated risk from toxaphene and published it as Simon & Manning. The OIG explicitly said the calculations should be provided. The GEC asked for the calculations from EPA Region 4 and they could not produce the calculations, nor would the authors. The GEC has this correspondence from EPA Region 4.

2.) EPA Region 4 claims prevalent congeners (Hx-Sed and Hp-Sed, or toxaphene with 6 and 7 chlorines attached) are of lesser concern because they are eliminated from the body quickly. No data in support was presented, but there is a lot to the contrary.

3.) EPA claims there is no screening criteria for prevalent congeners, which is incorrect. Prior to the meeting in 1991 when an agreement was made to change EPA Method 8081, the parties agreed previous testing did report "total" or "apparent toxaphene," which did report all toxaphene chemicals present. Furthermore, the method advocated by the OIG, Gas Chromatography - Negative Ion Mass Spectroscopy (GC-NIMS) has been used in Glynn County for fish and water since at least 2000 and has been identifying and quantifying the very chemicals EPA Region 4 claims there are no screening criteria. Under the Performance Standards Act, scientifically accepted and peer reviewed analytical methods can be used by the EPA. In the case of NIMS, the EPA has been using the method for over 20 years and the results extensively published in scientific peer reviewed journals. EPA Region 4 inferred that since research is being conducted about analytical methods that testing cannot be done at the school, which is misleading and outright wrong. The presentation concerning risks appears to be intended to baffle and confuse the BOE concerning the OIG findings, recommendations, and appropriate methods to test the school to definitively determine risk to students.

- Slide: Region 4 Response… EPA Region 4 claims weathered toxaphene poses less risk, but produced no data in support. Available science contradicts EPA Region 4's position, and identifies the chemicals being excluded and not reported as being MORE toxic than the technical toxaphene mixture. The ATSDR Toxicological profile for Toxaphene states:

> "Toxaphene components A and B have been isolated and found to possess toxicity that is 6 and 14 times greater, respectively, than the technical toxaphene mixture as measured by comparing intraperitoneal LD50 values in mice (Casida et al. 1974). Toxicant A has been identified as a mixture of 2,2,5-endo,6-exo,8,8,9, 10-octachlorobomane and 2,2,5-endo,6-exo,8,9,9,10- octachlorobomane (Matsumura et al. 1975; Turner et al. 1975) and **toxicant B has been identified as 2,2,5- endo,6-exo,8,9, 10-heptachlorobomane** (Casida et al. 1974). **It has further been determined that toxicant B and four of its derivatives, each with an additional chlorine atom at position 3-exo,8,9, or 10, may be responsible for the bulk of toxaphene's acute toxicity** (Saleh et al. 1977)."

Important to note is that the EPA OIG identified toxicant B, Hp-Sed, as being one of the most prevalent chemicals present. Attachment C identifies the congeners that are accepted as being technical toxaphene, which do include the very chemicals EPA Region 4 continues to advocate for not reporting, even when they are known to be present. As Attachment C demonstrates, EPA Region 4 has arbitrarily excluded chemical components of the technical toxaphene mixture with 6 and 7 chlorines attached (Hp-Sed and Hx-Sed), which are the chemical components identified by the OIG as most prevalent, and as the most toxic by ATSDR.

Contrary to the contentions of EPA Region 4 that these chemicals pose less risk and lesser concern, ATSDR found:

> "Information on the toxicities of components in the original mixtures is limited to perhaps 10 congeners, the most familiar being the appreciably toxic and persistent toxicant A and toxicant B."

The ATSDR Toxicological profile for Toxaphene states the following about the toxicological effects of toxaphene on children:

> "Pregnant women, fetuses, nursing infants, and very young children may be at greater risk of adverse health effects from pesticide exposure than the general population (Calabrese 1978). Exposure to organochlorine insecticides, such as toxaphene, may adversely affect reproductive physiology (i.e., hormonal balance) in certain women (Calabrese 1978). Embryos, fetuses, and neonates up to age 2-3 months may be at increased risk of adverse effects following pesticide exposure because their enzyme detoxification systems are immature (Calabrese 1978). Animal studies suggest that detoxification of the toxaphene mixture may be less efficient in the immature human than the metabolism and detoxification of the single components such as toxicant A or B (Olson et al. 1980). Infants and children are especially susceptible to immunosuppression because their immune systems do not reach maturity until 10-12 years of age (Calabrese 1978)."
>
> "Animal studies suggest that detoxification of the toxaphene mixture may be more inefficient in immature animals and possibly also in children than the metabolism and detoxification of the single components such as toxicant A or B."
>
> "Humans living in areas surrounding hazardous waste sites may be exposed to toxaphene via ingestion of contaminated water or even ingestion of soil, particularly by children. Inhalation exposure to toxaphene via volatilization from contaminated water or soil may also occur."
>
> "Subsets of the human population that may be unusually susceptible to the toxic effects of toxaphene include pregnant women, their fetuses, nursing babies, young children, people with neurologic diseases (particularly convulsive disorders), and individuals with protein-deficient diets. Others at increased risk include people with hepatic, cardiac, renal, or respiratory diseases, those with immune system suppression, and those ingesting alcohol or consuming therapeutic or illicit drugs."

Slide: Conclusions… 1.) EPA Region 4, based upon the use of previous testing from 1993 the OIG found inappropriate, concluded there is no site related impact. Relying on an analytical method known to exclude the chemicals that are most prevalent and most toxic underscores EPA Region 4's effort to prevent testing that will report all chemicals present.

2.) EPA Region 4's claim that toxaphene does not poses a health risk is not supported by data but rather a flimsy argument that there is no risk to students if unknown chemicals are present. Risk cannot be determined until the school is tested and all chemicals present are reported.

In closing, the cleanup of the Hercules 009 Landfill Superfund Site was based upon cleaning up toxaphene to 0.25 ppm would also cleanup the other chemicals such as dioxin, a waste product from the manufacture of toxaphene. If all the toxaphene chemicals are not reported, the other toxic chemicals in the toxaphene manufacturing wastes will not be cleaned up. The first step in protecting children is to report all chemicals present on Altama Elementary School property. In addition, sufficient information should be collected to assure the Glynn

County BOE that drainage ditch maintenance can be conducted without recontamination, and school property is not encumbered by chemical contamination.

Attachment J

Review of EPA's January 29, 2008, Presentation

by Dr. R. Kevin Pegg

At the request of the Glynn Environmental Coalition I reviewed the recent January 29, 2008 EPA PowerPoint presentation **to the Glynn County Board of Education**. There are factual errors and scientific inaccuracies contained within this presentation.

First, "toxaphene" is a trade name for a toxic and carcinogenic mixture of chlorinated organic chemicals. Toxaphene was never a chemically defined preparation. Camphene from pine stumps was chlorinated until a toxic endpoint was reached using a fly bioassay—a test to see how many flies died in a fixed period of time with a known quantity of toxaphene. Off-grade product with mixed results for fly killing was stored on the Hercules site for many years, or placed into the 009 landfill. Contamination outside of the 009 landfill repository cells was proven beyond doubt in numerous studies conducted during the mid-1990's. Toxaphene was found along the transportation route to the landfill, in the neighborhood adjacent the landfill, on the school grounds adjacent the landfill, in the drainage ditch separating the landfill from the school, and outside of the containment cells on landfill grounds.

All of the available science shows beyond doubt that toxaphene, including technical grade and so-called "weathered" toxaphene, is a biocide (kills across species lines), is mutagenic, and causes cancer in laboratory rodents. These studies have been replicated in numerous laboratories with appropriate scientific controls and are not in dispute. However, there are very few scientific studies showing which of the many chemicals in toxaphene are most toxic, most mutagenic, or most carcinogenic. When there are few peer–reviewed and replicated studies proving safety both the Environmental Protection Agency (EPA) and the Agency for Toxic Substances Disease Registry (ATSDR) mandate cleaning up the environment using the most conservative levels (the lowest amounts) of the target chemical. All Federal agencies involved in regulating foreign substances-- The Food and Drug Administration (FDA), United States Department of Agriculture, and Occupational Safety and Health Administration (OSHA) also use the common-sense and prudent approach of erring on the side of caution when it comes to complex chemicals.

Federal guidelines mandate that potential environmental exposure pathways to toxic chemicals must be defined. Pathways include exposure through air (volatile chemicals and small particles), surface or groundwater (soluble chemicals), or soil. Extensive toxaphene contamination was found in the soil of the elementary school adjacent the 009 Landfill Superfund Site. Further, there was ample evidence of human use (trails, trash) throughout the contaminated areas. Contemporaneous documents defined both past landfill site operations and contaminated spoil piles from the stream placed on school property as sources of the toxaphene on school property. It is a scientific fact that a completed exposure pathway for soil did exist on school grounds. Region 4 EPA's assertion that only groundwater exposure at this site is relevant is not consistent with the site history. Note that the slides entitled "2006 Groundwater Sampling" and "Toxaphene Exposure Risks" are entirely irrelevant for any discussion of a soil pathway. It is unclear why EPA is asserting groundwater data in regard to soil sampling issues, there is no logical reason for making a claim for soil safety based on water.

All of the available analytical science shows that toxaphene is a straightforward chemical mixture to analyze and characterize. The EPA has had in place, for decades, scientific methods for quantifying multi-component mixtures. Toxaphene can easily be quantified using gas chromatography with a variety of detectors. These instruments are common to nearly every laboratory, and the techniques are straightforward. Toxaphene is routinely quantified using this standard equipment and standard EPA methods in laboratories around the country and around the world. There is no scientific rationale for a special toxaphene method just to monitor toxaphene in Glynn County, Georgia. EPA's assertion that no method existed in 1993 to test for "weathered" toxaphene is nonfactual. Standard EPA methods would have quantified toxaphene at this site in 1993, and were in use at that time at other sites with far less toxaphene.

Risk modeling is a well-established science. When calculating risk the nature of the chemical is taken into consideration, the amount of chemical exposure—concentration of chemical and duration—is factored into the equation, and toxicology effects from animal and human exposure all are assigned values. These models are then placed into the public domain so that other toxicologists can validate the findings. There currently are mathematical risk assessment models for assessing toxaphene risk. EPA asserts in a slide titled "Re-evaluation of Site Risks" that "EPA Region 4 conducted a re-analysis of European toxicity data and determined that weathered toxaphene breakdown products are less toxic than technical toxaphene." If these models are published then the reference should be given, especially since Region 4 EPA is not a third party to this controversy. Region 4 actually created this controversy by using unscientific methodology, which cannot be set aside with non-reviewed internal studies and opinions. No scientist would accept Region 4's statement at face value without seeing EPA's model entire mathematical model used for the reassessment.

There is no scientific support for Region 4 EPA's claims that toxaphene in Brunswick, Georgia:

- requires special methods for detection;
- does not require monitoring; and,
- is proven safe based on Region 4's reassessment.

Further, the opinions expressed by EPA Region 4 are contrary to agency guidelines. Unlike other parts of the country, and the world, Glynn County-- likely one of the most toxaphene contaminated areas anywhere-- has not received the benefit of simple scientific analyses for toxaphene in soil. It is reasonable to expect Region 4 to follow the order of their own Inspector General to test the vicinity of the landfill with the EPA's validated methods, rather than rely on data using a discredited technique.

R. Kevin Pegg, Ph.D.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 31 2006

OFFICE OF
INSPECTOR GENERAL

MEMORANDUM

SUBJECT: OIG Ombudsman Report 2005-P-00022
Appropriate Testing and Timely Reporting Are Needed at the
Hercules 009 Landfill Superfund Site, Brunswick, Georgia

FROM: Paul D. McKechnie
Director of Public Liaison
Office of Congressional and Public Liaison

TO: J. I. Palmer, Jr.
Regional Administrator
Region 4

We have evaluated your final response dated June 20, 2006, to the subject report, as well as the related attachments (such as the second 5-year report dated June 2006) and additional documents provided by members of your staff. The latter included the article by Ted Simon and Randall Manning, *Development of a reference dose for the persistent congeners of weathered toxaphene based on in vivo and in vitro effects related to tumor promotion,* and the results of recent tests of the groundwater at the Hercules 009 Landfill site. The associated documents were reviewed by a chemist currently on our staff and by the subject matter expert who worked on the assignment who is now employed by another Federal agency. We also took into consideration the comments provided to us on September 7 and October 10, 2006, by the Glynn Environmental Coalition and its consultants.

We believe additional research is necessary to increase the confidence in Region IV's assessment on the human health risks posed by toxaphene degradation products, however, we are closing this report because you have adequately addressed the recommendations we made. Our basis for reaching this conclusion is described in the attached letter dated October 23, 2006. As this letter points out, for scientific and regulatory transparency, you should provide a detailed description of how the preliminary remediation goals (PRGs) for weathered toxaphene were calculated. Some other key points related to your response that are detailed in the letter are:

- The PRGs Region IV developed for weathered toxaphene, not the drinking water program's maximum contaminant level for technical toxaphene, should now be used to evaluate the human health risk.

- When toxaphene contamination is suspected, the groundwater and soil analyses should test for Hx-Sed and Hp-Sed because they would be the dominant toxaphene degradation products.

- The analysis performed on the groundwater samples collected at the Hercules 009 Landfill in March 2006 (not March 2005) included quality controls sufficient to ensure the results can be accurately interpreted.

As we noted in Report 2006-P-00007 dated December 16, 2005, *More Information Is Needed On Toxaphene Degradation Products,* additional research and scientific study is needed to assess the health risk posed by the human exposure to toxaphene degradation products. We urge you to work closely with the Office of Research and Development as they prepare their multi-year research plan, so it includes toxaphene degradation products. Similarly, we believe the Office of Research and Development and the Office of Solid Waste and Emergency Response will need help from you to develop the analytical method using negative ion mass spectroscopy.

If you or your staff has any questions regarding this matter, please contact me at 617-918-1471 or Christine Baughman, the Project Manager, at 202-566-2902.

Attachment

cc: Susan Bodine, Assistant Administrator for Solid Waste and Emergency Response
George Gray, Assistant Administrator for Research and Development
Benjamin Grumbles, Assistant Administrator for Water
Stephanie Lankford, Region 4 Audit Liaison
Johnsie Webster, OSWER Audit Liaison
Cheryl Varkalis, ORD Audit Liaison
Mike Mason, OW Audit Liaison
Laurie Dubriel, Special Assistant to the Administrator
Winston A. Smith, Director, Waste Management Division, Region 4
Leo Francendese, Remedial Project Manager, Region 4
Daniel Parshley, Project Manager, Glynn Environmental Coalition

October 31, 2006

Paul Mckechnie
Director Public Liaison/Ombudsman
Environmental Protection Agency
Office of Inspector General
Office of Congressional and Public Liaison
1200 Pennsylvania, Ave, N.W. (2491T)
Washington, D.C. 20460

Dear Paul,

At your request, I am providing you my technical opinion on EPA Region IV's final response (Dated June 20, 2006) to the Ombudsman's Recommendations 2.1 and 2.2 in the Report 2005-P-00022 (dated Sept. 26, 2005). The Ombudsman Report 2005-P-00022 concerned EPA Region IV's assessment, during the second 5-Year Review, of the public health risk posed by degraded toxaphene at the Hercules 009 Landfill Superfund site. As a former EPA/OIG Environmental Scientist on your staff, I served as the subject matter expert for each of the Ombudsman reports on toxaphene (i.e., Reports 2005-P-00022 and 2006-P-00007). This experience provides me with an in depth knowledge of the subject and I present my observations and findings for your consideration. Since I am no longer an EPA employee, this review and subsequent development of my technical opinion were performed pro bono.

I received and reviewed the following five documents to develop my technical opinion on Region IV's final response to the OIG's Recommendations 2.1 and 2.2 in Report 2005-P-00022:

- [EPA Region IV's] Final Response to the Recommendations and Final Report for the Hercules 009 Landfill OIG/Ombudsman Report *Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site Brunswick, Georgia Assignment 2004-124* (dated June 20, 2006).

- The Hercules 009 Landfill April 2006 GC/ECD and GC/ECNI-MS-SIM ground water testing results performed by Pace Analytical Laboratories on behalf of Hercules Incorporated (dated June 15, 2006).

- Ted Simon, Randall Manning; Development of a reference dose for persistent congeners of weathered toxaphene based on in vivo and in vitro effects related to tumor promotion. Regulatory Toxicology and Pharmacology, Vol. 44 (2006), pages 268-281.

- Comment from the Glynn Environmental Coalition on the June 20, 2006, EPA Region 4, Final Response to the Recommendations and Final Report for the Hercules 009 Landfill OIG/Ombudsman Report *Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site Brunswick, Georgia* (dated September 7, 2006) including the enclosed attachments from R. Kevin Pegg, Ph.D. and Kathleen Burns, Ph.D.

- Comments to OIG on Hercules 009 Superfund Reports by Jennifer Sass, Ph.D. (dated October 10, 2006).

The purpose of a 5-year review is to assess if the remedy is still protective in light of any new science or site information that has occurred since the last assessment. Since toxaphene is well known in the scientific literature to degrade in the environment, the 5-year review needs to determine the amount of exposure (if any) and the resulting risk to the public from degraded toxaphene from the site. This is accomplished by accurately measuring the amount of degraded toxaphene in the groundwater at the site, by determining if any of the contaminated toxaphene groundwater has left the site, and by determining the human health risk posed by any degraded toxaphene that might have left the site.

Evaluation of Hercules 009 Groundwater Testing

The second 5-year review of the Hercules 009 site used the Gas Chromatography/Negative Ion Mass Spectrometry (GC/NIMS) method to determine the amount of degraded toxaphene in the groundwater. However, the March 2005 GC/NIMS groundwater results have several limitations:

- The test results do not positively identify individual toxaphene degradation congeners (i.e., through a mass spectrum or selective ion monitoring confirmation) or determine the amount of individual toxaphene degradation congeners (i.e., p26, p50, Hx-Sed, Hp-Sed, etc.) present in the groundwater. This severely limits the ability to technically interpret the results with an acceptable level of confidence.

- The Quality Control used in March 2005 did not incorporate a Laboratory Control Sample (LCS) that contained known amounts of individual toxaphene degradation congeners. Therefore, without LCS results for individual congeners, the ability of the method to detect and confirm the presence of individual toxaphene congeners is questionable.

However, the GC/NIMS groundwater samples taken subsequently at the Hercules 009 Landfill site in April 2006 can be accurately interpreted. These GC/NIMS groundwater sample results are the type of testing the OIG/Ombudsman has been requesting in order to accurately measure the amount of degraded toxaphene in the groundwater at the site and to determine if any of the contaminated toxaphene groundwater has left the site.

The GC/NIMS groundwater samples taken at the Hercules 009 Landfill site in April 2006 positively identify (i.e., by Selective Ion Monitoring (SIM)) and quantitate the following eight individual toxaphene congeners: p26, p41, p40, p44, p50, p62, Hx-Sed, and Hp-Sed. In reviewing the results, the following observations and findings can be made:

- The method blank results show no laboratory contamination of toxaphene congeners.

The Laboratory Control Sample (LCS) and LCS duplicate recoveries are from 63% to 95% for the eight individual congeners and show that the GC/NIMS analysis is performing well for the detection of these eight individual toxaphene congeners. The LCS quality control results document the method's ability to detect individual toxaphene congeners in samples reliably.

- Matrix Spike (MS) and Matrix Spike Duplicate (MSD) quality control sample recoveries are from 60% to 96% for the eight individual congeners and show that the groundwater matrix does not interfere with the analysis.

- Only two groundwater monitoring wells, N-06SR and N-11, were found to have degraded toxaphene congeners significantly above the Level of Quantitation (LOQ) (See Table 1). These results are consistent with the published science on the degradation of technical toxaphene. The dominant congeners generated by the microbial breakdown of technical toxaphene are Hx-Sed and Hp-Sed with the other toxaphene congeners being present at much lower levels. The other toxaphene degradation congeners of concern (i.e., p26, p40, p41, p44, p50, and p62) would only become the dominant congeners upon the subsequent metabolism of this microbially degraded toxaphene (e.g., Hx-Sed and Hp-Sed) by higher organisms (e.g., fish or humans). The groundwater results for monitoring wells N-06SR and N-11 show that the technical toxaphene has degraded and that Hx-Sed and Hp-Sed are the dominant congeners with the other toxaphene congeners being present at much lower levels.

Ground Water Well	Hx-Sed (ppb)	Hp-Sed (ppb)	p26 (ppb)	p40 (ppb)	p41 (ppb)
N-06SR	0.186	0.128	0.009	≤0.005	0.005
N-06SR Duplicate	0.156	0.116	0.009	0.034	0.005
N-11	0.133	0.095	≤0.005	0.012	≤0.005
N-14S	≤0.005	≤0.005	≤0.005	≤0.005	<0.005
N-14D	<0.005	<0.005	<0.005	<0.005	<0.005

Table 1: Subset of the April 2006 GC/NIMS Groundwater Results

- The groundwater results for the furthest down-gradient monitoring well, N-14, did not detect toxaphene degradation products above the LOQ (See Table 1). This indicates that the toxaphene degradation products found in groundwater wells N-06SR and N-11 have not left site.

OIG Recommendation 2.1

The OIG recommendation to the EPA Region IV was to use the GC/NIMS to definitively determine if toxaphene breakdown products are present in and around the surrounding groundwater at the Hercules 009 Landfill site, and (if so) in what amounts.

EPA Region 4 has implemented the OIG Recommendation 2.1 with the April 2006 GC/NIMS groundwater testing at the Hercules 009 Landfill. These groundwater results definitively show that the technical toxaphene can and has degraded and that Hx-Sed and Hp-Sed (i.e., the microbial toxaphene breakdown products) are present at a maximum

concentration of 0.186 ppb and 0.128 ppb, respectively. Several of the other toxaphene congeners (e.g., p26, p40, and p41) are also present, but at much lower levels. Since the April 2006 GC/NIMS groundwater results are consistent with the published science on the degradation of technical toxaphene and since the LCS and MS quality control results indicate that the GC/NIMS method was performing well, the April 2006 GC/NIMS groundwater results can be concluded to accurately characterize the site's groundwater conditions for toxaphene degradation products.

Unfortunately, EPA Region IV and I continue to disagree as to whether environmental testing for toxaphene degradation products by the GC/NIMS methodology should include Hx-Sed and Hp-Sed. **Region IV does** not agree with the OIG's stated opinion that Hp-Sed and Hx-Sed congeners need to be definitively determined in environmental testing for toxaphene degradation products (see Region IV Final Response cover memo, page 2; and Attachment C of the Region IV Final Response, page 38). In my opinion, the published science is clear that the dominant congeners generated by the microbial breakdown of technical toxaphene in soil are Hx-Sed and Hp-Sed with the other toxaphene congeners being present at much lower levels. Therefore, if the EPA or the potentially responsible party (PRP) are testing to determine the nature and extent of the contamination at a site by toxaphene degradation products, the dominant toxaphene congeners in the soil or groundwater samples will be Hx-Sed and Hp-Sed. The other toxaphene degradation congeners of principal concern for the human health evaluation (e.g., p26, p50, and p62) would only become the dominant congeners upon the subsequent metabolism of this microbially degraded toxaphene (e.g., Hx-Sed and Hp-Sed) by higher organisms (e.g., fish or humans). Therefore, if the EPA or PRP test a site for only the p26, p50, and p62 congeners, the EPA or PRP will significantly under estimate the amount of contamination by toxaphene degradation products at the site.

Furthermore, the EPA and/or the PRP need to monitor the groundwater at a site to insure that toxaphene contaminated groundwater is not leaving the site. Since Hx-Sed and Hp-Sed would be the dominant congeners in groundwater, how can EPA or the PRP monitor the groundwater contamination and determine if the contamination is leaving the site without monitoring for Hx-Sed and Hp-Sed? Furthermore, the additional cost to test for the Hx-Sed and Hp-Sed congeners in the GC/NIMS method is minimal (i.e., the cost of including the Hx-Sed and Hp-Sed in the calibration standards and spike solutions for the LCS and MS quality control samples). There is no practical or scientific reason to exclude Hx-Sed and Hp-Sed in the testing for contamination by toxaphene degradation products. Therefore, it is my opinion that it is imperative that the EPA-approved GC/NIMS method under development by the Office of Research and Development include Hx-Sed and Hp-Sed as target congeners in the method.

Evaluation of the Human Health Risk to Degraded Toxaphene

EPA Region IV Final Response (Cover Memo) compares the concentrations of toxaphene degradation products in the groundwater to the drinking water maximum contaminant level (MCL) of 3.0 ppb for technical toxaphene. The composition of the congeners present in technical toxaphene is distinctly different than the composition of the congeners found in degraded toxaphene. The composition of technical toxaphene is mostly comprised of the higher chlorinated level of

boranes, while the degraded toxaphene is principally made of the lower chlorinated levels of boranes such as Hx-Sed, Hp-Sed, p26, p50 and p62, etc. Furthermore, since the last significant use of technical toxaphene was in 1982 and since technical toxaphene is known to degrade in the environment, the human population is no longer exposed to technical toxaphene, but is exposed to toxaphene degradation products. Therefore, the continued application of the drinking water MCL of 3.0 ppb for technical toxaphene in the risk assessment of toxaphene degradation products is scientifically inappropriate. For that matter, since the human population is and will no longer be exposed to technical toxaphene, the drinking water MCL of 3.0 ppb for technical toxaphene can be retired for the lack of an appropriate risk management application.

In response to the OIG Recommendation 2.2 to assess the risk to human health from the potential exposure to toxaphene breakdown products, EPA Region IV conducted a re-analysis of the European MATT (2000) toxicity data and developed a reference dose for weathered toxaphene. Ted Simon and Randall Manning published their findings in the following scientific journal: Regulatory Toxicology and Pharmacology, Vol. 44 (2006), pages 268-281. EPA Region IV states in their Final Response (See attachment B, page 2) that "… the Simon/Manning approach should be considered the best available science; therefore, the Region's reliance on this approach to assess the risk associated with this site is appropriate."

In my opinion, the Simon and Manning paper is significant in the field of scientific research into toxaphene because it is the first published paper that quantifies the risk of weathered toxaphene. The authors make a number of key determinations (e.g., weathered toxaphene's mode of action is as a promoter, applied the unconventional use of a reference dose to a carcinogen, applied a uncertainty factor of a 100, etc.) whose application for calculating an acceptable exposure limit to weathered toxaphene is open for debate and to further research and study within the scientific community. However, the Simon/Manning paper does represent the best and only available scientific information that quantifies the human health risk to weathered toxaphene for use in the second 5-year review of the Hercules 009 Landfill. Science is dynamic and continuously evolves as new information becomes available, so the Simon/Manning paper is not the last word on the issue, but represents the next step into the understanding of the amount of risk posed by weathered toxaphene. More scientific information should be available in five years to allow for a better estimate of the human health risk posed by weathered toxaphene for the next 5-review of the Hercules 009 Landfill in 2011.

EPA Region IV states in their Final Response (See attachment B, page 2) that "… the Simon/Manning approach should be considered the best available science; therefore, the Region's reliance on this approach to assess the risk associated with this site is appropriate." However, EPA Region IV does not use the Simon/Manning approach to assess the risk associated with this site. EPA compares the concentrations of toxaphene congeners in the groundwater to the drinking water MCL of 3.0 ppb. However, in my opinion, to be consistent with their statement on the Simon/Manning approach, EPA Region IV needs to evaluate the concentrations of toxaphene degradation products against the Preliminary Remediation Goals (PRGs) established

in the Simon/Manning paper for ∑3PC and weather toxaphene of 0.03 ug/L and 0.6 ug/L, respectively (See Table 5 in the Simon and Manning paper). Unfortunately, the Simon/Manning paper does not show how the PRGs were calculated. Therefore, I cannot independently verify them (i.e., EPA Region IV should be required to provide a detailed description of how these PRGs were calculated for scientific and regulatory transparency). However, EPA Region IV clearly states that it is the "best available science." Thus, EPA Region IV should apply these PRGs to the assessment of the risks associated with weathered toxaphene at the Hercules 009 Landfill and other toxaphene contaminated Superfund sites in Region IV. In other words, the EPA Region IV should use the 0.6 ug/L PRG for weathered toxaphene (which is 5-fold more restrictive than the 3.0 ppb drinking water MCL being applied by the Region) to evaluate the concentrations of degraded toxaphene congeners found in the groundwater.

When the April 2006 GC/NIMS groundwater results for the Hercules 009 Landfill site are compared against the PRGs for ∑3PC and for weathered toxaphene, the concentration of the toxaphene degradation products do not exceed either PRG. The groundwater samples from monitoring well N-06SR contained the highest levels of toxaphene degradation products. Specifically, the groundwater sample and duplicate from N-06SR contained 0.328 ug/L and 0.320 ug/L of weathered toxaphene, respectively. Both results are below the 0.6 ug/L PRG for weathered toxaphene. Furthermore, the groundwater sample and duplicate from N-06SR contained 0.009 ug/L and 0.009 ug/L for ∑3PC, respectively. Both results are below the 0.030 ug/L PRG for ∑3PC. Therefore, the level of groundwater contamination by toxaphene degradation products at the Hercules 009 Landfill site does not exceed the preliminary remediation goals and does not pose a health risk to the community at these levels.

OIG Recommendation 2.2

The OIG recommendation to the EPA Region IV was to assess the risk to human health by exposure to toxaphene breakdown products.

EPA Region IV has met the OIG Recommendation 2.2 with the development and publication of the Simon and Manning paper and their development of the Preliminary Remediation Goals for ∑3PC and Weathered Toxaphene of 0.03 ug/L and 0.6 ug/L, respectively (See Table 5 in the Simon and Manning paper). However, the EPA Region IV should be required to provide a detailed description of how these PRGs were calculated for scientific and regulatory transparency.

Protectiveness Statement

Based on the April 2006 GC/NIMS groundwater results indicating that the toxaphene degradation products have not left the site through the groundwater and also based on the observation that the maximum concentration of toxaphene degradation products is below the PRGs for ∑3PC and weather toxaphene of 0.03 ug/L and 0.6 ug/L, respectively, I concur with the Regional findings of the second 5-year review that the Hercules 009 Landfill site remedy is protective of human health and the potential exposure pathways are under control in regard to the contaminant toxaphene and its degradation products.

Conclusion

The two Ombudsman reports on toxaphene have been influential in shifting the entrenched paradigm of the EPA and PRPs to perpetually test for technical toxaphene and subsequently evaluate the risk against the limits set for technical toxaphene. The Ombudsman's efforts have promoted the recognition that currently, toxaphene only exists in the environment in a degraded, weathered state and that the regulatory and scientific communities need to test for and assess the risk posed from human exposure to weathered toxaphene. Furthermore, the completion of the EPA-approved GC/NIMS method by the end of 2008 and the subsequent use of this method by EPA and PRPs will definitively determine the extent of degraded toxaphene contamination left in the environment from 32 years of heavy use as an insecticide.

Sincerely,

_/s/_____
Michael Wilson
Former Environmental Scientist with the EPA/OIG

cc: Christine Baughman