OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

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

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Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CLE	Cod Liver Extract
Corps	U. S. Army Corps of Engineers
DDE	Dichlorodiphenyldichloroethylene
DDT	Dichlorodiphenyltrichloroethane
DNA	Deoxyribonucleic Acid
EPA	U. S. Environmental Protection Agency
EUSES	European Union System for the Evaluation of Substances
GA/DNR	Georgia Department of Natural Resources
GC/ECD	Gas Chromatograph/Electron Capture Detector
GC/NIMS	Gas Chromatograph/Negative Ion Mass Spectroscopy
GEPD	Georgia Environmental Protection Division
HCH	Hexachlorocyclohexane
IRIS	Integrated Risk Information System
MATT	Monitoring, Analysis, and Toxicity of Toxaphene in Marine Foodstuff
MNA	Monitored Natural Attenuation
NIMS	Negative Ion Mass Spectroscopy
OIG	Office of Inspector General
OSWER	Office of Solid Waste and Emergency Response
PCB	Polychlorinated Biphenyls
ppb	Parts Per Billion
ppt	Parts Per Trillion
RPM	Remedial Project Manager
SESD	Science and Ecosystem Support Division
TCDD	Tetrachlorodibenzo-p-dioxin
TDI	Tolerable Daily Intake

Cover photo: Aerial view of the Hercules 009 Landfill, which is in the center and left-center of this photograph, provided by Hercules Incorporated.

U.S. Environmental Protection Agency
Office of Inspector General

2005-P-00022
September 26, 2005

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

The Glynn Environmental Coalition, a nonprofit community organization whose goal is to have a safe and healthy place to live and raise a family, brought several concerns to the Ombudsman's attention regarding the Hercules 009 Landfill site near Brunswick, Georgia, in EPA Region 4.

Background

Between 1975 and 1980, Hercules Incorporated operated the Hercules 009 Landfill to dispose of waste material from producing toxaphene, an agricultural pesticide. The site became part of EPA's Superfund program in 1984. Construction on the cleanup was completed in 1999, but some contaminants remained at the site, so every 5 years the site must be reviewed to ensure that the cleanup is functioning as intended and it does not adversely affect human health and the environment.

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report and addendum, click on the following links:

www.epa.gov/oig/reports/2005/20050926-2005-P-00022.pdf

www.epa.gov/oig/reports/2005/20050926-2005-P-00022A.pdf

Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site, Brunswick, Georgia

What We Found

The testing method that EPA uses to monitor for the presence of toxaphene in groundwater is inadequate. Toxaphene degrades over time, changing into other products (toxaphene breakdown products). EPA's testing method does not identify and measure the amount of toxaphene that has degraded, only toxaphene that has not degraded.

The available toxicity data on the toxaphene breakdown products are not specific as to what constitutes a safe, acceptable level of exposure. Because toxaphene breakdown products may pose a risk to human health, they should be monitored. A different analytical method, one that monitors toxaphene breakdown products, should be used rather than the conventional EPA method.

EPA's report on the 5-year review of the Hercules 009 Landfill is over a year late, because

- Region 4 was gathering additional data to reduce uncertainty about how much toxaphene was present in the groundwater.
- The U.S. Army Corps of Engineers took longer to prepare the first draft report than expected.
- The EPA manager for the site changed twice during the review period.
- EPA and others made extensive comments on the draft reports.

What We Recommend

We recommend that EPA Region 4:

- use an analytical method that monitors both toxaphene and its breakdown products in the groundwater at the Hercules 009 Landfill and take appropriate action if toxaphene breakdown products are found.
- issue the report on the Hercules 009 Landfill 5-year review.

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

OFFICE OF
INSPECTOR GENERAL

September 26, 2005

MEMORANDUM

SUBJECT: Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site, Brunswick, Georgia
Report No. 2005-P-00022

FROM: Paul D. McKechnie /s/
Acting Ombudsman
Office of Congressional and Public Liaison

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

This is our final report on our review of complaints regarding the Hercules 009 Landfill Superfund site conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG identified and corrective action the OIG recommends. It represents the opinion of the OIG and findings contained in this report do not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established resolution procedures.

Action Required

In accordance with EPA Manual 2750, you are required to provide a written response to this report within 90 calendar days of the date of this report. You should include a corrective actions plan for agreed upon actions, including milestone dates. We have no objections to the further release of this report to the public. For your convenience, this report will be available at http://www.epa.gov/oig/publications.htm.

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

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Chapter 1
Introduction

Objectives

The Glynn Environmental Coalition, a nonprofit community organization whose goal is to have a safe and healthy place to live and raise a family, brought some issues regarding the Hercules 009 Landfill, Brunswick, Georgia, to the attention of the Ombudsman at the U.S. Environmental Protection Agency's (EPA) Office of Inspector General (OIG). (The OIG Ombudsman reviews and reports on public concerns regarding EPA activities, including Superfund.)

As a result, the OIG conducted a review of the issues to determine:

- If human health at the Hercules 009 Landfill Superfund site and/or surrounding area were threatened because the analytical method used to test for the pollutant toxaphene underestimated the amount of toxaphene breakdown products.

- If the February 2004 draft report on the 5-year review, which addressed the above and various other issues, was issued in a timely manner by EPA.

Site Information

Hercules Incorporated began producing toxaphene, an agricultural pesticide, in 1948 and continued production through 1980. Toxaphene was one of the most heavily used insecticides in the United States until 1982, when EPA cancelled the registrations for most uses; all uses were banned in 1990. A registration is a license allowing a pesticide product to be sold and distributed for specific uses in accordance with specific use instructions, precautions, and other terms and conditions. Between 1975 and 1980, Hercules Incorporated operated the Hercules 009 Landfill under a permit issued by the Georgia Environmental Protection Division (GEPD). The permit allowed the Brunswick, Georgia, Hercules plant to dispose of waste water sludge left over from having produced toxaphene. Part of the Hercules 009 Landfill was also used for disposing empty toxaphene drums and toxaphene-contaminated glassware, rubble, and trash. The GEPD monitored the Hercules 009 Landfill while it operated.

The Hercules 009 Landfill is located in the eastern portion of Glynn County, Georgia, near the City of Brunswick. The site is a 16.5 acre property, although the landfill occupies only about 7 acres on the north end of the property. It is bordered by Georgia State Highway 25 (Spur 25) on the west; an automobile dealership on the north; a pine forest on the east; and several homes, a church, a school, and a strip shopping center on the south/southeast. A shopping mall built in 1985, a bank, and a restaurant are located approximately 1000 feet north of the landfill. In the forested area in the southeastern part of the site, outside of the protectively capped area, is a storage shed near a small pond. The property is surrounded by a fence with locked gates.

EPA added the Hercules 009 Landfill to the Superfund National Priority List in 1984. In December 1992, EPA completed an interim cleanup action at the site. As part of the interim action, private wells immediately down gradient of the landfill were replaced by the municipal water system. Further site cleanup action, known as remedial action, began at the site in June 1998. The remedial action involved stabilizing the site and constructing a landfill cover, which was then covered with clean fill material that was graded to promote adequate drainage, and seeded with grass. Although active cleanup of the groundwater was not included, groundwater monitoring was required to assess (1) any movement of contamination through groundwater and (2) reduction of contaminants through natural means, known as natural attenuation.

Background Information on Toxaphene

Unlike most organic environmental pollutants, toxaphene is not a single organic compound. As manufactured, the original toxaphene pesticide was a mixture of more than 200 closely related chlorinated organic compounds. This original toxaphene pesticide mixture is commonly known as “technical” toxaphene. Technical toxaphene consists mainly of polychlorinated bornanes with between six to nine chlorines attached. The term “congener” is used to refer to a single, structurally unique constituent of the mixture. In other words, at least 200 individual toxaphene congeners make up the original toxaphene pesticide mixture. Individual congeners are often given their own name, such as Hx-Sed and Hp-Sed. When the original toxaphene is released to the environment, it naturally breaks down or degrades. These breakdown products are a different mixture than the original toxaphene mixture, so it appears different to the testing instruments.

Scope and Methodology

The OIG began preliminary research on the site in late 2002 and completed work in April 2004. It started the field work on this review in June 2004 and completed it in January 2005.

We interviewed the present and two former remedial project managers (RPMs) from EPA Region 4 and other Region 4 officials, and reviewed site files. We also interviewed representatives of the U.S. Army Corps of Engineers (Corps) and the

Glynn Environmental Coalition. A representative of Hercules Incorporated provided the OIG team and Corps officials a tour of the site.

We interviewed representatives of EPA's Office of Research and Development and Office of Solid Waste and Emergency Response. The OIG team reviewed toxaphene testing protocols and about 50 journal articles on toxaphene toxicity and exposure issues. The team also obtained additional information from various State and Federal Internet sites.

On May 16, 2005, the OIG issued a draft report to EPA's Region 4 for review and comment. The Regional Administrator responded on June 29, 2005. This response, which included six attachments with detailed technical and legal comments, suggested alternative actions to address the matters discussed in the draft report. We provide a summary and general evaluation of the EPA comments and our response at the end of Chapter 2 and Chapter 3 of this report. We included the Regional Administrator's memorandum in Appendix B. The memorandum, together with the six attachments and other documents later provided by Region 4, are available as an addendum to this report. Appendix C is the OIG evaluation of the EPA response, including the review that Region 4 requested of their proposed interim strategy for risk assessment.

We performed our review in accordance with *Government Auditing Standards* issued by the Comptroller General of the United States. However, our review of management controls and compliance was limited to those related to this particular Superfund site.

The findings in this report are not binding in any enforcement proceedings brought by EPA or the Department of Justice under the Comprehensive Environmental Response, Compensation, and Liability Act to recover costs incurred not inconsistent with the National Contingency Plan.

Chapter 2

The Groundwater Should be Tested for Toxaphene Breakdown Products

EPA policy states that monitoring programs should identify any potentially toxic transformation products. Thus, the groundwater at the Hercules 009 Landfill site should be periodically tested for toxaphene and its toxic breakdown products. To determine if the groundwater is contaminated by toxaphene breakdown products, the EPA needs to use a new analytical method that specifically tests for these products. Until EPA knows whether the groundwater is contaminated by toxaphene breakdown products, it will be unable to definitively determine if the cleanup for the Hercules 009 Landfill protects human health. Appendix A contains a technical discussion of the matters addressed in this chapter.

Testing for Toxaphene Breakdown Products Is Needed

Part of the cleanup at the Hercules 009 Landfill site is monitored natural attenuation (MNA or natural attenuation). A natural attenuation remedy (or cleanup) is one in which environmental contamination remains on-site and is allowed to naturally decompose. For a natural attenuation cleanup to protect human health, the environmental contaminants cannot migrate off the site through, for example, the movement of contaminated groundwater. Therefore, contaminants known to be at the site, as well as any toxic chemicals resulting from the breakdown of those contaminants, should be periodically tested (i.e., monitored) in the groundwater. In the case of Hercules 009 Landfill, the surrounding groundwater is being periodically tested for the original toxaphene mixture put in the site between 1975 and 1980. However, this routine testing does not specifically look for, or definitively identify, individual breakdown products of toxaphene, i.e., the toxaphene breakdown products.

According to Superfund's guidance for monitored natural attenuation (OSWER—Office of Solid Waste and Emergency Response--Directive 9200.4-17P), EPA should look for the potential presence of toxic transformation products. Toxaphene breakdown products are a type of transformation product. Specifically, the guidance states:

> *The potential for creation of toxic transformation products is more likely to occur at non-petroleum release sites ... and should be evaluated to determine if implementation of a MNA [natural attenuation] remedy is appropriate and protective in the long term.*

Furthermore, the guidance states:

> *... all [MNA or natural attenuation] monitoring programs should be designed to accomplish the following: ... Identify any potentially toxic and/or mobile transformation products.*

In other words, EPA's guidance requires groundwater monitoring for breakdown products when the following two conditions are met: (1) the original contaminant is known to decompose and form breakdown product(s), and (2) these breakdown products are thought to be toxic and/or mobile in the groundwater. Since toxaphene is known to degrade in the environment and these breakdown products are thought to be toxic, EPA must evaluate the groundwater at the Hercules 009 Landfill site for toxaphene breakdown products.

EPA's Method Fails to Identify Toxaphene Breakdown Products in Groundwater

The EPA conventional analytical method (known as Method 8081) is currently used to monitor toxaphene in the groundwater at the Hercules 009 landfill site. EPA's method is a test procedure designed to look for the original, unaltered toxaphene mixture. However, microbes in the soil are known to decompose the original toxaphene mixture into just two major breakdown products (i.e., Hx-Sed and Hp-Sed) and several minor breakdown products. The original toxaphene mixture and the two principal toxaphene breakdown products look completely different to the analytical instruments. As a result, the groundwater monitoring data collected at the site, using EPA's method, only identified the original toxaphene mixture in the groundwater. The laboratory results from the EPA method clearly indicated that groundwater surrounding the site does not contain the original toxaphene mixture.

The groundwater surrounding the site could be contaminated with toxaphene breakdown products. Unfortunately, EPA's method does not look for, or specifically identify, toxaphene breakdown products. Therefore, the groundwater monitoring by EPA's method does not meet the Agency's requirement to monitor for toxaphene breakdown products, and the current groundwater monitoring data from the Hercules 009 Landfill site cannot be used to determine whether the groundwater could be contaminated by toxaphene breakdown products.

Using a Different Method Would Identify Breakdown Products

When the OIG looked at the groundwater monitoring data for evidence of toxaphene breakdown products, the OIG found some evidence suggesting that toxaphene breakdown products may be in the groundwater surrounding the Hercules 009 Landfill site. However, these groundwater monitoring data are insufficient to definitively determine the presence or absence of toxaphene breakdown products in the groundwater. Without such definitive data, any determination on the effectiveness of the cleanup remedy is inconclusive.

A new analytical method using Negative Ion Mass Spectroscopy (NIMS, or called the new method hereafter) should be used to test for toxaphene breakdown products in the groundwater. Academia and the European Union have successfully used the new method for at least 5 years to test for toxaphene breakdown products in the environment.

The new method provides definitive test results because the technique generates a mass spectrum for each compound in an environmental sample. A mass spectrum is analogous to a chemical "fingerprint." By comparing the "fingerprint" of an unknown compound in the Hercules 009 groundwater sample with the known "fingerprint" of the toxaphene breakdown products, a resulting match of the "fingerprints" would definitively identify the presence of toxaphene breakdown products.

On the other hand, if the "fingerprints" do not match, then the new technique would definitively determine that toxaphene breakdown products are not present in the groundwater. Therefore, the use of the new technique for groundwater monitoring at the Hercules 009 Landfill site provides the certainty needed to determine whether the groundwater is contaminated by toxaphene breakdown products. This information could then be used in the 5-year review to accurately determine the effectiveness of the Hercules 009 Landfill cleanup remedy.

Region 4 Is Concerned about Using the New Method

Region 4 officials are concerned about using the new (or NIMS) method to test groundwater at the Hercules 009 Landfill because the method is not approved by EPA. When using environmental data for public health decisions, Region 4 prefers to use approved methods that have been validated by several laboratories. The EPA conventional method (Method 8081) was validated. Consequently, EPA knows the results will be accurate when Method 8081 is used to test for the original toxaphene mixture.

The OIG agrees that using an EPA-approved method is better than a method not approved by EPA. However, EPA has no approved method to identify toxaphene breakdown products. Thus, to decide if the cleanup is effective, Region 4 must use an unapproved method to obtain the necessary information on the presence or absence of toxaphene breakdown products.

Under EPA's hazardous waste program, unapproved methods may be used. The conventional method (Method 8081) is in the EPA publication SW-846, entitled *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*. It is the official collection of analytical and sampling methods that EPA has evaluated and approved for use in complying with the hazardous waste regulations. SW-846 functions primarily as a guidance document setting forth acceptable, although not required, methods for the regulated and regulatory communities to use. The related EPA program office continually reviews advances in analytical instruments and techniques, and periodically updates SW-846 to improve method performance and cost effectiveness. However, the methods are guidance and not mandatory:

> *Except where explicitly specified in a regulation, the use of SW-846 methods is not mandatory in response to Federal testing requirements. ... The Agency does not intend to restrict the use of new analytical techniques. Advances in technologies applicable to the sampling and analysis of environmental media and hazardous wastes outpace the ability of the Agency to promulgate revisions to this manual. ... In summary, the methods included here provide guidance to the analyst and the regulated community in making judgements [sic] necessary to generate data that meet the data quality objectives for the intended use of the results.*

The EPA Region 4 laboratory has the capability to run the new (NIMS) method. However, the Region 4 laboratory personnel will need to learn the procedures, show they work, and practice using them before actually testing groundwater samples from the Hercules 009 Landfill. Thus, implementing the new method will take more laboratory resources, but is needed to obtain the necessary information to decide if the cleanup is effective.

Recommendations

We recommend that the Regional Administrator, Region 4:

2.1 Use negative ion mass spectroscopy to definitively determine if toxaphene breakdown products are present in the surrounding groundwater at the Hercules 009 Landfill site, and (if so) in what amounts.

2.2 If toxaphene breakdown products are found in the groundwater, assess the resulting risk to human health and take appropriate action.

Agency Comments and OIG Evaluation

The Agency generally agreed with our recommendations in Chapter 2. Under a voluntary interim action, Hercules Incorporated had samples collected in March 2005 from the monitoring wells at the Hercules 009 Landfill analyzed. These samples were analyzed using the negative ion mass spectrometry as well as EPA method 8081. The results of these analyses, which were provided as Attachment 1 to the Region 4 response and are in the Addendum to this report, were less than the maximum contaminant level for toxaphene in drinking water (i.e., 3 micrograms per liter). Region 4 later provided results of analytical testing they had performed using EPA method 8081. Their results showed significantly more toxaphene in one well (N-11) at the site. These results are in the Addendum to this report.

The OIG evaluated these analyses of the groundwater. As discussed in Appendix C, the quality control does not adequately show that the substances to be measured were not destroyed when the samples were prepared. We believe this situation confirms the need for EPA to develop and validate a standard NIMS method for analyzing samples for toxaphene breakdown products.

Region 4 confirmed they have the instrumentation necessary to perform the NIMS procedure, but additional resources would be needed to implement the method in the Region 4 laboratory. They would be willing to help validate the method.

> *Region 4's laboratory is willing to participate in a multi-laboratory method validation study for toxaphene congeners in environmental samples. However, since the Agency as a whole would obviously benefit from a validated NIMS method for toxaphene congeners, we believe that a multi-laboratory method validation study should be initiated at the program level by the Office of Solid Waste and Emergency Response. A validated method will serve both the regulated community and the Agency by assuring that analytical data produced by the method are defensible, of known quality, and suitable for risk assessment decision making.*

Region 4 proposed two interim strategies to assess the risk to human health posed by the toxaphene breakdown products, which they called weathered toxaphene. The proposed strategy preferred by Region 4 uses toxicity criteria developed by Region 4 staff. It is based, in part, on the sole toxicological study of weathered toxaphene, which is the Monitoring, Analysis, and Toxicity of Toxaphene in Marine Foodstuff (a.k.a. MATT) from the European Union, but they identified several concerns about the study. Region 4 agreed that additional toxicity studies would be helpful in filling data gaps, and (in Attachment 2 to the Region 4 response) suggested several studies. Region 4 requested that the OIG assess the soundness and applicability of these criteria. The other strategy uses toxicity criterion for technical, or original, toxaphene.

We evaluated the proposed strategies, and believe the strategy using toxicity criteria for toxaphene is inappropriate because the toxicity of weathered toxaphene could be significantly different. The toxicity criterion developed by the Region 4 staff for weathered toxaphene is innovative in that Region 4 developed a reference dose for weathered toxaphene. A reference dose is the concentration of a chemical believed to cause health problems. Thus, to ensure no ill effects, people should not be exposed to more than the reference dose. According to a Region 4 toxicologist (in the updated Attachment 2 to the Region 4 response, which is in the Addendum to this report):

> *This use of the reference dose represents one of the first instances in which EPA has applied a threshold-type toxicity to a potentially carcinogenic chemical. This procedure is consistent with EPA's new cancer guidelines and with the goal of harmonization of cancer and non-cancer risk assessment.*

As discussed in more detail in Appendix C, because developing this reference dose is so innovative, it should be subjected to internal and external peer review before being applied. Given the problems in analyzing the groundwater from the Hercules 009 Landfill, the need for a risk assessment for this site has not yet been established.

Chapter 3

Reporting on the Cleanup's Effectiveness Was Not Timely

Every 5 years EPA must review the effectiveness of the Hercules 009 Landfill cleanup, determining whether the cleanup is operating as intended and still protects human health and the environment. EPA did not issue the report on the second 5-year review timely; though due in September 2003, it remains in draft form. The chief reason for delay was because Region 4 officials wanted to ensure the cleanup was effective.

The latest report draft, dated February 2004, concluded that the cleanup was operating as intended. We initially believed the report should be issued, concluding that the effectiveness of the cleanup cannot be determined because the EPA conventional toxaphene test method (Method 8081) cannot determine whether breakdown products are present in the groundwater. However, we now agree Region 4 can conclude the cleanup was operating as intended.

Reviews Must Occur Every 5 Years

According to Section 121(c) of the Comprehensive Environmental Response, Compensation, and Liability Act and related regulations, cleanup actions must be reviewed every 5 years when hazardous substances, pollutants, or contaminants remain at the site, as was the case with the Hercules 009 Landfill. According to EPA's June 2001 *Comprehensive Five-Year Review Guidance*, the purpose of the 5-year review was to evaluate, through data gathering and observation, how well the site's remedy is working. The technical evaluation should address the following three questions. We believe the answer to Question B would be affected if toxaphene breakdown products were found in the groundwater surrounding the Hercules 009 Landfill.

- Question A – Is the remedy operating as intended by the decision documents?
- Question B – Are the exposure assumptions, toxicity data, cleanup levels, and remedial action objectives used when the remedy was selected still valid?
- Question C – Has any other information come to light that could call into question if the remedy protects human health and the environment?

EPA issued the report on the first 5-year review in September 1998. Thus, according to Agency guidance, the next 5-year review was due in September 2003.

Second Report's Delay Was Chiefly to Ensure Cleanup Effectiveness

For the second review, the U.S. Army Corps of Engineers, or the Corps (while working for EPA) gathered information from July 2002 through December 2002. The Corps sent EPA the first draft 5-year review report in January 2003 and the most recent, complete draft in February 2004. As of January 2005, the report on the second 5-year review still had not been issued. It was delayed primarily because of Region 4's efforts to decide if the cleanup protects human health and the environment. Reaching such a decision was complicated by the issues addressed in Chapter 2. Delay resulted when EPA tried to resolve some of the technical concerns by re-evaluating some existing information and obtaining additional data.

In September 2003, the RPM (the Remedial Project Manager) asked the Region 4 groundwater expert to review the hydrological data for the Hercules 009 Landfill site and determine if the monitoring wells were properly located. In December 2003, this expert sent the RPM a groundwater flow map and a memorandum noting that the monitoring wells were properly located to evaluate the groundwater.

The 5-year review draft reports used groundwater monitoring data collected through November 2002. In June 2004, Hercules Incorporated performed another round of groundwater testing. Region 4's laboratory also analyzed samples from this round, but used a different option to measure the toxaphene. Another round of groundwater testing was performed in September 2004, with the Region 4 laboratory again analyzing the samples. The results of this round became available in November 2004.

Other factors delaying the report were the following:

- Corps officials acknowledged that due to staffing, data gathering, and other problems, they took 8 months to complete their fieldwork and submit the first draft report to EPA.

- The EPA official in charge of the site, the RPM, changed in April 2002 and again in March 2003. The Corps and current RPM believe that additional review time by new RPMs delayed the report.

- The Glynn Environmental Coalition submitted extensive comments on the February 2004 report draft. Several sources outside the Region were asked to submit responses, so the Region required additional time to collate and address responses.

- In January 2004, the Glynn Environmental Coalition requested a substantial amount of information, and the Region delayed the report to respond to the request.

- Once the Ombudsman notified Region 4 that we intended to review actions at the site, Region 4 staff said they intended to delay issuing the report on the 5-year review. They want to know what the Ombudsman's report will contain, so the reports do not conflict.

EPA Policy Requires the Reviewer to Make a Decision

According to EPA's June 2001 *Comprehensive Five-Year Review Guidance,* at the end of the technical analysis and evaluation phase of the 5-year review, the reviewer must make a decision about the cleanup's effectiveness and document this decision (or determination) in a report on the review. Based on the answers to the three technical questions, the reviewer may decide that the cleanup protects human health, will protect it once the cleanup is completed, will protect it in the short term, or will not protect it. The reviewer can also conclude that protection cannot be determined until further information is obtained. If a protection statement cannot be made, a time frame should be provided when such a statement will be made, through an addendum. If this is the case, the next 5-year review is due 5 years from the date that the report is signed, not from the signature date of the addendum.

Further Definite Information Is Needed

Between the first draft report of the 5-year review and the most recent one, the conclusion on the cleanup's effectiveness changed; we agree with the Corps' original conclusion that additional information is needed to responsibly make a determination. The protection determination proposed by the Corps in the January 2003 draft report stated that the cleanup action should be protective when the groundwater cleanup goals were reached. However, it also stated that the data being collected was not appropriate to determine if the cleanup is functioning. The Corps believed the data were not appropriate based on three main factors: toxicity of toxaphene breakdown products, appropriateness of the selected groundwater sampling methodology, and appropriateness of the analytical method used to test the groundwater.

In the February 2004 draft, the first sentence of the determination remained the same, i.e., the cleanup actions at the site are expected to be protective upon attainment of groundwater cleanup goals. However, the subsequent sentences in the first paragraph of the determination were deleted, including the caveat about the data:

> *The review of documents, [applicable and relevant and appropriate requirements], risk assumptions and analytical data and site inspections indicate that the data being collected is not appropriate to determine if the remedy [cleanup] is functioning as intended by the ROD [Record of Decision on site cleanup]. Ground-water [sic] data from the monitoring well network at the*

site does not appropriately represent the concentrations of total toxaphene present in the ground water.

The Corps believed the additional information provided by Region 4 supported this change in the protection determination. We initially did not agree. As discussed in this report, Region 4 should identify and measure both toxaphene and its breakdown products. However, since additional actions were taken to ensure that the community around the site is not exposed to the groundwater, we agree the remedy is effective.

Implement Recommendations Proposed by the Corps

Based on their review, the Corps recommended six corrective actions at the Hercules 009 Landfill. Although we agree with all of them, we were particularly interested in the three related to the groundwater. One of these three concerned testing for toxaphene breakdown products, which we addressed in Chapter 2 of this report. Another concerned the deed restrictions to control future land use. The third concerned verifying that no one in the vicinity is using the groundwater. The latter two recommendations should be implemented immediately because doing so would further protect human health while the testing issue is resolved.

As part of the cleanup, restrictions were to be placed in the property deed to limit using the land, and to prevent excavating at the site and using the groundwater. The Corps did not find such deed restrictions in the property records. Therefore, the Corps recommended that, with EPA oversight, Hercules Incorporated place deed restrictions to control future land use. According to the RPM, this recommendation is being addressed.

To address the threat of contaminated groundwater that could affect residential drinking wells down gradient of the Hercules 009 Landfill, in December 1992, the municipal water lines were extended to reach the residents adjacent to the site. Later, the private wells of the residents who received municipal water were to be properly abandoned. The document summarizing the cleanup actions taken at the site did not confirm that all private wells were properly abandoned. The Corps recommended that EPA make sure no one is still on private wells and that no one has put in new wells in that area.

Recommendation

3.1 We recommend that the Regional Administrator, Region 4, issue the report on the Hercules 009 Landfill 5-year review.

Agency Comments and OIG Evaluation

The draft report contained three recommendations in Chapter 3, all of which the Region 4 officials disagreed with. We removed the second and third of the three recommendations because Region 4 provided documentation that (1) the consent decree was recorded in the records of Glynn County, and (2) Hercules Incorporated investigated the status of wells in the immediate area of the Hercules 009 Landfill and concluded that no new private drinking water wells were installed. Thus, no one in the vicinity of the site was using the groundwater. A Region 4 hydrologist evaluated the perimeter monitoring well system and concluded it is sufficient to evaluate migration of contaminants. The hydrologist's report was Attachment 4 to the Region 4 response.

The remaining recommendation in the draft report was that the Regional Administrator, Region 4, issue the report on the Hercules 009 Landfill 5-year review with the conclusion that whether the groundwater cleanup protects human health cannot be determined at this time, and further evaluation is needed. A timeframe should be estimated for such an evaluation.

Because of the recent evidence (see Chapter 2) provided by the NIMS data and the toxicity criteria developed by Region 4 based on the MATT laboratory study, Region 4 proposed that the data and toxicity review be included in the release of the 5-year review and a determination of protectiveness be issued. They believed this position was further supported by their above conclusions that no one was using the groundwater and the contaminants (if any) were not leaving the site.

The OIG agrees with Region 4 that there appears to be no pathway for toxaphene breakdown products in the groundwater to reach people near the site. Therefore, we revised the recommendation to require the report on the 5-year review be issued. The report can state that the remedy is effective and protects human health, although our reasons, as discussed in more detail in Appendix C, differ slightly from those of Region 4.

Technical Discussion on Toxaphene

In order to evaluate the continued effectiveness of the Hercules 009 Landfill remedy, the Record of Decision (EPA/ROD/R04-93/144) requires periodic testing of the groundwater for toxaphene contamination. Both Hercules Incorporated and the U.S. Environmental Protection Agency (EPA) use EPA's analytical Method 8081 to test for the original toxaphene pesticide mixture in the groundwater. However, the original toxaphene pesticide mixture is known to degrade in the environment and its degradation products are probably at least as toxic as the original toxaphene pesticide. Since EPA's monitored natural attenuation guidance requires EPA to anticipate and to test for the presence of potentially toxic degradation products in the groundwater, EPA is required to evaluate the groundwater around the Hercules 009 Landfill Superfund site for the potential presence of toxaphene degradation products. However, analytical Method 8081 was not designed for and is inadequate to detect and measure toxaphene degradation products. Therefore, EPA needs to use a different analytical method, such as negative ion mass spectroscopy, to definitively assess the presence or absence of toxaphene degradation products in the groundwater at the Hercules 009 Landfill site.

Basics of Toxaphene Chemistry

A basic understanding of the chemical structure of toxaphene is needed to address the issue. Unlike most organic environmental pollutants, toxaphene is not a single organic compound. As manufactured, the original toxaphene pesticide is a mixture of more than 200 closely related chlorinated organic compounds. This original toxaphene pesticide mixture is commonly known as "technical" toxaphene. Technical toxaphene consists mainly of polychlorinated bornanes with between six to nine chlorines attached. The term, congener, is used to refer to a single, structurely-unique constituent of the mixture. In other words, at least 200 individual toxaphene congeners make up the original toxaphene pesticide mixture. Individual congeners are often given their own names, such as Hx-Sed, Hp-Sed, p26, or p50.

Technical Toxaphene Degrades in the Environment

In the Office of Inspector General's (OIG's) review of the available scientific literature on the environmental degradation of the original toxaphene mixture (a.k.a. technical toxaphene), we found numerous references to biotic and abiotic degradation, and to aerobic and anaerobic degradation. The aerobic degradation of technical toxaphene occurs at the slowest rate and has an aerobic half-life report of about 10-14 years (Fingerling 1996). On the other hand, anaerobic degradation of technical toxaphene occurs at a much faster rate and has an anaerobic half-life of about 6 weeks. Therefore, since the use of toxaphene was severely restricted in 1982 (i.e., about 23 years ago), any technical toxaphene left in the environment from 1982 or before has theoretically undergone two or more half-lives. Thus, at most, only 25 percent of the original starting material should theoretically still be present. By contrast, the only reported condition under which toxaphene does not degrade is autoclaved soil (i.e., all microbes in the soil have been killed off) (Fingerling 1996). Therefore, technical toxaphene is expected to degrade in the environment and its degradation is mediated primarily by microbes living in the soil.

Anticipated Toxaphene Degradation Products

Upon instrumental analysis by a Gas Chromatograph/Electron Capture Detector (GC/ECD), the original technical mixture (i.e., a mixture of 200 or more congeners) produces a complex, multi-peaked chromatogram (see Figure 1B below). However, technical toxaphene is known to undergo microbial degradation in soil. Since the soil at the Hercules 009 Landfill site has been stabilized with cement, the free exchange of oxygen into the soil from the air is unlikely. Therefore, anaerobic microbial degradation is the most likely degradation process for the buried toxaphene waste at the Hercules 009 Landfill site.

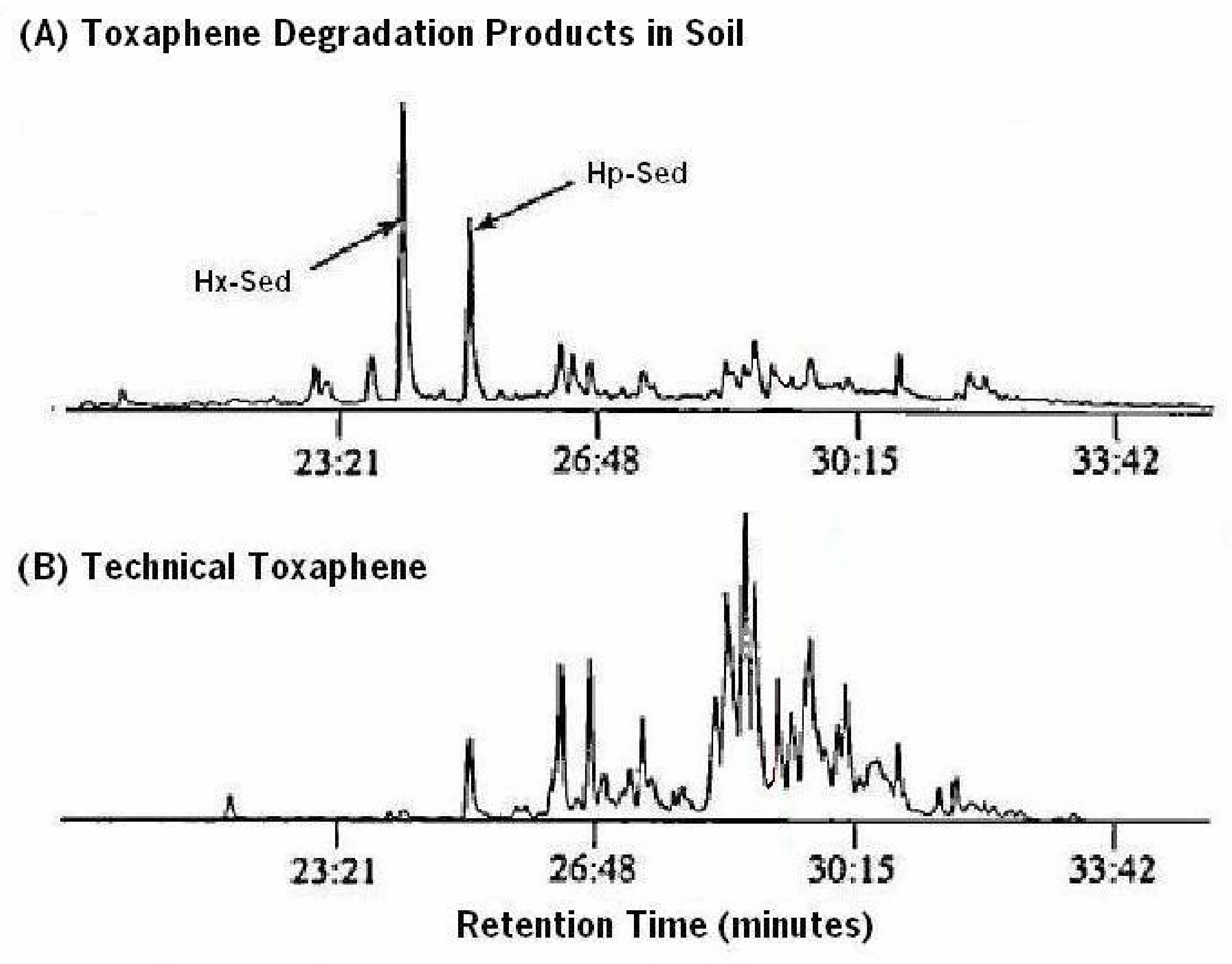

Figure 1: Chromatograms of Technical Toxaphene and Degraded Toxaphene are Completely Different

The major anaerobic microbial degradation products in soils or sediments are known to be Hx-Sed and Hp-Sed (Braekevelt 2001). This microbial degradation of technical toxaphene produces a much simplified chromatogram (see Figure 1A above). Therefore, upon analysis at an environmental laboratory, the degraded toxaphene chromatogram appears completely different then the technical toxaphene chromatogram.

Although Hx-Sed and Hp-Sed are the major anaerobic degradation products in soil, degraded toxaphene chromatogram (see Figure 1A) also shows a significant number of other, less abundant anaerobic microbial degradation products. These less abundant toxaphene congeners in soil have been identified and are known to include the p26, p50, p40, p41, and p44 (Maruya 2001). As discussed in more detail later, these less abundant toxaphene degradation products constitute the majority of risk to human health because they are not effectively metabolized by the body, which causes them to bioaccumulate in the body. Hx-Sed and Hp-Sed are readily metabolized by the body and excreted, so they should not constitute a major risk to human health. However, since Hx-Sed and Hp-Sed are the major anaerobic degradation products, they are easier to detect than the other less abundant toxaphene congeners and could be used to indicate that toxaphene degradation products are present in the sample.

The implication of toxaphene's degradation is that humans are exposed to toxaphene's degradation products and not to the original technical toxaphene mixture (de Geus 1999), (McHugh 2003). Consequently, EPA's approach of using Method 8081 to test for the original technical toxaphene in the environment to identify toxaphene contamination is incorrect. EPA needs to test for individual toxaphene degradation products (i.e., specific congeners) in order to identify the presence or absence of toxaphene contamination in the environment.

<u>Evaluating the Potential Risk to Humans from Toxaphene Exposure</u>

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. Detailed information is lacking on the potential human exposure to toxaphene degradation products and their toxicity, which limits the ability to conduct a thorough risk assessment. However, the potential risk to human health from toxaphene exposure can still be conceptually understood.

In general, a major factor needed to evaluate the level of risk to human health is to determine the major human exposure pathways to toxaphene's degradation products and to determine all potential sources. The Hercules 009 Landfill site is just one of the potential exposure sources. A toxaphene exposure study from the Netherlands used an EUSES (European Union System for the Evaluation of Substances) model to estimate the exposure of the Dutch population to toxaphene (Fiolet and van Veen 2001). This model identified that the main route of exposure to relatively soluble toxaphene congeners is approximately 80 percent from fish and 11 percent from drinking water. Another toxaphene exposure study by Buranatrevedh also concluded that the main route of exposure is about 93 percent from fish and about 7 percent from surface waters (Buranatrevedh 2004). Based on these national toxaphene exposure studies, the main exposure risk to toxaphene is clearly from fish (i.e., 80-93 percent) and from potential sources of drinking water (i.e., 7-11 percent). Although specific site conditions and other site specific variables at Hercules 009 Landfill will shift the relative levels for these various exposure routes, these national toxaphene exposure studies identify that the principle exposure routes of concern to the surrounding community are the fish in the diet and the potential for contaminated drinking water. The remaining exposure routes (i.e., air and soil) are practically negligible.

Another major factor needed to evaluate the level of risk to human health is what specific toxaphene congeners pose chronic risk to humans. The major toxaphene congeners found in fish are p26, p50, and p62, but p40, p41, and p44 are also present to a lesser extent (Fiolet and van Veen 2001). The major anaerobic microbial degradation products in soils that may contaminate the groundwater are Hx-Sed and Hp-Sed, but p26, p50, p40, p41, and p44 are also found in soil to a lesser extent (Maruya 2001).

Although humans are exposed to a variety of toxaphene degradation congeners, most of these congeners can be rapidly metabolized via dechlorination, dehydrodechlorination, and oxidation, primarily through the action of the mixed function oxidase system and other hepatic microsomal enzymes (EPA 1999). For example, the primary toxaphene degradation products in soil (i.e., Hx-Sed and Hp-Sed) are expected to be easily metabolized and excreted with reported half-lives in fish of 5 and 13 days respectively (Smalling 2004). However, a limited number of toxaphene congeners (i.e., p26, p50, p40, p41) are poorly metabolized and cannot be readily excreted, causing these congeners to accumulate in the body. These poorly metabolized congeners share a common structural pattern of alternating single chlorine substitutions (i.e., endo, exo) on the #2, #3, #5, and #6 carbons of the six-member ring (Maruya 2000). Specifically, the poorly metabolized p26 and p50 congeners have half-lives of about 1 year in wild fish (Smalling 2004). Therefore, although humans are exposed to a variety of toxaphene degradation products, the human body can metabolize and eliminate the majority of these congeners. However, five toxaphene congeners (i.e., p26, p50, p 40, 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 a mixture of these five congeners needs to be determined in more detail than is currently available in the scientific literature.

Human Exposure to the p26 and p50 Toxaphene Degradation Congeners

The following two academic studies have independently identified and documented human exposure to the individual toxaphene degradation congeners:

– In 1996, Dr. Gill used negative ion mass spectroscopy (NIMS) to detect and measure toxaphene congeners in human blood serum (Gill, et al. 1997). Specifically, Dr. Gill's study documented the presence of p26, p50, p44, p40, and p41 congeners at a concentration of 2 to 200 parts per trillion (ppt) or up to 0.2 parts per billion (ppb) in human blood serum from Native Canadian Communities. These five toxaphene congeners represented 95 percent of the toxaphene congeners found in human serum.

– In 2003, Dr. Barr used a sophisticated analytical technique to detect and measure toxaphene congeners in pooled human blood serum collected by the Red Cross in Atlanta in 1987, in Chicago in 1992, and in Cincinnati in 1994 (Barr 2004). Specifically, Dr. Barr's study documented the presence of p26, p50, and possibly p40+41, and p44 congeners at a concentration of 3 to 30 ppt (i.e., 0.03 ppb) in human blood serum from an undefined number of American blood donors.

These studies are critically important in identifying and simplifying the assessment of the risk to humans resulting from environmental exposure to toxaphene. These studies dramatically indicate that human risk is not to "technical" toxaphene's 200-plus congeners, but that the long-term chronic toxaphene exposure in humans is limited and simplified to just five toxaphene congeners (i.e., p26, p50, p40, p41, and p44) that the human body has difficulty metabolizing and eliminating, causing them to accumulate in the body.

Carcinogenicity of p26 and p50 Congeners

The EPA's Integrated Risk Information System (IRIS) database identifies technical toxaphene as a B2 probable human carcinogen with a cancer potency factor of 1.1 mg/kg/day. However, there is limited scientific data on the carcinogenicity of persistent toxaphene degradation congeners, such as p26 and p50. But other chemical mixtures of congeners show that individual congeners can be significantly more carcinogenic then the original technical mixture. The classic example is dioxin where 2,3,7,8-TCDD (tetrachlorodibenzo-p-dioxin) is up to 10,000 times more carcinogenic than other dioxin congeners. Another example is that bioaccumulated PCB congeners appear to be more carcinogenic than the original "commercial" PCB mixture (EPA 7C-R293-NTSX). This clearly indicates that the carcinogenicity of the original technical toxaphene mixture cannot be applied to the carcinogenicity of the individual congeners, specifically, p26 and p50.

The European Union has conducted an Investigation into the Monitoring, Analysis, and Toxicity of Toxaphene in Marine Foodstuffs (i.e., MATT project). The MATT project predicted the tumor-promoting potency of technical toxaphene and a Cod Liver Extract (CLE) containing p26, p50, p62 in a bioassay measuring the inhibition of intracellular communication between Hepa1c1c7 cells (Fair CT PL.96.3131). The CLE toxaphene congener mixture mimics the environmental exposure to the toxaphene congeners that are found in humans (e.g., p26 and p50). The results from this bioassay indicate that the CLE toxaphene mixture is a more potent tumor promoter than the original technical toxaphene mixture. The MATT project estimated a tolerable daily intake (TDI) to "weathered" toxaphene residues of 0.69 mg/kg/day. In general terms, MATT's TDI estimate makes the toxaphene degradation products found in humans to be about twice as carcinogenic as the original technical toxaphene mixture. However, more definitive toxicology studies are needed to verify the carcinogenicity of the individual p26 and p50 toxaphene congeners.

Embryotoxicity of p26 and p50

In a 1997 study using a rat embryo culture model, the p26 and p50 toxaphene congeners caused abnormalities in the central nervous system (Calciu 1997). The total morphological scores at 100 ng/ml for p26 and p50 were slightly worse than the total morphological score for the technical toxaphene. The significant finding from this study is that both the target site and type of toxicity are highly congener-specific. Therefore, the toxicity of technical toxaphene cannot and should not be used to predict the embryotoxic effects of the p26 and p50 congeners in humans. Thus, more scientific research is needed to evaluate the specific embryotoxic effects of p26 and p50 to humans.

Dr. Gill's study found concentrations of p26 and p50 at concentrations as high as 0.2 ppb in human blood serum (described above). The lowest dose in Dr. Calciu's rat embryo culture study was 100 ppb. The difference is a factor of 500, but the rat embryo culture study results represent only a 48-hour exposure to the rat embryos. This short exposure time does not directly correspond to human exposures to p26 and p50 over the full term of a pregnancy (i.e., human fetuses are exposed to a lower dose but for a longer period of time). Furthermore, the results from the rat embryo culture study represent dramatic development changes in which even subtle changes in human fetal development would be considered unacceptable. Therefore, additional research is needed to evaluate the potential for more subtle effects on embryo development when exposed to lower doses of p26 and p50 that correspond to actual human exposure levels. For example, in 1980, Dr. Olson observed behavior changes in rat offspring when pregnant rats were given low doses of technical toxaphene, p42a congener (i.e., toxicant A), or p32 congener (i.e., toxicant B) as measured by swimming test and maze retention test (Olson 1980).

The embryotoxicity of toxaphene's persistent degradation products needs to be evaluated in the context of co-exposure with other persistent organochlorines (i.e., dichlorodiphenyltrichloroethane (DDT)/dichlorodiphenuldichloroethylene (DDE), hexachlorocyclohexanes (HCHs), and polychlorinated biphenyls (PCBs)). The amount of p26 and p50 in human milk has been found to range from a low of 6 ug/kg lipid weight (i.e., ppb) in southern Canada to a high of 294 ug/kg lipid weight in Northern Quebec (Skopp, S., et al. 2002). This shows that babies are exposed through the mother's exposure to toxaphene degradation products before and after birth. Unfortunately, this observation about mother's milk is potentially problematic because an epidemiological study by Jacobson (Jacobson 1996) indicates that developing embryos are the most susceptible target of organochlorines (i.e., PCBs). Jacobson's study linked organochlorine exposure during fetal development to impaired cognitive development (e.g., low IQ scores). Therefore, the embryotoxicity from toxaphene exposure needs to be evaluated in combination with the concurrent exposure to the other organochlorines (i.e., DDT/DDE, HCHs, and PCBs) in order to accurately assess the risk to cognitive impairment.

Superfund's Remedy Requires the Evaluation of Toxic Degradation Products

Monitored natural attenuation (MNA) is part of the remedy at Hercules 009 Landfill site. Superfund's monitored natural attenuation guidance (OSWER Directive 9200.4-17P) requires EPA to evaluate for the potential presence of toxic transformation products. Toxaphene degradation products are a sub-category of transformation products. Specifically, the MNA guidance states:

> "*The potential for creation of toxic transformation products is more likely to occur at non-petroleum release sites ... and should be evaluated to determine if implementation of a MNA remedy is appropriate and protective in the long term.*"

Furthermore, the MNA guidance states:

> "*... all [MNA] monitoring programs should be designed to accomplish the following: ... Identify any potentially toxic and/or mobile transformation products.*"

Therefore, the Superfund's MNA 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 evalaute 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.

EPA Method 8081 Tests for Technical Toxaphene

EPA Method 8081 is an analytical testing technique that uses a laboratory instrument called a gas chromatograph with an electron capture detector, which is referred to as a GC/ECD. When an environmental sample is tested by the GC/ECD, the instrument products a chromatogram as a record of what was contained in the sample (see Figure 2A).

Each peak in the chromatogram of a known technical toxaphene standard (see Figure 2B) represents 1 of the 200 unique congeners in the technical toxaphene mixture. There are actually so many peaks that they clump together in some areas of the chromatogram. Method 8081 detects toxaphene by identifying five peaks to the right of the red line in the environmental sample (see Figure 2A) and comparing their shape and position to five peaks to the right of the red line in a known technical toxaphene standard (see Figure 2B). In this example, since both chromatograms match on the right hand side, the laboratory would report that toxaphene is present in this hypothetical enviromental sample. EPA Method 8081 was designed and quite dependable for detecting the original technical toxaphene mixture in an environmental sample.

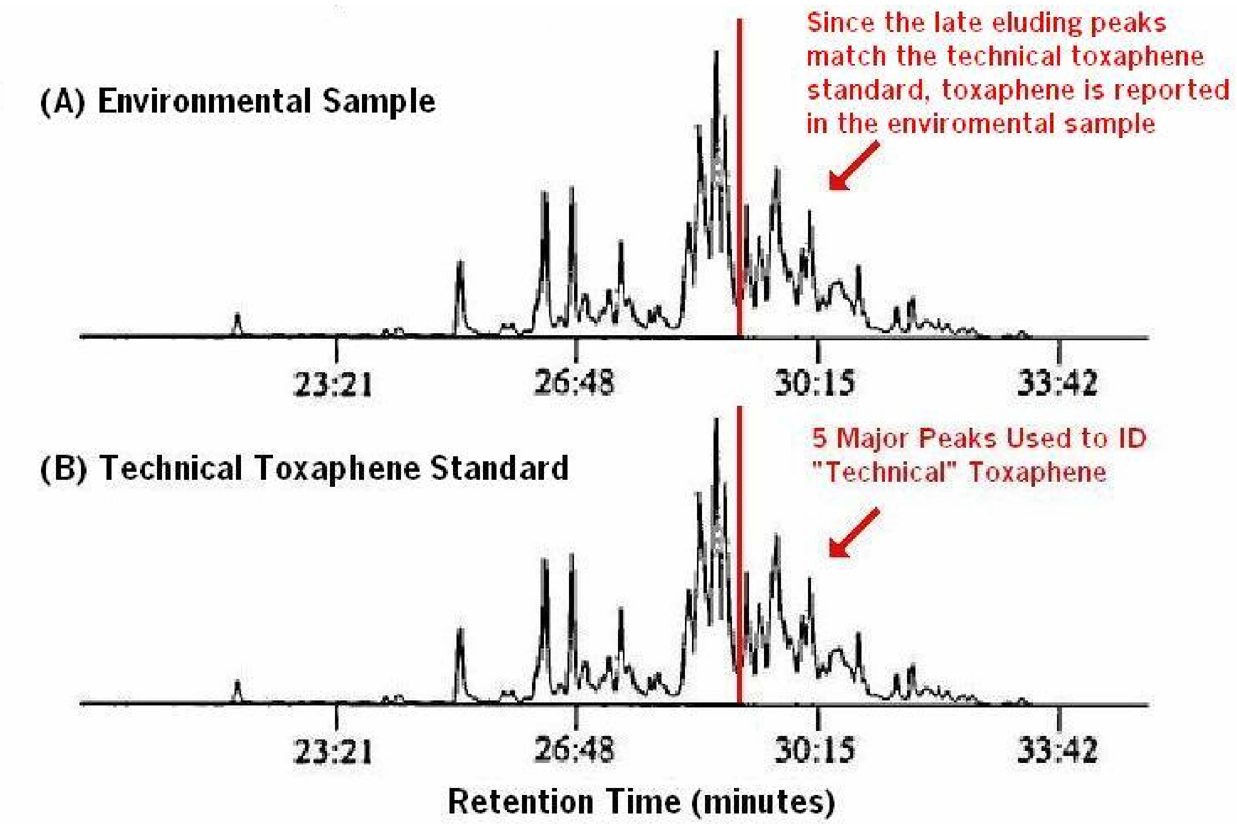

Figure 2: GC/ECD Chromatograms of Technical Toxaphene

<u>EPA Method 8081 Does Not Identify Toxaphene Degradation Products</u>

EPA Method 8081, which is listed in EPA's Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (i.e, SW-846), uses a GC/ECD to analyze for the presence of toxaphene contamination. In order to identify the presence of a pollutant in an environmental sample, the retention time of a peak (i.e., representing a compound) in the sample's chromatogram is compared against the retention time of a known chemical standard. However, technical toxaphene is not a single compound, but a mixture of more than 200 chlorinated bornanes which produces a complex chromatogram (see Figure 3B below). For the purposes of detecting toxaphene in a sample, EPA Method 8081 calls for a peak profile match against at least five peaks in the latter section of the toxaphene window (i.e., see the peaks after about 29 minutes in the chromatogram 3B). In other words, the observed relative abundance of late eluting toxaphene congeners (i.e., octa- and nonachlorobornanes) has to closely match the relative abundance of the octa- and nonachlorobornane congeners found in the technical toxaphene standard. EPA Method 8081 is appropriate and highly accurate for detecting technical toxaphene. However, EPA 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 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 known to be present. This example demonstrates the manner in which EPA Method 8081 fails to detect toxaphene degradation products (i.e.,"weathered" toxaphene or individual toxaphene congeners) in environmental samples.

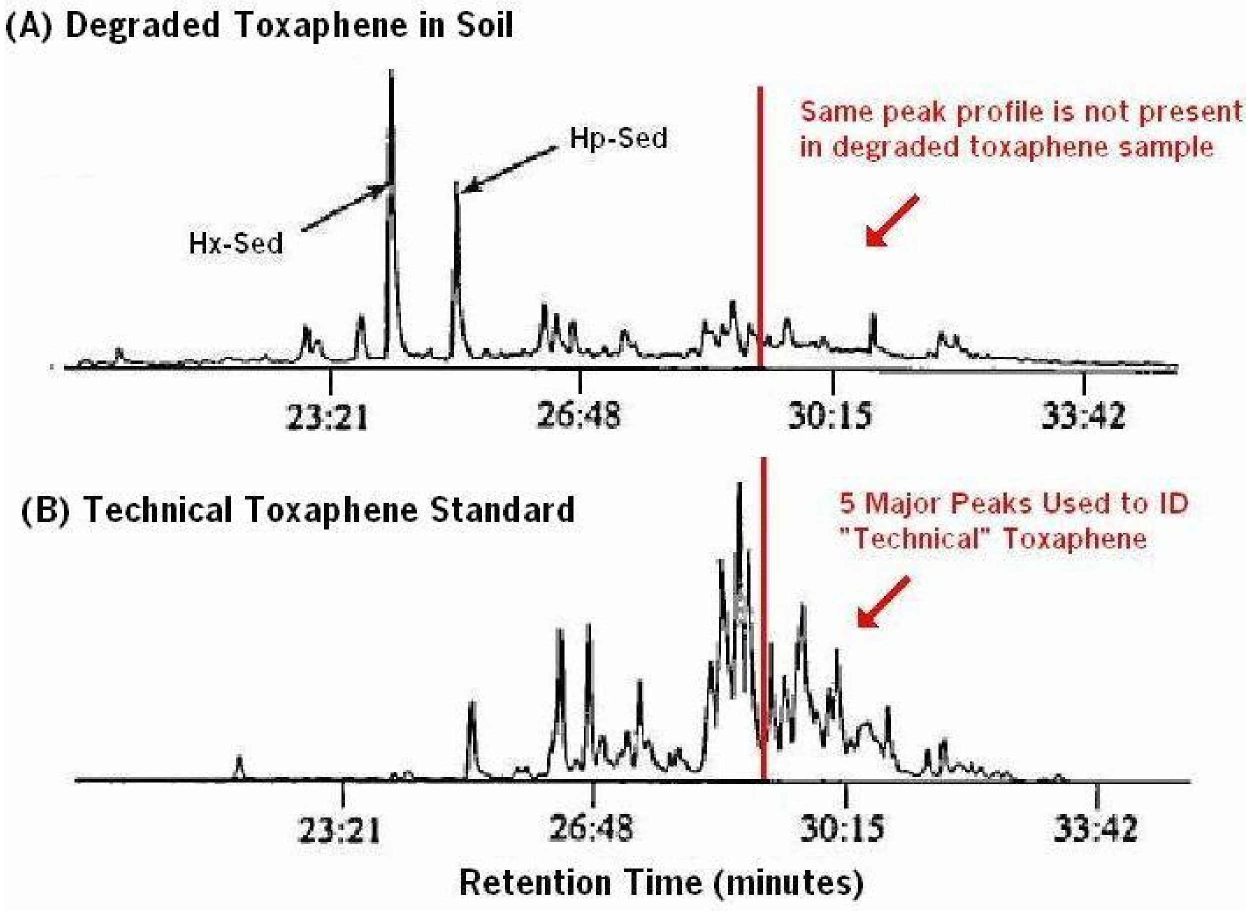

Figure 3: EPA Method 8081 Analyzes for Only Technical Toxaphene

An example of EPA Method 8081's failure to detect toxaphene's degradation products occurred in 1997 during the Georgia Department of Natural Resources' (GA/DNR) study to measure the toxaphene levels in several species of fish and shellfish in and around Terry Creek.   Terry Creek is another Superfund site in the Brunswick, Georgia, area that is contaminated with toxaphene due to previous manufacturing operations by Hercules Incorporated. The results of GA/DNR's study indicated no detectable quantities of toxaphene in every single fish sample analyzed. However, in 2001, Dr. Maruya re-analyzed the same fish and shellfish samples that were collected and analyzed by GA/DNR, but this time used a congener-specific technique called Gas Chromatography/Negative Ion Mass Spectroscopy (GC/NIMS) (Maruya 2001). The GC/NIMS analytical technique was able to identify and quantify individual toxaphene congeners that were present in the fish samples at concentrations up to 1,420 parts per billion (ppb). The GC/NIMS's identification of toxaphene contamination at Terry Creek is in stark contrast to the results obtained by EPA Method 8081 that indicated no toxaphene contamination. Therefore, this example clearly shows that EPA's Method 8081 does not detect degraded toxaphene in the environment.

Gas Chromatogaph/Negative Ion Mass Spectrometry Can Be Used to Identify Toxaphene Degradation Products

Unlike the GC/ECD technique used in EPA Method 8081, GC/NIMS can definitively identify and measure individual toxaphene degradation products in the environment. The weakness in the GC/ECD technique used in EPA Method 8081 is that peak identification is based on only one factor: retention time. Therefore, even if the retention times match between the sample peak and the standard, there is still uncertainty about the identity of the peak. By contrast, the GC/NIMS technique uses two factors to identify peaks: retention time and a mass spectrum. A mass spectrum is analogous to a "fingerprint" of the compound. If the mass spectrum from the sample matches the mass spectrum of the standard, this definitively identifies the compound.

The GC/NIMS methodology has been routinely used in academia since about 1993. The European MATT project has been using the GC/NIMS method to monitor and document the levels of toxaphene degradation products in fish from the North Atlantic. Since the GC/NIMS method has been developed and successfully implemented by others, EPA's formal validation and standardization of the GC/NIMS method should not present any major technical difficulties. Also, including the GC/NIMS method in SW-846 would significantly facilitate (1) evaluating toxaphene degradation products in the environment by the regulated community and (2) gathering congener-specific data needed for accurate risk assessments of exposure to toxaphene's degradation products.

Estimated Retention Time of Toxaphene Degradration Products

As described, EPA Method 8081 fails to identify toxaphene degradation products mainly because the identification criteria are based on seeing the late eluting peaks in technical toxaphene. However, an experienced chemist can still look for potential toxaphene degradation products in the GC/ECD data from the Hercules 009 Landfill. Although the Hercules 009 GC/ECD data does not include standards for the Hx-Sed and Hp-Sed toxaphene degradates, the expected retention time for Hx-Sed and Hp-Sed can be estimated from data published in the scientific literature (Figure 4 below). Since each technical toxaphene varies slightly by manufacturer, the technical toxaphene standard below is specifically from Hercules Incorporated in order to allow a subsequent comparison with the Hercules 009 Superfund site data. The estimated retention time window for the Hx-Sed and Hp-Sed toxaphene congeners (i.e., the main toxaphene congeners expected in anaerobic soil) occurs at the front edge of the technical toxaphene window. Notice that the Hx-Sed peak is to the left and taller than the Hp-Sed peak.

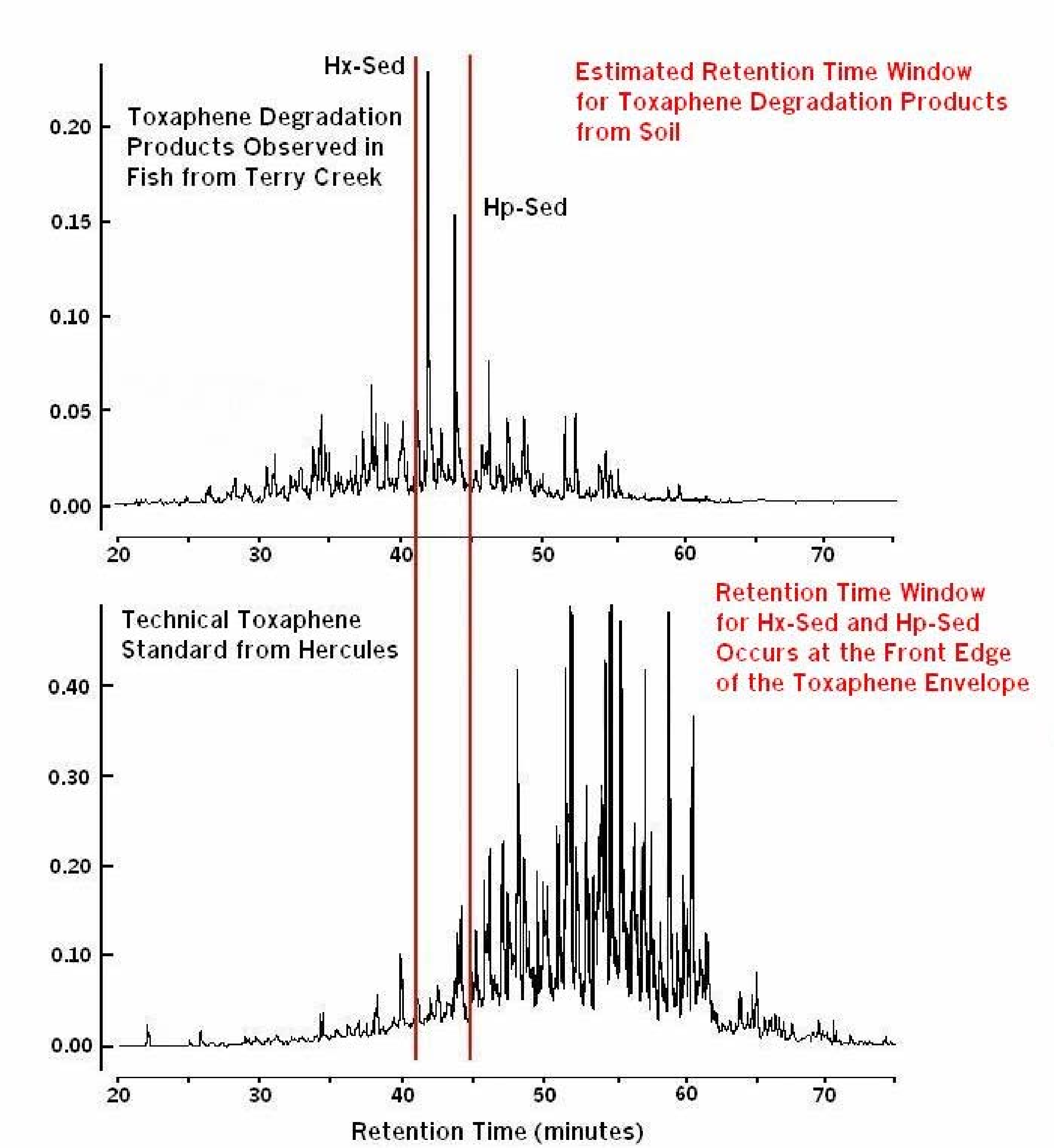

Figure 4: Estimated Retention Time Window for Hx-sed and Hp-sed

Hercules 009 GC/ECD Data Suggest Toxaphene Degradation Products May Be in the Groundwater

On January 8, 2003, the contractor for Hercules Incorporated, RMT Incorporated, provided EPA with the November 2002 groundwater sampling results, which were used in EPA's Hercules 009 Landfill 5-year review. RMT's subcontract laboratory (i.e., EnChem, Inc.) used EPA Method

8081A to analyze the toxaphene groundwater samples and reported non-detect (i.e., <5.2 ug/L) for all toxaphene results. Fortunately, the sampling results included a chromatogram for each of the groundwater monitoring wells. This allowed for comparing the Hercules 009 Landfill groundwater samples against the Hercules technical toxaphene standard to check for the possibility of toxaphene degradation products (Figure 5 below).

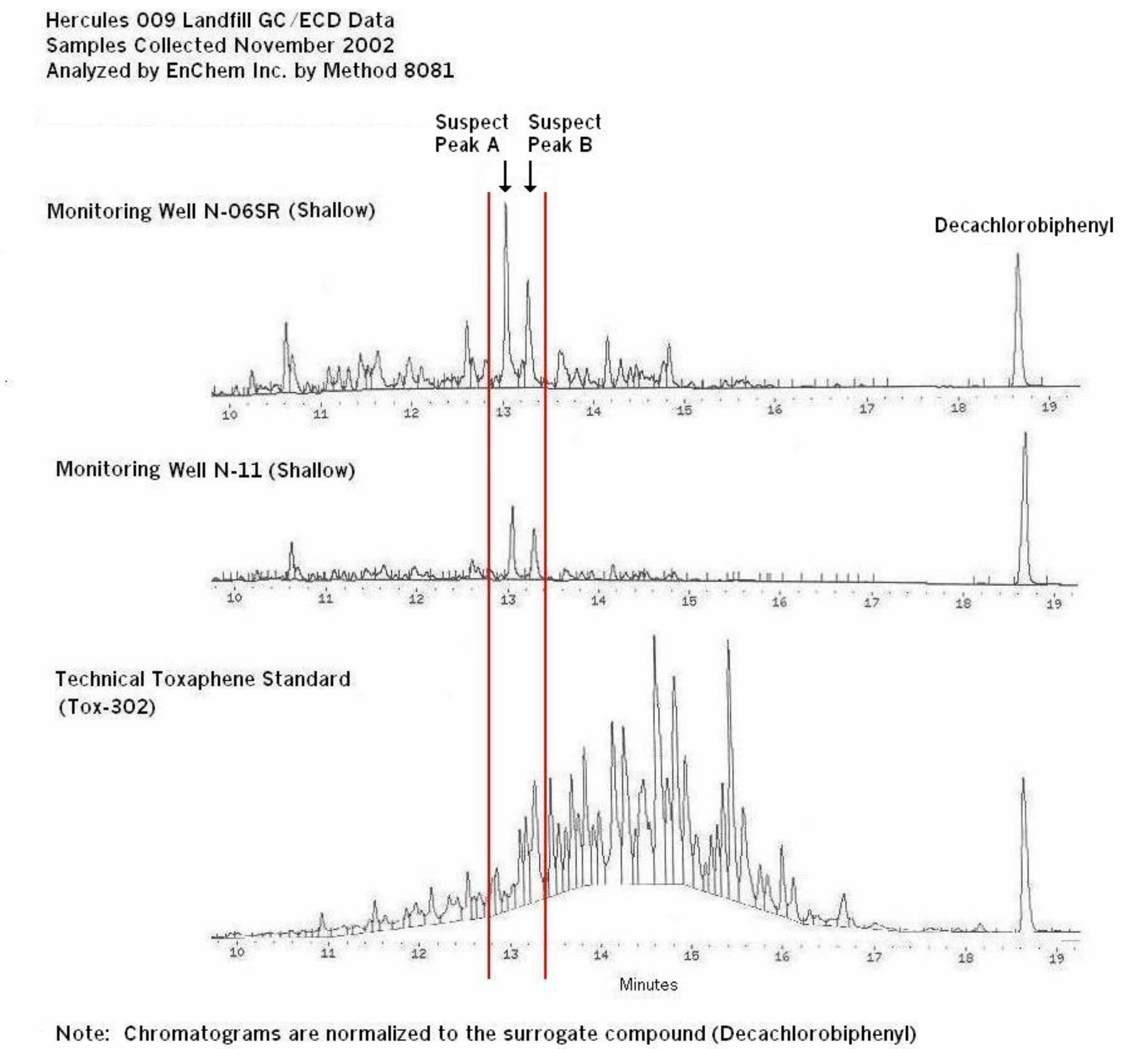

Figure 5: Potential Toxaphene Degradation Products in the Groundwater at Hercules 009 Landfill

As described above in the previous section, the estimated retention time window for the Hx-Sed and Hp-Sed toxaphene congeners occurs at the front edge of the technical toxaphene window. When the estimated retention time windows for Hx-Sed and Hp-Sed are superimposed on the chromatograms from monitoring wells N-06SR and N-11, two prominent peaks are present that resemble the Hx-Sed and Hp-Sed peak profile (i.e., the left peak is taller than the right peak). These chromatograms provide suggestive evidence that Hx-Sed and Hp-Sed might be present in the Hercules 009 Landfill groundwater. However, these peaks cannot be positively identified as toxaphene degradation products due to significant limitations in the data set. First, there are no Hx-Sed or Hp-Sed standards to establish their retention time, which is the key criterion for identifying compounds in a GC/ECD analysis (i.e., no standards, no identifications). Second, the critical weakness with all GC/ECD data is the lack of a mass spectrum that could be used to determine the structure of the compound making each of these peaks. The limitations of this GC/ECD data set clearly show the value of GC/NIMS analysis.

If the samples had been run by GC/NIMS instead of GC/ECD, a quick review of the mass spectra for each of the peaks could easily determine if these peaks were toxaphene congeners or not (e.g., examples of negative ion mass spectra are provided in Figure 6). For example, the negative ion mass spectrum for Suspect Peak A could be compared against the negative ion mass spectrum of a hexachlorinated bornanes (Figure 6(a)). Likewise, the negative ion mass spectrum for Suspect Peak B could be compared against the negative ion mass spectrum of a heptachlorinated bornanes (Figure 6(b)). If the spectra matched, EPA could conclude that there were toxaphene degradation products in the groundwater. However, with only the GC/ECD data, a definitive determination on the identity of these suspect peaks cannot be made.

GC/NIMS Can Definitively Determine the Identity of Suspected Hx-Sed and Hp-Sed Peaks

GC/NIMS could be used to definitively determine the identity of the Suspect A and B peaks observed in the Hercules 009 Landfill GC/ECD data (see Figure 5). The retention time and mass spectrum for Suspect Peak A would be compared against the retention time and mass spectrum for Hx-Sed. The mass spectrum for Hx-Sed looks like the diagram in Figure 6(a). The retention time and mass spectrum for Suspect Peak B would be compared against the retention time and mass spectrum for Hp-Sed. The mass spectrum for Hp-Sed looks like the diagram in Figure 6(b). The additional feature of the GC/NIMS technique of comparing and matching a peak's mass spectrum allows for the definitive identification of the peaks.

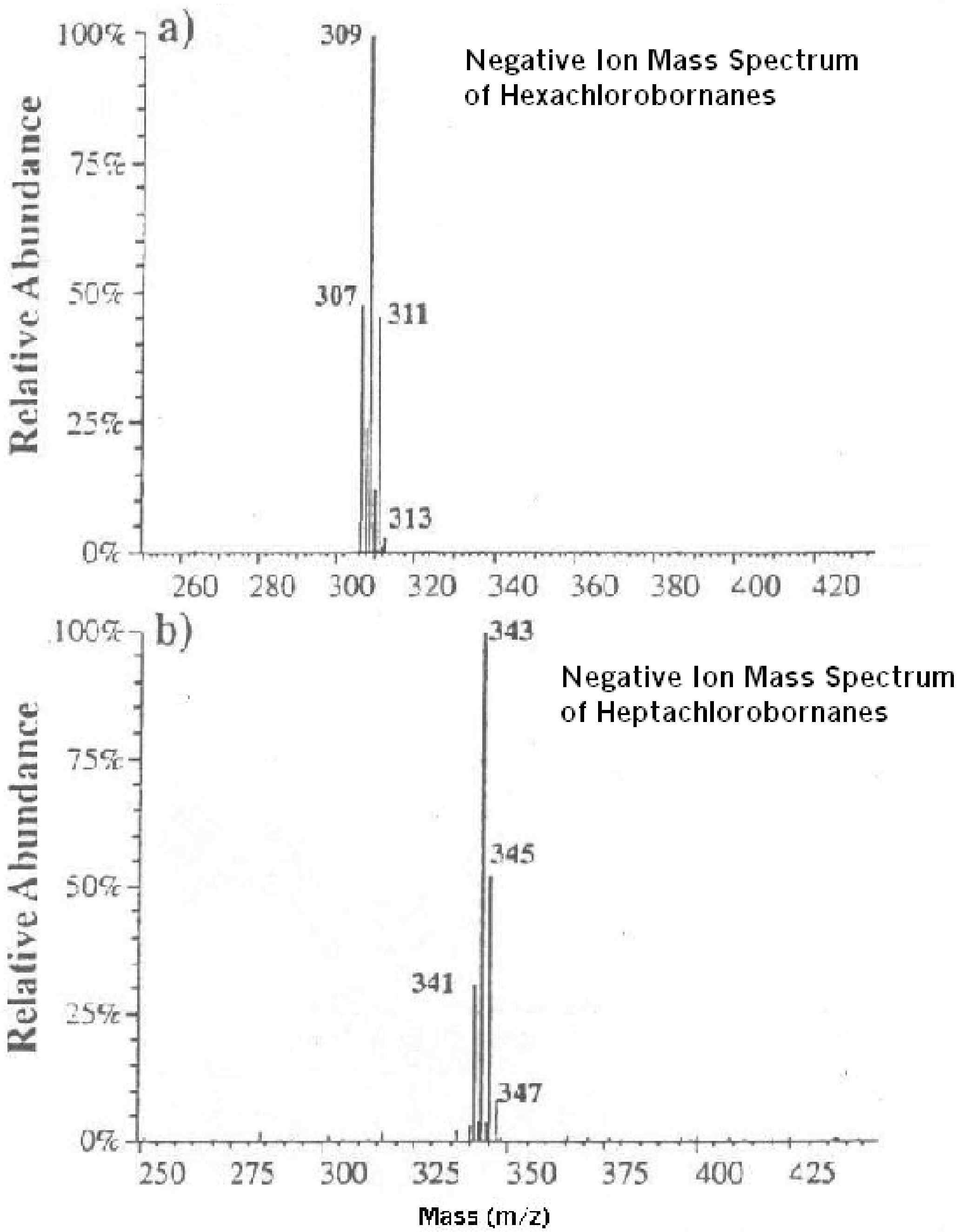

Figure 6: Negative Ion Mass Spectrums
for Hexachlorobornane and Heptachlorobornane

Technical Summary of Toxaphene Issue

EPA should recognize that toxaphene degrades in the environment and that all of EPA's toxaphene data collected using EPA Method 8081 are inadequate to screen for toxaphene's degradation products in the environment. To address this problem, EPA should test toxaphene contamination using a congener-specific analytical method such as GC/NIMS. EPA's validation and standardization of the GC/NIMS method would facilitate evaluating toxaphene degradation products in the environment. Finally, EPA should recognize that the chronic health risk to humans is from the five persistent toxaphene congeners (i.e., p26, p50, p40, p41, and p44) that accumulate in the human body. Therefore, EPA needs additional studies on the carcinogenicity and embryotoxicity of these five persistent toxaphene congeners to be able to accurately evaluate this risk associated with their exposure to humans. Without congener-specific laboratory results and without knowing the toxicity of specific congeners, EPA is unable to definitively quantify the risk to human health posed by the toxaphene degradation products left in the environment and the food chain.

No Immediate Human Health Risk at Hercules 009 Landfill

Although the OIG's review indicates that the current monitoring and analytical testing at the Hercules 009 Landfill site is inadequate to determine if any toxaphene degradation products have leaked into the groundwater and that these toxaphene degradation products may be toxic, the OIG believes that there is no immediate risk to the surrounding population because the remedial action for Operable Unit Two has connected the nearby residents to the municipal drinking water supply. However, to prevent the potential long-term contamination of the groundwater, EPA needs to definitively determine if Hx-Sed, Hp-Sed, p26, and/or p50 toxaphene congeners occur in the groundwater down gradient of the Hercules 009 site.

OIG Technical Conclusions

– The original "technical" toxaphene mixture degrades in the environment.

– The chronic health risk to humans is from exposure to toxaphene's persistent degradation products (e.g., p26, p50, p40, p41, and p44) and not the original technical toxaphene mixture.

– 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 an EPA GC/NIMS method into SW-846.

– EPA needs to conduct specific research into both the carcinogenicity and embryotoxicity of the five persistent human toxaphene congeners (i.e., p26, p50, p40, p41, and p44) to develop acceptable human exposure limits to the individual congeners and/or to the mixture of these five congeners.

- Considering both the uncertainty as to whether the Hercules 009 Landfill sites groundwater is contaminated with toxaphene degradation products and the uncertainty about the human toxicity of these toxaphene degradation products, Superfund’s 5-year review for the Hercules 009 Landfill site should conclude that whether the MNA remedy protects human health cannot be determined at this time. As a result of this uncertainty in the data, the Region needs to definitively determine if the groundwater is contaminated with the Hx-Sed and Hp-Sed toxaphene congeners generated by the microbial degradation of “technical” toxaphene.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
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61 FORSYTH STREET
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June 29, 2005

MEMORANDUM

SUBJECT: Comments on the Draft Ombudsman Report
Appropriate Testing and Timely Reporting Are Needed at the Hercules 009 Landfill Superfund Site, Brunswick, Georgia; Assignment 2004-124

FROM: J. I. Palmer, Jr.
Regional Administrator

TO: Paul D. McKechnie
Acting Ombudsman
Office of Congressional and Public Liaison

Thank you for the opportunity to provide comments on the draft report. The following comments relate to the subject document, and are provided primarily to address the action required in EPA Manual 2750. In accordance with the memorandum transmitting the draft report, we have followed the instructions to "address the factual accuracy of the draft report and indicate concurrence or noncurrence with each finding and proposed recommendation. If you do not concur with the proposed recommendation, please provide any alternative actions you wish to be considered for the final report." The comments are a consolidation of input from Region 4's Analytical Support Branch of the Science and Ecosystem Support Division, and the Superfund Remedial and Technical Support Branch of the Waste Management Division. In addition, the Region has included comments from the Region 4 Office of Environmental Accountability (OEA) that address noted excerpts in the draft report.

Excerpt from the Draft Ombudsman Report Page 8, Recommendation 2.1:

"Use negative ion mass spectroscopy to definitely determine if toxaphene breakdown products are present in the surrounding groundwater at the Hercules 009 Landfill site, and (if so) in what amounts."

Response to Recommendation 2.1

The Region has used negative ion mass spectrometry (NIMS) to determine the presence of weathered toxaphene (WT). After the issuance of the Preliminary Technical Draft from the OIG, samples were collected from the 009 Landfill monitoring wells by Hercules, Inc., under a voluntary interim action on March 5th and analyzed by Keith Maruya at the Skidaway Institute of

Oceanography using the NIMS method from a peer reviewed scientific publication. The Hercules, Inc., March 2005 Data Report is attached as an addendum.

Region 4's laboratory is willing to participate in a multi-laboratory method validation study for toxaphene congeners in environmental samples. However, since the Agency as a whole would obviously benefit from a validated NIMS method for toxaphene congeners, we believe that a multi-laboratory method validation study should be initiated at the program level by the Office of Solid Waste and Emergency Response. A validated method will serve both the regulated community and the Agency by assuring that analytical data produced by the method are defensible, of known quality, and suitable for risk assessment decision making.

Excerpt from the Draft Ombudsman Report, Page 8 Recommendation 2.2:

"If toxaphene breakdown products are found in the groundwater, assess the resulting risk to human health and take appropriate action."

Response to Recommendation 2.2

In response to the Preliminary Technical Draft from the OIG, Region 4 conducted a thorough literature review for information on the toxicity of WT and reached the following conclusions:

Application of the MCL to Groundwater at 009 Landfill
The NIMS analytical results from groundwater at the 009 Landfill are all significantly less than the MCL for technical toxpahene (TT) of 3 ug/L. Based on the Region 4 preliminary toxicity assessment, it is reasonable to assume that this MCL is protective for WT as well as TT. The Region 4 Draft Report on WT toxicity is attached as an addendum and a short summary is provided below.

Toxicity Criterion for Weathered Toxaphene
To develop a human toxicity criterion for WT, three choices must be made: (1) the critical toxic endpoint; (2) the threshold dose value based on the critical endpoint; and (3) the uncertainty/safety factors applied to determine a reference dose.

Region 4 toxicologists believe that the most appropriate endpoint for WT is tumor promotion. This endpoint was chosen because it appears most relevant to humans, and focusing on this endpoint is also protective of other toxic endpoints, such as immunologic and developmental effects.

The Monitoring, Analysis and Toxicity of Toxaphene in Marine Foodstuffs (MATT) study from the European Union is the sole toxicological study based on WT and thus chemically is most relevant to human exposure. The critical study was performed in rats with changes in liver cells that represent precancerous changes as the endpoint. The no observable adverse effect level (NOAEL) from this study was 0.69 mg/kg-day as calculated by MATT or 0.6 mg/kg-day in the Region 4 analysis. Note these values are very similar.

The following uncertainty factors were considered: 10 for animal-to-human extrapolation and 10 for human variability. In spite of the paucity of studies on WT, the literature is replete with studies on TT that cover a range of endpoints. Many of these studies resulted in higher and less protective NOAELs. The studies that had similar values for NOAELs were ingestion or oral gavage studies based on TT. The bulk of toxaphene administered orally is excreted or metabolized quickly; hence, the internal doses of WT and TT and the subsequent toxaphene body burdens end up being of similar magnitude. Because of the large database of toxicity studies of TT, we believe no additional database insufficiency uncertainty factor was needed. Hence, the combined uncertainty factor is 100.

This derivation of a reference dose for WT based on tumor promotion is consistent with the recently finalized EPA cancer guidelines which state that the consideration of mode of action vis-à-vis toxicity is paramount in the development of a toxicity criterion.

<u>The Need for Peer Review</u>

Unfortunately, the laboratory studies on WT toxicity that the MATT report relied on have not yet undergone peer review because of logistical issues (one of the authors moving to a new university). Region 4 agrees with the OIG report that additional toxicity studies may be helpful. Peer review would also be helpful in elucidating some of the apparent errors in interpretation of EPA cancer potency factor derivation identified in the MATT report.

On page 19 of the OIG report, the MATT was quoted as indicating that WT is approximately twice as carcinogenic as TT. This statement of the MATT report is incorrect and unfortunately repeated in the OIG report. It is not entirely clear on what basis the MATT report makes this statement, but there are two possibilities.

First, the MATT report presented a misunderstanding of the EPA TT slope factor in which the MATT confused the units. The upshot of this misunderstanding is that the MATT toxicity criterion appears for WT about twice as stringent at the EPA toxicity criterion for the original TT mixture. In truth, the EPA toxicity criterion is 300 times more stringent than the MATT criterion.

Second, the MATT interpreted some empirical data obtained from a cell culture system and possibly made a large and unfounded conceptual leap. In this cell culture system, the toxic endpoint was disruption of intercellular communication. Calculations indicated that the WT was twice as effective in blocking intercellular communication as TT. However, to make the leap of claiming that effects on intercellular communication in a cell culture system is tantamount to a carcinogenic response in a whole animal is a very large leap indeed. This conceptual leap is not endorsed by Region 4 toxicologists.

Interim Strategy for Risk Assessment
In keeping with the OIG intention of using the best available science, Region 4 has two proposals for an interim strategy. The preferred approach is to use the toxicity criterion for WT developed by Region 4 Technical Services and based on the laboratory study in the MATT. Presently, the Region 4 report is still in draft, but should be finalized relatively soon. Hence, Region 4 requests that the OIG review both the MATT laboratory study and the Region 4 derivation of toxicity criteria to determine their soundness and applicability. An alternative approach is to use a toxicity criterion based on TT. The EPA toxicity criterion for TT now on IRIS was last revised in 1991. The toxicity value is based on rodent bioassays conducted in 1978 and 1979. In 2000, Goodman[1] reanalyzed these data using newer methods based on EPA guidance and concluded that TT was actually tenfold less toxic than the IRIS value. Region 4 believes that our preferred approach represents the best available science and would provide a reasonable interim approach.

Excerpt from the Draft Ombudsman Report Page 13, 3.1:

"Issue the report on the Hercules 009 Landfill 5-year review with the conclusion that the protectiveness of the groundwater cleanup cannot be determined at this time, and further evaluation is needed. A timeframe should be estimated for such an evaluation."

Response to Recommendation 3.1:

Based on the recent evidence provided by the NIMS data and the toxicity criterion developed by Region 4 based on the MATT laboratory study, Region 4 proposes that the data and toxicity review be included in the release of the 5-year review and a determination of protectiveness be issued.

Excerpt from the Draft Ombudsman Report Page 13, 3.2 :

"Ensure that restrictions are placed in the property deed to control future use of the land and groundwater."

Response to Recommendation 3.2:

When Hercules, Inc., entered into the Consent Decree for RD/RA with the U.S., it agreed to perform all operation and maintenance activities required to maintain the effectiveness of the

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[1] Goodman JI, Brusick DJ, Busey WM, Cohen SM, Lamb JC, Starr TB. (2000) Reevaluation of the cancer potency factor of toxaphene: recommendations from a peer review panel. Toxicol Sci. 2000 May;55(1):3-16.

Remedial Action. As set out in the Record of Decision, operation and maintenance of the multi-media cover was to continue for a minimum of 30 years. (See Section 9.A.1). The Consent Decree for RD/RA requires Hercules, Inc., to not only record a certified copy of the Consent Decree with the Glynn County registry of deeds, but to also include within any instrument conveying any interest in the property a notice describing the restrictions applicable to the property, the provisions of the Consent Decree with respect to institutional controls and EPA's right of access, and the obligations of successors-in-title. In addition, Hercules, Inc., and any successor-in-title must provide written notice to EPA of any proposed conveyance of any interest in the title. As part of EPA's statutory mandate for a 5-year review of a remedy's effectiveness if waste is left in place, the Consent Decree for RD/RA further obligates Hercules, Inc., to conduct any studies and investigations that EPA might request in support of its 5-year review. Moreover, no conveyance by Hercules, Inc., of any interest in property, however minor, will release or otherwise affect the liability of Hercules, Inc., to comply with the terms of the Consent Decree for RD/RA.

In light of the fact that the remedy has achieved the performance standards established in the Record of Decision and is believed to be currently performing as designed, EPA's statutory authorities and the enforcement-based tools arising from the Consent Decree for RD/RA are presently believed to be adequate institutional controls. Of course, if environmental or other conditions change, existing State-based legal authorities may in the future also be utilized to facilitate proprietary controls, such as an environmental easement designed to protect groundwater, if determined by EPA to be necessary.

Excerpt from the Draft Ombudsman Report Page 13, 3.3:

"Confirm that no one in the vicinity is using the groundwater."

Response to Recommendation 3.3 :

Since the perimeter monitoring wells are properly functioning as an intended early warning system, it becomes unnecessary to document private well water use outside the perimeter. Nonetheless, Hercules, Inc. has investigated the status of private registration of new wells in the immediate area. In checking with the Glynn County Environmental Department, Hercules was informed that the County has no record for the past several years of anyone advising them of the intent to drill a private drinking water well in the immediate area of the 009 Landfill. Hercules has also been informed by the previously affected residents that they continue to use city water for drinking purposes. Finally, Hercules has conducted a visual canvassing of the area to locate well house structures. This effort indicates that no new private drinking water wells have been installed in the immediate area surrounding the site.

The perimeter well monitoring system has been evaluated by a hydrogeologist in Region 4's Technical Services Section. The ability to capture leachate was the focus of the evaluation and the leachate capture system was found to be effective. The Final Technical Memo is attached as an addendum. These wells are closest to the source and allow the earliest warning signal that downgradient wells may be affected. Since the recent NIMS and MATT comparison demonstrate that the perimeter wells do not pose a risk and the monitoring wells act as an effective early warning signal, it is unnecessary to obtain additional groundwater samples from locations beyond the perimeter well system.

Attachments (6)

1. Hercules, Inc., March 2005 Data Package for 009 Landfill using NIMS

2. A Re-analysis of the European MATT (2000) Toxicity Data and Development of a Reference Dose for Weathered Toxaphene (DRAFT)

3. Differences between Cancer and Non-Cancer Risk Assessment using Toxaphene as an example

4. October/December 2003 Technical Memos from SRTSB/TSS describing sufficiency of the monitoring wells to detect migration

5. Cover Memo and Complete Comments from SESD

6. Cover Memo and Complete Comments from OEA

cc w/o attachments:
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Appendix C

OIG Technical Comments on the Region 4 Response

OIG Draft Recommendation 2.1:

"Use negative ion mass spectroscopy to definitely determine if toxaphene breakdown products are present in the surrounding groundwater at the Hercules 009 Landfill site, and (if so) in what amounts."

OIG Technical Comments on Region 4's Response:

The groundwater at the Hercules 009 Landfill was recently analyzed using negative ion mass spectroscopy (NIMS). In March 2005, Hercules Incorporated voluntarily collected an additional set of groundwater samples from the Hercules 009 Landfill's monitoring wells. These samples were subsequently analyzed by EnChem using Method 8081A and also by Keith Maruya from the Skidaway Institute of Oceanography using a NIMS methodology. EnChem found no measurable concentration of chlorinated camphene in monitoring well N-11. Skidaway found an estimated concentration of 0.74 µg/L (a.k.a. parts per billion, or ppb) of chlorinated camphene in monitoring well N-11. Thus, all reported chlorinated camphene values from EnChem and Skidaway were below the level of concern of 3.0 µg/L for technical toxaphene.

The OIG's review of the scientific literature regarding toxaphene found several sources that identified potential problems with analyzing for toxaphene degradation products. The Agency for Toxic Substances and Disease Registry's (ATSDR's) Toxicological Profile for Toxaphene reported that sulfuric acid cleanup of toxaphene sample extracts modify the toxaphene peak profile (ATSDR, 1996, p. 147). This suggests that the sulfuric acid cleanup procedure has the potential to destroy or alter the ratio of toxaphene degradation congeners. In 1997, Alder reported that gas chromatograph injector temperatures greater than 240^o C have been observed to decompose or to decrease the observed response of the toxaphene congeners p50 and p62 prior to their measurement by the detector (Alder 1997). In 1995, Andrews found during a round-robin study on the analysis of toxaphene that only 15 to 30 percent of the toxaphene components were eluted from the silica or florisil columns with a nonpolar solvent (Andrews 1995). These observations indicate that the analysis for toxaphene degradation products is difficult and the analytical results can vary significantly depending on how the analysis was conducted.

The case narrative for the March 2005 Hercules 009 Landfill data from both EnChem and Skidway indicated that sulfuric acid was used to cleanup the extracts and that the gas chromatograph injector temperature may have been as high as 250^o C. The OIG is concerned that the sulfuric acid cleanup and that the gas chromatograph injector temperature, if it exceeded 240^o C, may have lowered the amount of chlorinated camphene detected.

Following OIG discussions with Region 4 concerning these procedural issues with the method, Region 4 provided additional test results from Region 4's Science and Ecosystem Support Division (SESD). For their analyses, the sample extracts were not subjected to sulfuric acid cleanup and the gas chromatograph injector temperature was known to be below 240^{o} C. In data dated November 28, 2004, and January 13, 2005, SESD reported chlorinated camphene sample results for monitoring well N-11 of 4.0 JN µg/L and 6.4 JN µg/L, respectively. These results are significantly higher than Enchem's and Skidaway's chlorinated camphene results. SESD's chlorinated camphene results of 6.4 µg/L for monitoring well N-11 are 8.6 times greater than Skidaway's chlorinated camphene results of 0.74 µg/L. SESD's reported chlorinated camphene results are above the level of concern of 3.0 µg/L for technical toxaphene.

These results for chlorinated camphene show that the analysis of toxaphene is a complicated process in which the type and skill used in the extraction, cleanup, and testing procedures can directly impact the reported analytical results. To verify and document that all analytical variables are under control, a laboratory normally analyzes a spiked laboratory quality control sample (i.e., positive control sample) to confirm that the laboratory's processing of the sample extract did not destory or lose the compound(s) of interest (i.e., Hx-Sed, Hp-Sed, p26, and p50). Instead, all three laboratories (i.e., EnChem, Skidaway, and SESD) spiked the laboratory quality control sample with technical toxaphene. This quality control procedure demonstrates the performance of the method used adequately detects and measures technical toxpahene, but does not demonstrate the method's performance on individual toxaphene congeners. To document how well the method performs with the individual congeners of interest, such as Hx-Sed, Hp-Sed, p26, and p50, the laboratories needed to spike and measure the recoveries for the individual toxaphene degradation products (i.e., Hx-Sed, Hp-Sed, p26, and p50) and not technical toxaphene.

An example of this congener-specific quality control spiked sample can be seen in Foreid's 2000 paper referenced by Keith Maruya's letter dated August 4, 2005 (Foreid 2000). Foreid specifically spikes p26, p50, and p62 and demonstrates spiked sample recoveries for each congener of greater than 94 percent. These quality control results clearly demonstrated that the specific silica fractionation and sulphuric acid cleanup procedure used by Foreid did not destroy or degrade the toxaphene congeners of interest. This type of quality control results on individual congeners would have greatly assisted in interpreting the EnChem, Skidaway, and SESD results from the Hercules 009 Landfill. Unfortunately, this type of quality control results were unavailable for the Hercules 009 Landfill data because there is no standardized, validated, or EPA approved method to analyze for toxaphene degradation products. 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.

The OIG agrees with Region 4 that developing and validating a NIMS method for toxaphene congeners needs to be initiated and supported at the national program office level. Due to the degraded nature of the remaining toxaphene contamination left in the environment (i.e., a substantial amount due to the bulk use of toxaphene over many years), the NIMS method is needed by the EPA to accurately determine the extent of the remaining contamination in the environment and to provide toxicologically-relevant analytical data for assessing the risk to human health from these remaining toxaphene breakdown congeners. Therefore, future groundwater monitoring at the Hercules 009 Landfill should use, if developed and validated, the EPA-approved NIMS method.

The OIG disagrees with the statement in the Hercules Incorporated cover letter dated April 11, 2005, that "… the ECD-NCIMS method is essentially the same as Method 2 (Total Area Under the Curve)…". The NIMS method has the ability to positively identify the presence of individual toxaphene congeners and to measure the concentration of individual toxaphene congeners, while Method 2 can not. Method 2 does not provide congener specific information on toxaphene that is needed to evaluate the risk to humans from the potential exposure to the persistent toxaphene degradation congeners. Thus, these two analytical methods are not "essentially" the same.

OIG Draft Recommendation 2.2:

"If toxaphene breakdown products are found in the groundwater, assess the resulting risk to human health and take appropriate action"

OIG Technical Comments on Region 4's Response:

Regarding assessing the toxicity of toxaphene, since humans are exposed to toxaphene degradation products (e.g., mainly p26 and p50) and since individual congeners can have dramatically different toxicities, the toxicity criteria for weathered toxaphene must be developed and used. The OIG believes that the toxicity criteria for technical toxaphene should not be used, because the public is no longer exposed to the original mixture of toxaphene congeners.

Regarding a critical toxic endpoint, the OIG agrees with Region 4 that weathered toxaphene acts as a tumor promoter and not as a tumor initiator (i.e., causing direct damage to deoxyribonucleic acid, also known as DNA). The OIG also agrees with Region 4 that the use of the reference dose represents one of the first instances in which EPA has applied a threshold-type toxicity to a potentially carcinogenic compound. Due to the novelty of the application under the EPA's new cancer guideline, developing a reference dose for weathered toxaphene needs to be peer-reviewed and a consensus reached both internal and external to the EPA before a threshold limit for expose to toxaphene degradation products can be set and used for risk assessment.

Region 4's response stated that the MATT study conducted by the European Union is the sole information on the toxicity of weathered toxaphene. However, Region 4's response indicated that the MATT study may have some technical and conceptual issues that a pending peer review may elucidate. The MATT study does not clarify the mode of action as to whether the ultimate carcinogen is from the persistent congeners or from non-persistent congeners. Therefore, the OIG believes that the MATT study results alone do not provide sufficiently robust toxicity data to support setting a threshold limit for weathered toxaphene. Consequently, the OIG believes additional research is needed to characterize and assess the mode of action of the toxaphene degradation products to generate a sufficient quantity and of high-quality toxicity data on weathered toxaphene to support a threshold limit. The OIG agrees with Region 4 that additional research should focus on the toxicity of the persistent toxaphene degradation products, namely, p26 and p50, but also the less abundant products p62, p 40, p41, and p44, because they are most likely to produce the toxic effects.

OIG Draft Recommendation 3.1:

"Issue the report on the Hercules 009 Landfill 5-year review with the conclusion that the protectiveness of the groundwater cleanup cannot be determined at this time, and further evaluation is needed. A timeframe should be estimated for such an evaluation."

OIG Technical Comments on Region 4's Response:

The Ombudsman contends that the 5-year review can be issued stating that the cleanup of the Hercules 009 Landfill protects human health for the following reasons:

- The OIG observed a reoccurring pattern in the Hercules 009 Landfill groundwater monitoring data from 2002, 2004, and 2005. The analytical results from monitoring wells N-06SR and N-11 suggest that toxaphene degradation products (i.e., measured as chlorinated camphenes) are present and may exceed the 3.0 µg/L level of concern for technical toxaphene at these locations. Monitoring wells N-06SR and N-11 always had the highest observed concentrations of chlorinated camphenes during each individual sampling event. By contrast, the analytical results from the remaining monitoring wells for the site, many of which are down gradient of wells N-06SR and N-11, suggest that the toxaphene degradation products in the groundwater have not left the Hercules 009 Landfill property. Thus, the surrounding community is not being exposed to toxaphene degradation products through the groundwater exposure pathway.

- No groundwater wells are being used in the vicinity of the Hercules 009 Landfill.

- Although a deed restriction was not placed on the Hercules 009 Landfill property to prevent drilling and using wells on the property in the future, the consent decree was recorded in the records of Glynn County.

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Appendix D

Distribution

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