



OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Ombudsman Report

More Information Is Needed On Toxaphene Degradation Products

Report No. 2006-P-00007

December 16, 2005



Report Contributors: Christine Baughman
Tapati Bhattacharyya
Stephen Schanamann
Frances E. Tafer
Michael H. Wilson

Abbreviations

CLE	Cod liver extract
DDT/DDE	Dichlorodiphenyltrichloroethane and its metabolic byproduct, DDE
EPA	U.S. Environmental Protection Agency
GA/DNR	Georgia Department of Natural Resources
GC/ECD	Gas chromatography with electron capture detector
HCH	Halogenated hydrocarbons
IRIS	Integrated Risk Information System
MATT	Investigation into the Monitoring, Analysis, and Toxicity of Toxaphene
MCL	Maximum containment level
MNA	Monitored natural attenuation
NIMS	Gas chromatography with negative ion mass spectroscopy
NPDWR	National Primary Drinking Water Regulations
OIG	Office of Inspector General
PCB	Polychlorinated biphenyl
ppb	Parts per billion
ppt	Parts per trillion
PWS	Public water system
RfD	Reference dose
SW-846	Test Methods for Evaluating Solid Waste, Physical/Chemical Methods
TCDD	Tetrachlorodibenzo- <i>p</i> -dioxin
TDI	Tolerable daily intake
ug/L	Micrograms per liter

Cover photo: An airplane applying pesticides to a field.



At a Glance

Catalyst for Improving the Environment

Why We Did This Review

The Glynn Environmental Coalition, a nonprofit community organization, brought to the Ombudsman's attention concerns about toxaphene at a Superfund site in Georgia.

Background

Toxaphene is an agricultural pesticide that was heavily used in the United States during the 1960s and 1970s. EPA banned it for most uses in 1982, and for all uses in 1990, because it posed a risk of significant adverse impacts on humans and the environment. To further protect people from the effects of toxaphene, EPA limited how much toxaphene can be in drinking water and required related monitoring. The EPA Superfund program is cleaning up numerous sites contaminated with toxaphene.

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

To view the full report, click on the following link:

www.epa.gov/oig/reports/2006/20051216-2006-P-00007.pdf

More Information Is Needed On Toxaphene Degradation Products

What We Found

Toxaphene in the environment changes, or degrades. The resulting degradation products are different from the original toxaphene in chemical composition and how they appear to testing instruments, so they could go unreported. The analytical methods EPA uses to identify and measure toxaphene are not designed to identify toxaphene degradation products. However, a new testing method used by others specifically tests for toxaphene degradation products. We believe EPA should validate, approve, and use this method.

Certain toxaphene degradation products accumulate inside people. Although studies indicate that some of these degradation products may be harmful, more research is needed to determine how much of a risk these products pose to people.

What We Recommend

We recommend that the EPA Administrator direct

- The Assistant Administrators for Water and for Solid Waste and Emergency Response to validate and approve the new analytical method that tests for toxaphene degradation products, and use the new method to analyze environmental samples.
- The Assistant Administrator for Research and Development to work with others in EPA to arrange for the specific research needed to determine the risk that toxaphene degradation products may pose to people.



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

THE INSPECTOR GENERAL

December 16, 2005

MEMORANDUM

SUBJECT: More Information Is Needed On Toxaphene Degradation Products
Report No. 2006-P-00007

TO: Stephen L. Johnson
Administrator

This is our final report on a review of toxaphene 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 has identified and corrective action the OIG recommends. This report represents the opinion of the OIG and the 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 action plan for agreed upon actions, including milestone dates. We have no objection 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 202-566-0847 or Eileen McMahon, the Assistant Inspector General for Congressional and Public Liaison, at 202-566-2546.

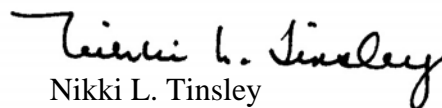

Nikki L. Tinsley

Table of Contents

At a Glance

Chapters

1	Introduction	1
	Purpose	1
	Background Information	1
	Scope and Methodology	2
2	Exposure and Risk Information about Toxaphene Degradation Products Is Needed.....	4
	Toxaphene Degrades in the Environment.....	4
	Some Degradation Products Accumulate in Humans	4
	Studies Indicate Degradation Products May Pose a Risk	5
	More Studies Are Needed	5
	Degradation Products Should Be Monitored	6
	A Different Analytical Method is Needed to Identify Degradation Products....	6
	EPA Should Approve the NIMS Method	7
	Recommendations	8
	Agency Comments and OIG Evaluation	8

Appendices

A	Technical Discussion on Toxaphene	A-1
B	Superfund Sites Listing Toxaphene as a Contaminant of Concern	B-1
C	Agency Response to Draft Report	C-1
D	OIG Technical Comments on the Agency Response	D-1
E	Distribution	E-1

Chapter 1

Introduction

Purpose

The purpose of this report is to bring issues related to toxaphene, an agricultural pesticide, to the attention of EPA management. The issues about toxaphene stem from a complaint made by the Glynn Environmental Coalition (a nonprofit community organization) to the Ombudsman at the U.S. Environmental Protection Agency's (EPA's) Office of Inspector General (OIG). The OIG Ombudsman reviews and reports on public concerns regarding EPA activities, including Superfund, which is the EPA program to clean up uncontrolled hazardous waste sites. The complaint pertained to toxaphene found at the Hercules 009 Landfill Superfund site in Georgia, in EPA Region 4. We have issued a separate report to the Regional Administrator of Region 4 recommending appropriate actions regarding the Hercules 009 Landfill (Report No. 2005-P-00022, September 26, 2005). However, since we found that the issues related to toxaphene were broader than just that site, we believe EPA needs to address them nationwide.

Background Information

Toxaphene first became available commercially in 1948. Toxaphene came in various forms and was used against insect pests of cotton, tobacco, forests, turf, ornamental plants, grains, vegetables, and livestock. It was also used in the 1950s and early 1960s by fisheries in several States to remove unwanted fish from lakes and ponds. This use was discontinued or prohibited when unexpectedly high amounts remained in some lakes. During the 1960s and 1970s, it was the most heavily used pesticide in the United States, with the southern United States and California using it the most.

Toxaphene poses a risk of significant adverse impacts on humans and the environment. If people breathe, eat, or drink large amounts of toxaphene, it may damage the lungs, nervous system, and kidneys, and can even cause death. Consequently, with a few exceptions, EPA cancelled the registrations for all uses of toxaphene in November 1982. 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. Although most of the existing stocks of cancelled products had to be sold and used before 1984, some could be sold and used according to label specifications through 1986. EPA banned all uses of toxaphene in 1990.

Although toxaphene can no longer be used, some remains in the environment. People must be protected from its effects. Therefore, under the Safe Drinking Water Act, EPA set a limit on the amount of toxaphene that can be in the drinking water: the limit is 0.003 milligrams per liter. As a result, public water systems must monitor the level of toxaphene in their drinking water. Also because of health risks associated with toxaphene, various States have issued a total of 25 advisories that people not eat fish from 10 locations around the country. Toxaphene was identified as a contaminant of concern in at least 16 Superfund sites; these sites, most of which are located in the southeastern part of the United States, are identified in Appendix B. Other information indicates toxaphene has been found in as many as 58 Superfund sites.

When toxaphene is released in the environment, it transforms into substances known as toxaphene degradation products that may be harmful to human health. The extent of the health risk depends on the amount of degradation products to which people are exposed, and the types of danger the substances pose. Therefore, to assess the potential human health risk associated with toxaphene degradation products, information on both amounts and dangers is needed. Chapter 2 of this report addresses (1) identifying and measuring toxaphene degradation products to determine exposure, and (2) potential dangers. Appendix A contains a technical discussion of these matters.

Scope and Methodology

We began field work on this review in June 2004 and completed it in January 2005. During that period, we interviewed EPA officials in Region 4, the Office of Solid Waste and Emergency Response, and the Office of Research and Development. We also met with representatives of the Glynn Environmental Coalition, U.S. Army Corps of Engineers, and the Skidaway Institute of Oceanography. The OIG team reviewed toxaphene testing protocols and about 50 journal articles on toxicity and exposure issues related to toxaphene, and obtained additional information from various Federal Internet sites.

On August 12, 2005, the OIG issued a draft report to the EPA Administrator for review and comment. The Deputy Administrator responded on September 26, 2005. This response, which included comments from the Office of Research and Development, Office of Solid Waste and Emergency Response, and Office of Water, stated that EPA generally concurred with the recommendations. They suggested some specific changes to the report. As appropriate, we revised the report based on their comments. We provide a summary and general evaluation of the EPA comments and our response at the end of Chapter 2. We included the Deputy Administrator's memorandum in Appendix C. Appendix D is the OIG evaluation of the technical aspects of the EPA response.

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 directly related to the issue under review.

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

Exposure and Risk Information about Toxaphene Degradation Products Is Needed

Exposure and risk information is necessary to complete a risk assessment of the toxaphene degradation products that result when toxaphene is released into the environment. A few studies indicate these degradation products may pose a danger to human health, but more research on the risks is needed. To determine exposure, an analytical method that identifies and measures toxaphene degradation products is required. One is available, but needs to be approved by EPA for use in its programs.

Toxaphene Degrades in the Environment

Toxaphene was a mixture of many organic chemicals that, when released into the environment, slowly changed. The original toxaphene was produced by the chlorination of camphene, resulting in a mixture of more than 200 compounds, mostly polychlorinated camphenes and bornanes. Generally, from six to nine chlorines were attached to the camphenes and bornanes, and the average chlorine content was 67 to 69 percent.

In the environment, the original toxaphene mixture dechlorinates; it breaks down (or degrades) and the components lose chlorines. It degrades with or without air present. Exactly what happens to it in the environment depends on the situation. For example, microbes in the soil are known to break down the original toxaphene into two major degradation products (i.e., Hx-Sed and Hp-Sed) and several minor degradation products. Some of the less abundant degradation products identified in soil include p26, p40, p41, p44, and p50. These degradation products are a different mixture than the original toxaphene mixture, so they appear different to the testing instruments.

Some Degradation Products Accumulate in Humans

Toxaphene degradation products can be detected in human blood, urine, breast milk, and body tissues. Toxaphene or toxaphene degradation products generally get into the body through eating fish or drinking water contaminated with these substances. Babies may be exposed if they are breast fed and the mother had been exposed. The body processes (i.e., metabolizes) these substances and most of them leave the body. Hx-Sed and Hp-Sed are examples of degradation products that quickly leave the body. However, some of the degradation products stay in the body; they accumulate or build up. These include p26, p40, p41, p44, p50,

and p62. Because these degradation products accumulate in the body, they may pose a continuing risk to the person.

Studies Indicate Degradation Products May Pose a Risk

EPA was aware of the potential danger of toxaphene degradation products when it banned toxaphene. However, specifics were not known concerning which of the degradation products posed the danger and how much danger they posed. EPA's September 1986 Ambient Aquatic Life Water Quality Criteria for Toxaphene noted:

The compositional changes that occur in the field probably also mean that field toxicity differs to some unknown extent from toxicity determined in laboratory tests using technical-grade toxaphene. Using mice, houseflies, and goldfish, Khalifa et al. (1974), Saleh et al. (1977), and Turner et al. (1975, 1977) demonstrated that different toxaphene components have substantially different toxicities. Toxaphene that had "weathered" for 10 months in a lake was altered chemically (diminution of late eluting peaks) and was somewhat less toxic to fish than the original formulation (Lee et al. 1977). In contrast, Harder et al. (1983) found that sediment-degraded products of toxaphene were more toxic than the parent material to some saltwater fishes.

In recent years, new scientific data have emerged on the dangers posed by toxaphene degradation products that accumulate in a person, such as p26, p50, and p62. A 1997 study showed that p26 and p50 caused more abnormalities in the central nervous systems of rat embryos than toxaphene caused. Another study showed that a cod liver extract containing three toxaphene degradation products (p26, p50, and p62) promoted the growth of tumors more than the original toxaphene mixture. However, the quality of this study has not been evaluated and an EPA toxicologist in Region 4 is concerned that the authors of the study erred in their interpretations.

More Studies Are Needed

More scientific data are needed on the dangers posed by toxaphene degradation products. Since the continuing risk to humans is limited to the degradation products that accumulate in the body, future studies should center principally on p26, p40, p41, p44, p50, and p62. Hx-Sed and Hp-Sed should also be considered for study because, although they do not accumulate in people, they generally occur in larger amounts. Further, the studies should address the likelihood that these degradation products will cause tumors (i.e., cancer) or will harm embryos.

The EPA Office of Research and Development has already funded some studies related to toxaphene degradation products. EPA program offices would need to

provide funds to support additional studies. Such studies should be of interest to EPA's Office of Water and Office of Solid Waste and Emergency Response because, if studies show toxaphene degradation products pose a danger to human health, their programs would need to address the dangers by developing acceptable human exposure limits to mixtures of the substances. Further, until more is known, EPA will be unable to definitively determine if the cleanup of Superfund sites contaminated with toxaphene (such as the Hercules 009 Landfill) protect human health and the environment. In responding to the draft OIG report on the Hercules 009 Landfill, Region 4 agreed that additional toxicity studies of toxaphene degradation products may be helpful.

Degradation Products Should Be Monitored

Since toxaphene degradation products may pose a risk to human health, they should be monitored in the environment to obtain exposure information. As noted above, exposure information is necessary to perform a risk assessment. The ability to identify and measure toxaphene degradation products should be used by various EPA programs. Specifically, toxaphene degradation products should be targeted for analysis at toxaphene-containing sites (e.g., Superfund sites) or in toxaphene-containing media (e.g., water).

For a site to become part of the Superfund program, evidence must exist that a hazardous substance was released from the site. Under EPA's November 1992 Hazard Ranking System Guidance Manual, this evidence could include breakdown (or transformation) products. Also under the Superfund and other programs, according to EPA's April 1999 Use of Monitored Natural Attenuation at Superfund, RCRA Corrective Action, and Underground Storage Tank Sites, if a site has contaminants that are being allowed to naturally degrade (or attenuate), then monitoring should identify any potentially toxic and/or mobile transformation products. Similarly, drinking water must be monitored for contaminants with established standards, and for contaminants for which EPA may want to establish standards.

A Different Analytical Method is Needed to Identify Degradation Products

The analytical methods approved by EPA to identify and measure toxaphene do not evaluate toxaphene degradation products. The approved methods generally use a testing instrument called a gas chromatograph with electron capture detectors, and have been proved to be capable of testing for the original toxaphene mixture, but have not been formally validated for toxaphene degradation products. However, as noted above, the toxaphene degradation products are a different mixture than the original toxaphene mixture.

A new analytical method using a gas chromatograph with negative ion mass spectroscopy (NIMS) should be used to test for toxaphene degradation products.

Academia and the European Union have successfully used the NIMS method for at least 5 years to test for toxaphene degradation products in the environment.

The NIMS method provides definitive test results because the technique generates a mass spectrum for each compound in an environmental sample. A mass spectrum is like a chemical “fingerprint.” If the “fingerprint” of an unknown compound in the environmental sample matches the known “fingerprint” of the toxaphene degradation product, the resulting match of the “fingerprints” would definitively identify the presence of toxaphene degradation products. On the other hand, if the “fingerprints” do not match, then the NIMS method would definitively determine that toxaphene degradation products are not present. Therefore, the use of the NIMS method provides the certainty needed to determine whether the environment is contaminated by toxaphene degradation products.

EPA Should Approve the NIMS Method

Environmental data used to make public health decisions should generally be produced through analytical methods that have been proven (or validated) by several laboratories and approved by EPA. Both EPA’s Office of Solid Waste and Emergency Response and Office of Water have established procedures for approving analytical methods used by their programs. Since EPA has not approved the NIMS method, it should be subjected to the approval process of both offices.

People or companies may ask that EPA (i.e., the Office of Water, or the Office of Solid Waste in the Office of Solid Waste and Emergency Response) approve a new way to prepare a sample, a new way to analyze a sample, or a variation on an existing way. Such requests can also come from within EPA. If approval of a new analytical method is requested, those requesting approval must prove that the proposed method will accurately measure the amount of the specified substance in an environmental sample. If the new method will be used nationwide, three or more different laboratories must validate the method. Following validation, those requesting approval submit a variety of information to EPA about the new or revised method, including the results from the validation process, and explain why a change is needed.

If EPA agrees that a new analytical method should be adopted nationwide, how it is approved depends on whether it is for the Office of Water or the Office of Solid Waste and Emergency Response. The Office of Water must add the new method to the *Code of Federal Regulations*. This process takes several months, including publishing a proposed rule, evaluating the resulting comments from the public, and then issuing a final rule. The Office of Solid Waste approves the new method by adding it to its manual of EPA-approved methods. The public may review proposed updates to the manual before the changes become part of the manual.

Recommendations

1. We recommend that the Administrator direct the Assistant Administrators for Water and for Solid Waste and Emergency Response to:
 - a. Develop, validate, and approve the gas chromatograph with negative ion mass spectroscopy method to analyze toxaphene degradation products, especially p26, p40, p41, p44, p50, p62, Hx-Sed, and Hp-Sed; and
 - b. Use the gas chromatograph with negative ion mass spectroscopy method to analyze for toxaphene degradation products during sampling and testing at sites known to contain toxaphene, or whenever monitoring for toxaphene contamination.
2. We recommend that the Administrator direct the Assistant Administrators for Research and Development, for Water, and for Solid Waste and Emergency Response to arrange for specific research into the dangers of tumors (i.e., cancer) and of harm to embryos posed principally by a mixture of toxaphene congeners and metabolites found in fish.

Agency Comments and OIG Evaluation

In a memorandum dated September 26, 2005, the Deputy Administrator provided comments on the draft report from the Office of Research and Development, Office of Solid Waste and Emergency Response (both the Superfund program staff and solid waste program staff), and the Office of Water. In general, EPA officials concurred with the recommendations. The Deputy Administrator's memorandum is Appendix C.

The OIG's technical evaluation of the EPA response is Appendix D. In summary, we changed recommendation 1b in a manner similar to that suggested by the Office of Solid Waste. We also changed recommendation 2 as requested by the Office of Research and Development. Finally, based on the response from the Office of Water, we believe that Office has not fully appreciated the impact toxaphene degradation products may make on the National Primary Drinking Water Regulations.

Technical Discussion on Toxaphene

The original toxaphene pesticide mixture is known to degrade in the environment, so its degradation products may be present at Superfund sites (such as the Hercules 009 Landfill in Georgia) or in the drinking water. However, the analytical methods approved by EPA will detect and measure toxaphene, but not toxaphene degradation products. Therefore, EPA needs to use a different analytical method, such as gas chromatography with negative ion mass spectroscopy, to definitively determine if toxaphene degradation products are present in the environment and the food chain. Also, there are indications that some of the toxaphene degradation products may be at least as toxic as the original toxaphene. To assess the health risks these degradation products may pose to humans, research is needed on their carcinogenicity and embryotoxicity.

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 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 names, such as Hx-Sed, Hp-Sed, p26, or p50.

Technical Toxaphene Degrades in the Environment

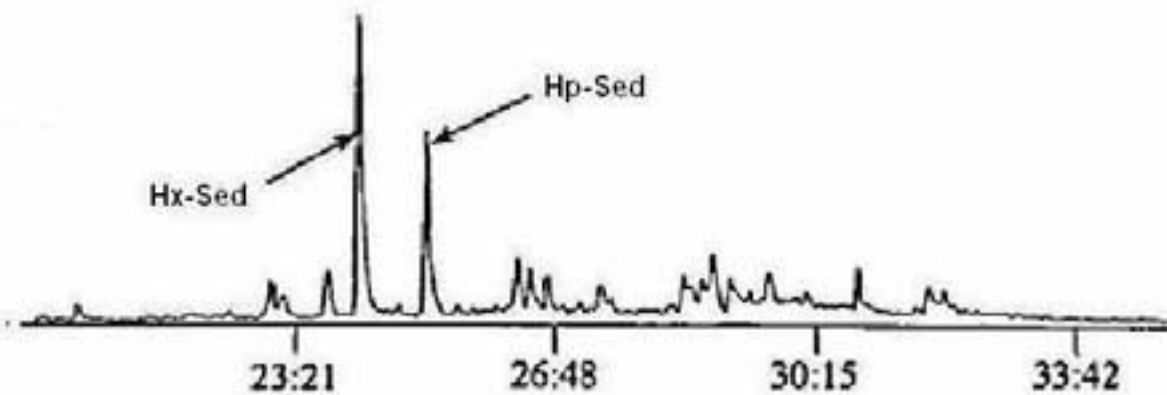
In the OIG’s review of the available scientific literature on the environmental degradation of technical toxaphene, we found numerous references to biotic and abiotic degradation, and to aerobic and anaerobic degradation. The aerobic degradation of technical toxaphene occurs at the slowest rate and has 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, 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 with electron capture detector (GC/ECD), the original technical mixture – 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.

(A) Toxaphene Degradation Products in Soil



(B) Technical Toxaphene

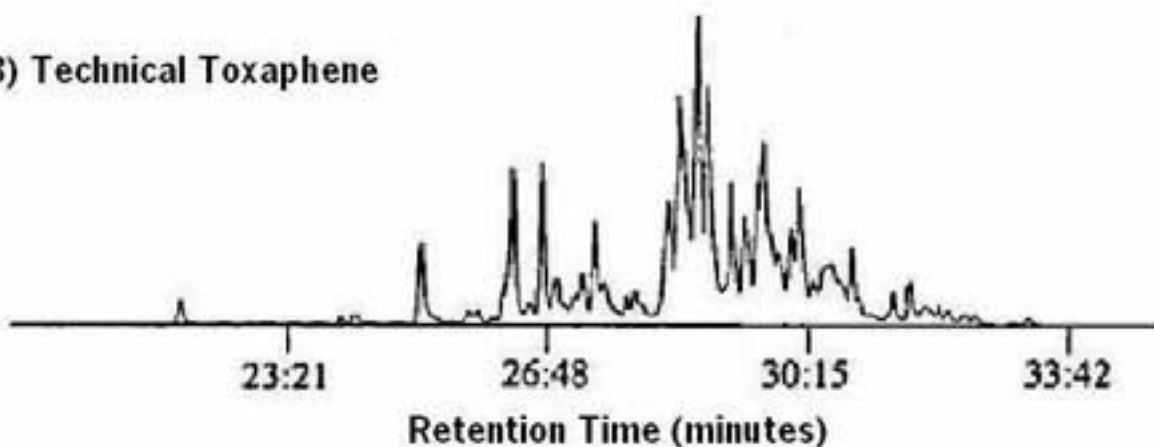


Figure 1: Chromatograms of Technical Toxaphene and Degraded Toxaphene are Completely Different

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 from 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 p26, p50, p40, p41, and p44 (Maruya,

2001a). 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. 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 GC/ECD 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.

Evaluating the Potential Risk to Humans from Toxaphene Exposure

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. Furthermore, 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 (sources) 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 a 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 Buranatrevadh, also concluded that the main route of exposure is about 93 percent from fish and about 7 percent from surface waters (Buranatrevadh, 2004). The remaining exposure routes (i.e., air and soil) are practically negligible. Based on these national toxaphene exposure studies, the main exposure risk to toxaphene is clearly from fish and from potential sources of drinking water. 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 principal exposure routes of concern to the surrounding community are the fish in the diet and the potential for contaminated drinking water.

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, 2001a).

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 Office of Water, 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 can not 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). However, five toxaphene congeners (i.e., p26, p50, p40, p41, and p44) are not readily metabolized and excreted and, thus, can accumulate in the human body.

In order 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 for humans, the toxicity of these five individual congeners, a mixture of these five congeners, or both, needs to be determined in more detail than is available in the scientific literature.

Human Exposure to 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 gas chromatography with 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 2-200 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, p41, and p44 congeners at a concentration of 3-30 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 category 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 than 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 polychlorinated biphenyl (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 (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, p50). The results reported 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, the MATT project's TDI estimate makes the toxaphene degradation products found in humans to be about twice as carcinogenic as the original technical toxaphene mixture. However, the report on the MATT project has not yet been peer reviewed.

An EPA Region 4 toxicologist believes that the conclusions reached in the MATT project may be incorrect and, in the response to the draft OIG report on the Hercules 009 Landfill, outlined why. Despite this, the MATT project is the sole toxicological study based on toxaphene degradation products and, thus, is chemically most relevant to human exposure. Region 4 may base its interim strategy for assessing the risk of toxaphene degradation products on the MATT laboratory study. The OIG believes more definitive toxicology studies are needed to verify the carcinogenicity of the individual p26 and p50 toxaphene congeners. Region 4 agreed that additional toxicity studies may be helpful and suggested additional research in the areas of in vitro testing of tumor promotion, whole animal developmental studies, and critical periods of exposure early or late in life.

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 on 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; 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 (referred to in the study as toxicant A), or p32 congener (referred to in the study as toxicant B) as measured by a swimming test and a 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., DDT/DDE, halogenated hydrocarbons (HCHs), and 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, 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. Jacobson's study linked organochlorine exposure during fetal development to impaired cognitive development (e.g., low IQ scores).

Monitoring Should Identify Toxic Degradation Products

Monitored natural attenuation (MNA) is part of the remedy at Hercules 009 Landfill site. Superfund's MNA guidance (OSWER Directive 9200.4-17P) states EPA should 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 expects 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, at Superfund sites suspected to contain toxaphene, EPA should evaluate the environmental samples 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 GC/ECD. When an environmental sample is tested by the GC/ECD, the instrument produces 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 environmental sample. EPA Method 8081 was designed and quite dependable for detecting the original technical toxaphene mixture in an environmental sample.

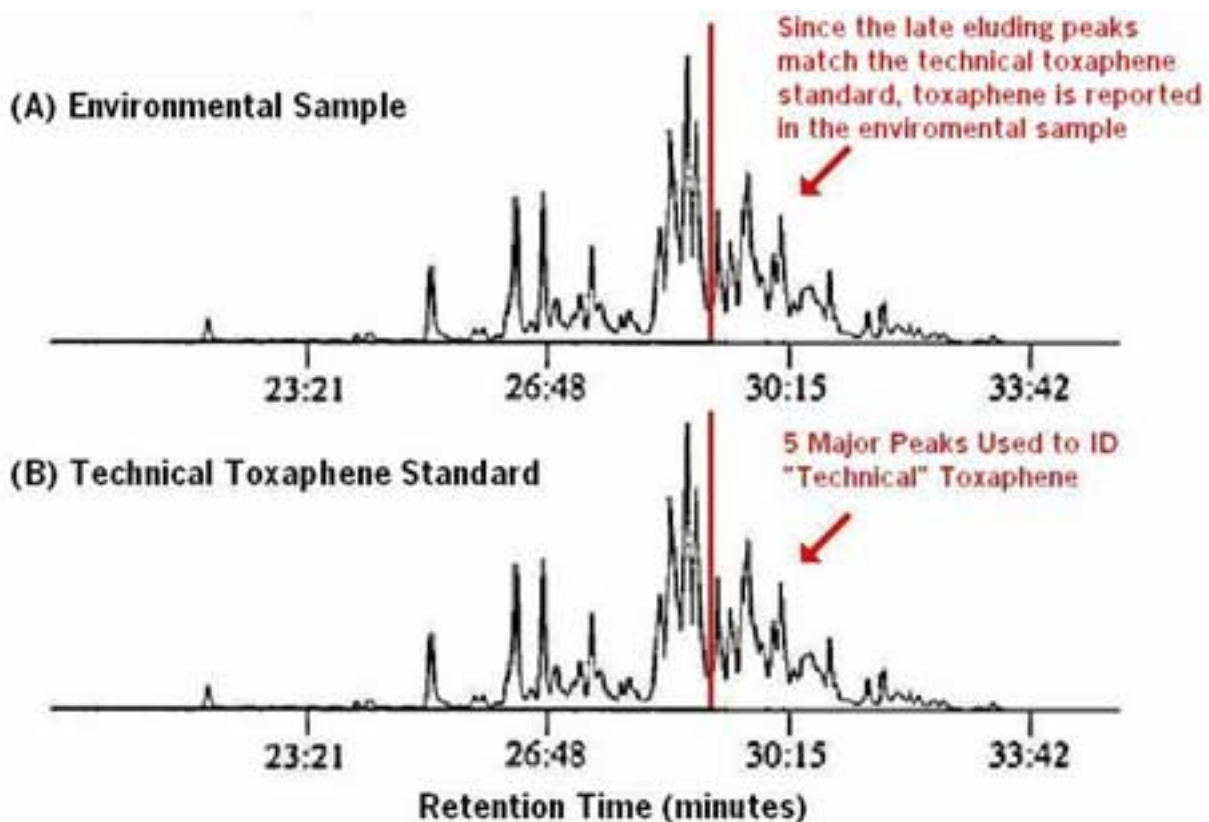


Figure 2: GC/ECD Chromatograms of Technical Toxaphene

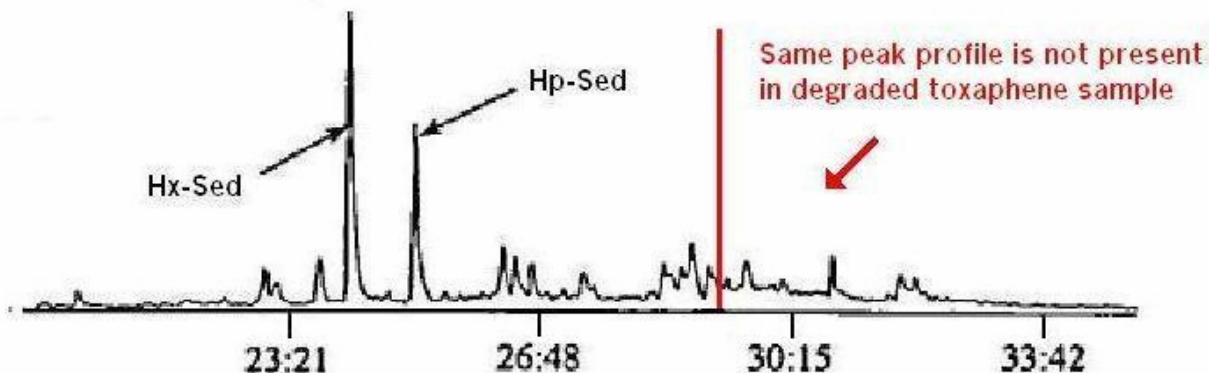
EPA Method 8081 Does Not Identify Toxaphene Degradation Products

EPA Method 8081, which is listed in EPA’s Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (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 (representing a compound) in the sample’s chromatogram is compared against the retention time of a known chemical standard. 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 (see the peaks after about 29 minutes in 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. While EPA Method 8081 is appropriate and highly accurate for detecting technical toxaphene, it 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 eluting 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, 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.

(A) Degraded Toxaphene in Soil



(B) Technical Toxaphene Standard

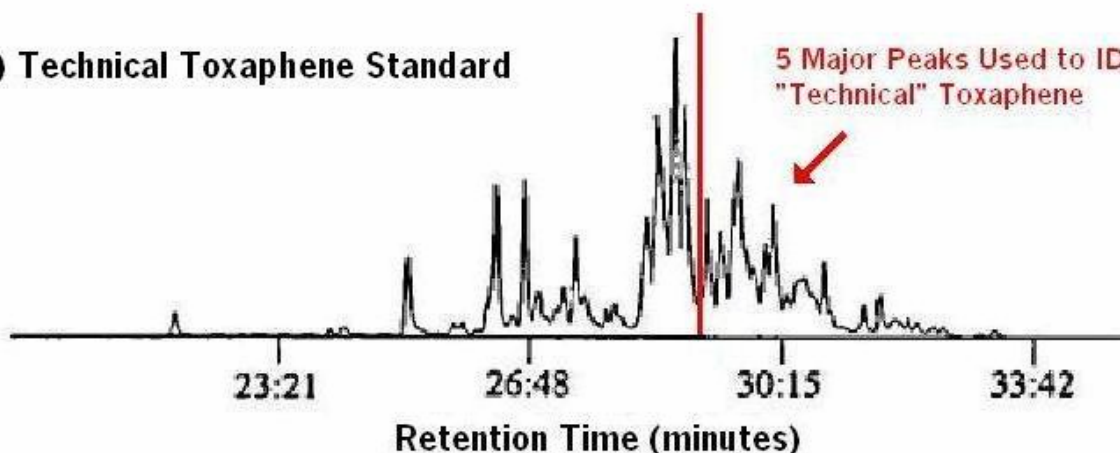


Figure 3: EPA Method 8081 Analyzes for Only Technical Toxaphene

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's) 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 of the Skidaway Institute of Oceanography re-analyzed the same fish and shellfish samples that were collected and analyzed by GA/DNR, but this time used both the GC/ECD technique and the NIMS congener-specific technique (Maruya, 2001b). The NIMS analytical technique was able to identify, while the GC/ECD technique was able to quantify, individual toxaphene congeners that were present in the fish samples at concentrations up to 1,420 parts per billion (ppb). The NIMS' identification of toxaphene contamination at Terry

Creek is in stark contrast to the results obtained by EPA Method 8081 alone that indicated no toxaphene contamination. Therefore, this example clearly shows that the analytical procedures specified in EPA Method 8081 do not identify degraded toxaphene in the environment.

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

Unlike the GC/ECD technique used in EPA Method 8081, NIMS can definitively and directly 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, the identity of the peak is still uncertain. By contrast, the 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 NIMS methodology has been routinely used in academia since about 1993. For the last 5 years, the European MATT project has been using the NIMS method to monitor and document the levels of toxaphene degradation products in fish from the North Atlantic. Since the NIMS method has been developed and successfully implemented by others, EPA’s formal validation and standardization of the NIMS method should not present any major technical difficulties. Also, including the NIMS method in SW-846 would significantly facilitate (1) the evaluation of toxaphene degradation products in the environment by the regulated community and (2) the gathering of congener-specific data needed for accurate risk assessments of exposure to toxaphene’s degradation products.

Estimated Retention Time of Toxaphene Degradation 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 do 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, which are 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.

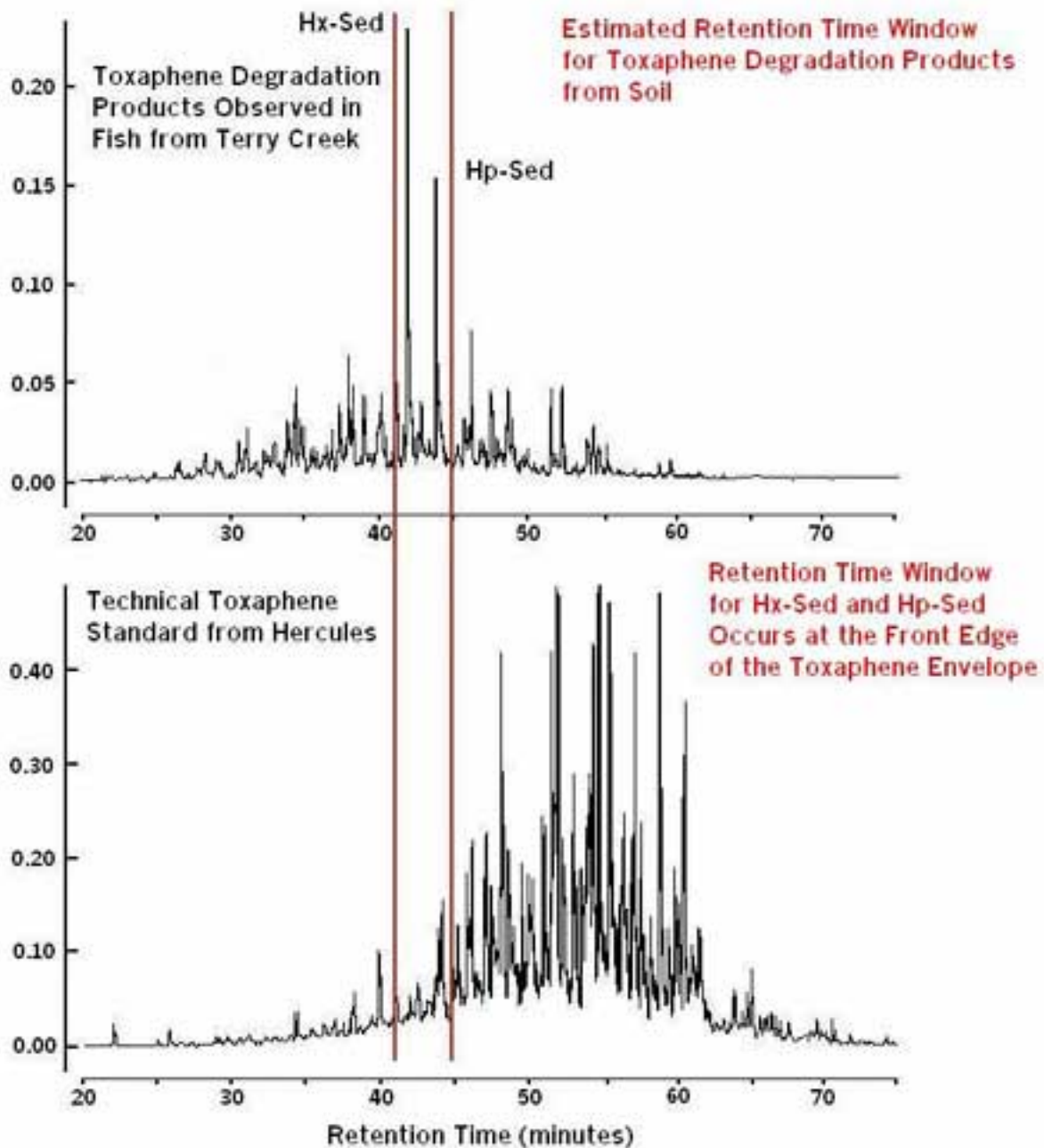


Figure 4: Estimated Retention Time Window for Hx-sed and Hp-sed

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 (EnChem, Inc.) used EPA Method 8081A to analyze the toxaphene groundwater samples and reported nondetect (i.e., <5.2 micrograms per

liter (ug/L)) for all toxaphene results. Fortunately, the sampling results included a chromatogram for each of the groundwater monitoring wells. This allowed for the comparison of the Hercules 009 Landfill groundwater samples against the Hercules technical toxaphene standard to check for the possibility of toxaphene degradation products (Figure 5 below).

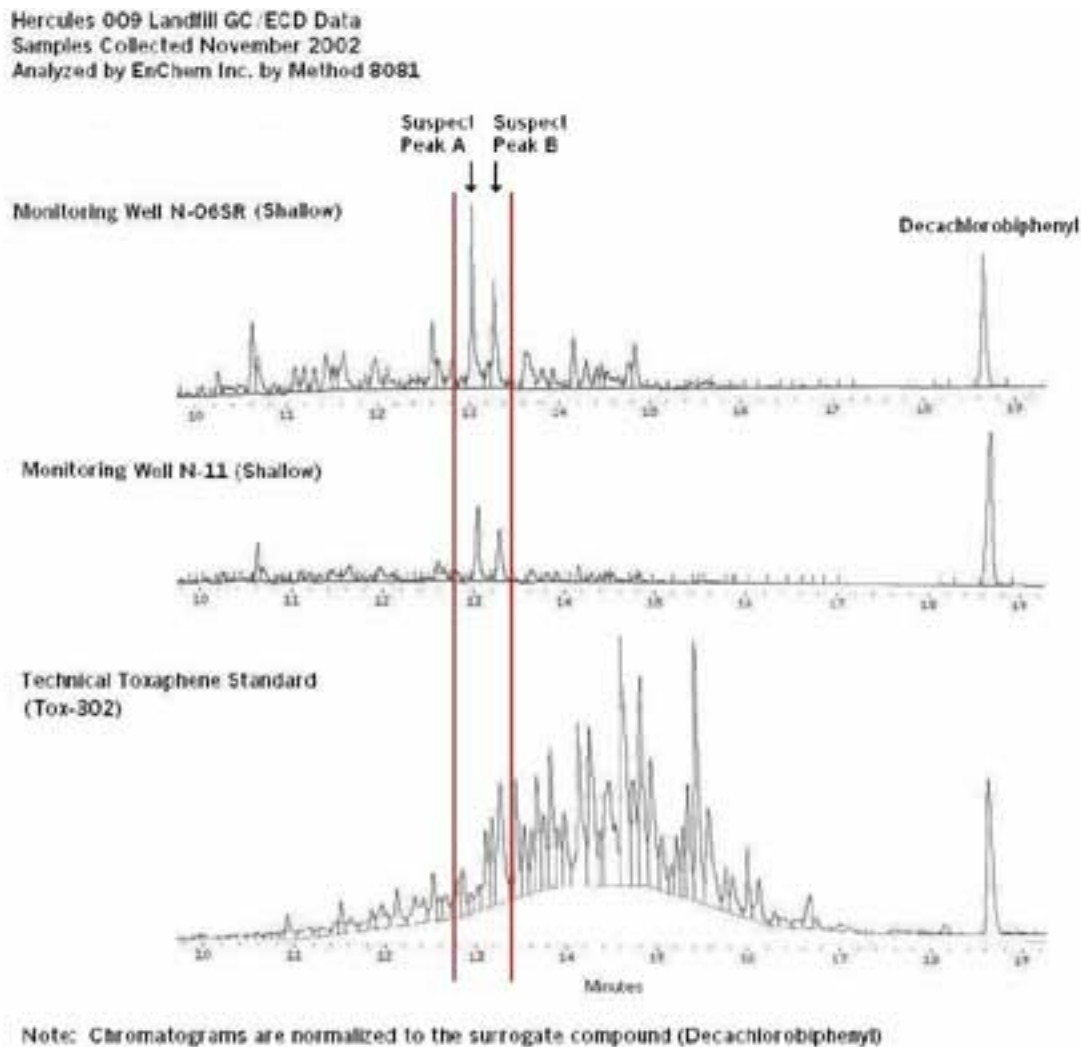


Figure 5: Potential Toxaphene Degradation Products in the Groundwater at Hercules 009 Landfill

As described 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 window for Hx-Sed and Hp-Sed is 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 NIMS analysis.

If the samples had been run by 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. For example, the negative ion mass spectrum for Suspect Peak A could be compared against the negative ion mass spectrum of hexachlorobornanes (Figure 6(a)). Likewise, the negative ion mass spectrum for Suspect Peak B could be compared against the negative ion mass spectrum of heptachlorobornanes (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.

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

NIMS could be used to definitively determine the identity of the Suspect A & 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 NIMS technique of comparing and matching a peak's mass spectrum allows for the definitive identification of the peaks.

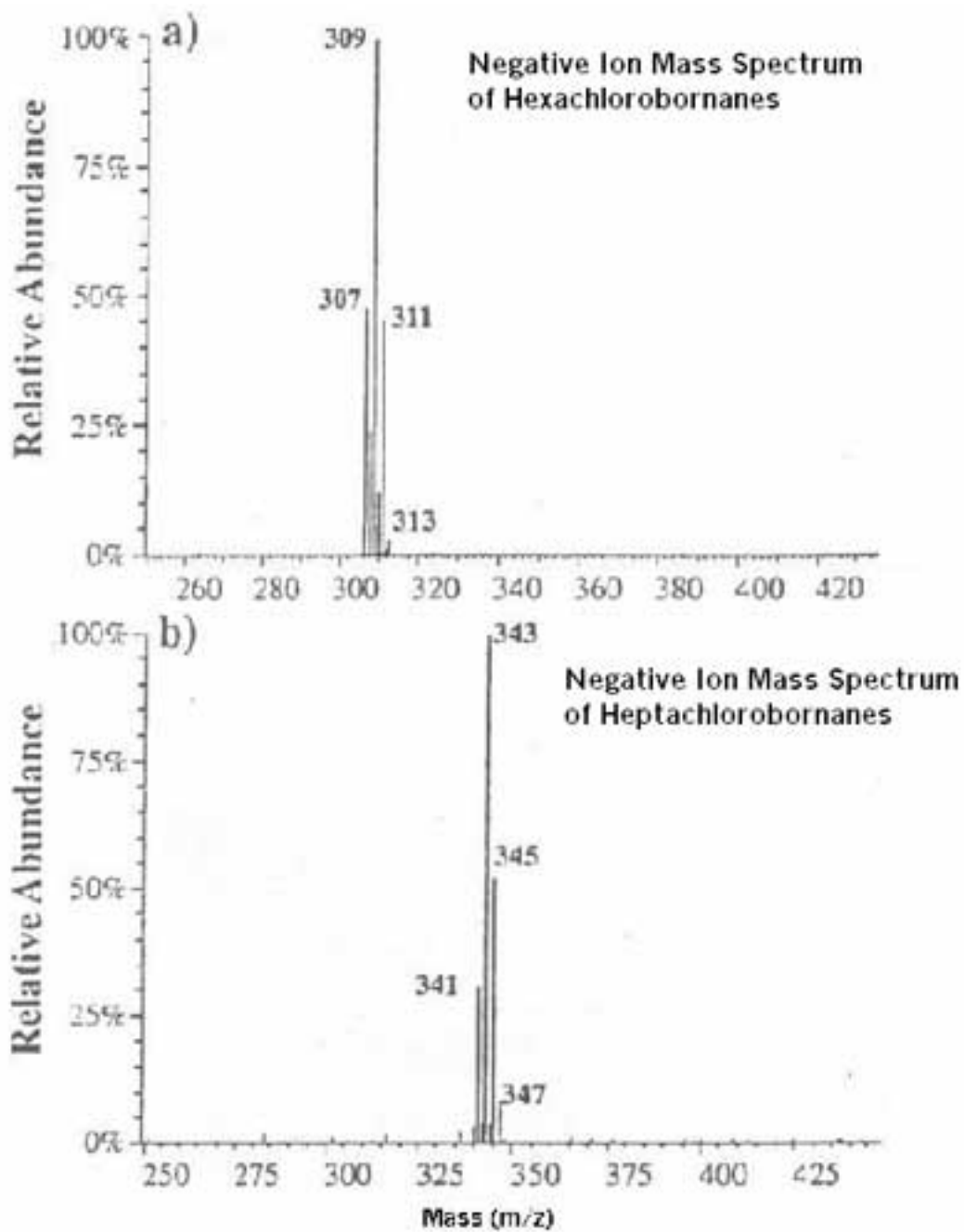


Figure 6: Negative Ion Mass Spectrums for Hexachlorobornane and Heptachlorobornane

Testing for Toxaphene Degradation Products in Our Nation's Drinking Water Supply

Since the 1991 promulgation of the National Primary Drinking Water Regulations (NPDWR) for the Phase II Synthetic Organic Compounds, EPA has required drinking water suppliers to test for toxaphene in the Nation's drinking water supply. The 1991 NPDWR for toxaphene approved the use of EPA Methods 505, 508, and 525.1. However, EPA's Performance Evaluation studies show laboratories most frequently use EPA Method 508 to determine toxaphene concentrations in drinking water (EPA, 2003a). As part of EPA's Six Year Review of NPDWR that was completed on July 18, 2003 (68 FR 42907), EPA collected occurrence data on toxaphene in the drinking water supplies from a representative cross-section of 16 States. These occurrence data represent over 52,000 analytical results, mostly from 1994 to 1997 for approximately 14,000 public water systems (PWSs) (EPA, 2002). EPA's analysis identified only 6 detections of toxaphene in 41,516 ground water samples and only 7 detections of toxaphene in 10,913 surface water samples (EPA, 2003b, Table B.53.b). EPA concluded that no PWSs are expected to exceed EPA's Maximum Contaminant Level (MCL) of 3 ug/L for toxaphene.

Unfortunately, EPA Method 508 shares the same problem described above for EPA Method 8081 used in EPA's hazardous waste program. EPA Method 508 uses the same GC/ECD analytical instrumentation and, likewise, only identifies technical toxaphene through pattern recognition against a technical grade toxaphene standard. EPA Method 508 does not detect or report the potential presence of toxaphene degradation products in the water sample. Therefore, EPA's toxaphene occurrence data from PWSs should only be interpreted to mean that no technical toxaphene is expected to be found exceeding EPA's MCL of 3.0 ug/L.

EPA's toxaphene occurrence data from PWSs do not address the possible contamination of the PWSs by toxaphene's degradation products. Volder and Li estimate at least 1.3 million tons of toxaphene were released into the total global environment from 1950 to 1993 (Volder, 1993). In the United States, toxaphene has been weathering from at least 1982 when most agricultural uses were stopped by the EPA. Decades of microbial degradation of this technical toxaphene should have converted the majority of the original technical toxaphene mixture into a mixture of its degradation products. Therefore, any current potential toxaphene contamination of the Nation's drinking water supplies is not from the original technical toxaphene mixture, but from toxaphene's degradation products. Since toxaphene degradation products have a lower level of chlorination than technical toxaphene, the degradation products should be more water soluble and, thus, potentially more mobile than the original technical toxaphene. Thus, EPA needs to definitively evaluate the possibility that the Nation's ground water and/or surface drinking water supplies could have become contaminated by toxaphene's degradation products. Such an evaluation would require testing at representative PWSs with an EPA-approved congener-specific NIMS method.

Need Congener-Specific Testing and Congener-Specific Health Risk Information to Implement Accurate Fish Advisories

As previously identified, the major route of human exposure to toxaphene degradation products is through consuming contaminated fish. Therefore, the need to issue accurate and timely fish advisories is critical to protecting human health.

EPA's fact sheet on toxaphene fish advisories (EPA, 1999) states that toxaphene analysis, similar to PCB analysis, can be conducted to identify the presence of individual or specific congeners. However, the fact sheet also states that there are no standardized congener-specific methods or EPA-approved congener-specific methods for toxaphene at this time. Therefore, EPA recommends the analysis of total toxaphene until further development of congener-specific analyses. However, the lesson learned from the 1997 GA/DNR study at Terry Creek was that total toxaphene analyses can completely fail to detect degraded toxaphene in fish. A subsequent congener-specific NIMS analytical technique performed by Skidaway Institute of Oceanography was able to definitively identify and quantify individual toxaphene congeners present in the same Terry Creek fish extracts at concentrations up to 1,420 ppb. This event clearly shows the need for implementing an EPA-approved congener-specific toxaphene analysis to identify toxaphene contamination and to support subsequent health risk decisions such as fish advisories.

EPA's fact sheet on toxaphene fish advisories (EPA, 1999) also recommends fish consumption limits based on EPA's default risk assessment parameters for technical toxaphene. The reference dose (RfD) for technical toxaphene is used to calculate the noncancer health endpoint, while the cancer slope factor for technical toxaphene is used to calculate the cancer health endpoint. Unfortunately, using the toxicity of technical toxaphene is not an appropriate basis for two reasons. First, humans are only exposed to a subset of toxaphene congeners (i.e., the degradation products found in fish which are dominated by p26 and p50) and not to the full distribution of toxaphene congeners found in technical toxaphene. Second, the toxicity of each individual toxaphene congener can be expected to vary significantly from the toxicity observed from the exposure to the original technical toxaphene mixture. Therefore, EPA's use of technical toxaphene's RfD and cancer slope factor to quantify the risk from toxaphene degradation products in fish should at best be considered only an estimation. Thus, EPA needs to determine the toxicity of the persistent toxaphene degradation products found in fish (e.g., p26, p50) in order to accurately determine the potential risk to human health.

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 Methods 8081 and 508 are inadequate to screen for toxaphene's degradation products. To address this problem, EPA should test toxaphene contamination using a congener-specific analytical method such as NIMS. EPA's validation and standardization of the NIMS method would facilitate evaluating toxaphene degradation products in the environment. 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. EPA needs additional studies on the carcinogenicity and embryotoxicity of these five persistent toxaphene congeners to accurately evaluate the risk they pose 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.

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, p44) and not the original technical toxaphene mixture.
- EPA needs to use a congener-specific analytical method to positively identify and quantify toxaphene degradation products in the environment. The OIG recommends standardizing and validating the NIMS method and inserting an approved EPA NIMS method into SW-846 and the water program’s testing methods.
- 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) in order to develop acceptable human exposure limits to the individual congeners and/or to the mixture of these five congeners.

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Superfund Sites Listing Toxaphene as a Contaminant of Concern

EPA Identifier	Site Name	City	State
ALD007454085	T.H. Agriculture & Nutrition Co. (Montgomery Plant)	Montgomery	AL
CA5570024575	Travis Air Force Base	Travis AFB	CA
COD980499248	Lowry Landfill	Aurora	CO
COD980717953	Sand Creek Industrial	Commerce City	CO
FLD004092532	Stauffer Chemical Co (Tampa)	Tampa	FL
FLD053502696	Helena Chemical Co. (Tampa Plant)	Tampa	FL
FLD981021470	Wingate Road Municipal Incinerator Dump	Fort Lauderdale	FL
GAD003269578	Woolfolk Chemical Works, Inc.	Fort Valley	GA
GAD042101261	T.H. Agriculture & Nutrition Co. (Albany Plant)	Albany	GA
GAD980556906	Hercules 009 Landfill	Brunswick	GA
GAD991275686	Marzone Inc./Chevron Chemical Co.	Tifton	GA
NCD980843346	Aberdeen Pesticide Dumps	Aberdeen	NC
NCD981475932	FCX, Inc. (Washington Plant)	Washington	NC
NCD981927502	Geigy Chemical Corp. (Aberdeen Plant)	Aberdeen	NC
NJD064263817	Syncon Resins	South Kearny	NJ
SCD058753971	Helena Chemical Co. Landfill	Fairfax	SC

Agency Response to the Draft Report



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY


WASHINGTON, D.C. 20460

SEP 26 2005

OFFICE OF THE
ADMINISTRATOR

MEMORANDUM

SUBJECT: EPA Response to OIG Draft Ombudsman Report, "More Information Is Needed On Toxaphene Degradation Products," Assignment 2004-1124

FROM: Marcus Peacock 
Deputy Administrator

TO: Nikki L. Tinsley
Inspector General

Purpose

The purpose of this memorandum is to provide EPA comments on the Office of Inspector General (OIG) Draft Ombudsman Report, "More Information Is Needed On Toxaphene Degradation Products," Assignment 2004-1124.

Background/Discussion

The OIG has requested several EPA offices (OW, OSWER, OPPTS and ORD) to review the draft report dated August 12, 2005 entitled, "More Information Is Needed On Toxaphene Degradation Products: (OIG Assignment 2004-1124). The report describes the limitations of some EPA analytical methods for determining the insecticide toxaphene, and the lack of information on potential adverse health effects of toxaphene. EPA is urged to develop more sensitive and selective methods, and conduct more studies on the health effects of certain toxaphene degradates.

The various EPA Offices appreciated the opportunity to respond to this draft report. In general, EPA concurs with the recommendations. Attached are detailed comments from OSWER, OW and ORD. OPPTS was consulted and did not submit any comments. If your staff has any additional questions, please have them contact the following Special Assistants in the Office of the Administrator, Doreen Vetter at 564-1509 or Sarita Hoyt at 564-1471.

Attachment

cc: William Farland
Tom Dunne
Ben Grumbles
Susan Hazen
Dianne Bazzle
Patrice Kortuem

**EPA Comments on OIG Draft Ombudsman Report
More Information Is Needed on Toxaphene Degradation Products
Assignment 2004-1124**

OFFICE OF RESEARCH AND DEVELOPMENT

1. On page 7, paragraph 3, the draft report states:

2. We recommend that the Administrator direct the Assistant Administrators for Research and Development, for Water, and for Solid Waste and Emergency Response to arrange for specific research into the dangers of tumors (i.e., cancer) and of harm to embryos posed principally by toxaphene degradation products p26, and p50, and perhaps by p40, p41, p44, and p62.

RESPONSE: We request the following change to this portion of the draft report:

2. We recommend that the Administrator direct the Assistant Administrators for Research and Development, for Water, and for Solid Waste and Emergency Response to arrange for specific research into the dangers of tumors (i.e., cancer) and of harm to embryos posed principally by a mixture of toxaphene congeners and metabolites found in fish.

Discussion: With respect to cancer and developmental effects, any future studies should focus on all congeners (Parlars 26, 40, 41, 44, 50, 62) and the two congeners (Hx-Sed and Hp-Sed) that are originally present in technical toxaphene and increase greatly as a result of reductive dechlorination. Hence, any chronic bioassays that are designed for both cancer and developmental studies should include a mixture of all congeners that are present in fish and not individual congeners since humans will be consuming fish and not individual congeners.

2. On pages A-18 and A-19, we noted several issues with reference citations:

AG

Most references include author initials but a few (e.g., Braekevelt and Calciu) list the author's first name.

References with multiple authors are cited in text as single authors (e.g., Maruya, 2001 or De Geus, 1999). They should be cited in text as "Maruya et al., 2001" or "De Geus et al., 1999."

There are two Maruya et al., 2001 references but they are not differentiated with "a" and "b". There is no way for the reader to tell which reference is being cited.

Fiolet and van Veen do not list any author initials at all. This reference is also misplaced alphabetically (should follow Fingerling et al.).

Some journal titles are abbreviated but others aren't. The Smalling et al. citation doesn't include the journal title at all. Some cite "Vol." or "vol." and some just have the volume number alone. Some have "#" in front of the issue, others cite the issue number inside parentheses.

Most references capitalize all major words in the title but a few of them don't. Sometimes the year is cited before the volume/page numbers and sometimes after. The FAIR CT PL.96.3131 reference doesn't cite any year at all.

3. Overview Comments

Background: We have been involved in analytical methodology for about 30 years including most forms of chromatography, mass spectrometry, sample handling, and cleanup techniques. Two papers were published (see below: Brumley et al, 1993 and 1998) on the application of electron capture negative ion mass spectrometry (ECNIMS) including the toxaphene application as well as the related chlordane application. The negative ion approach has been around over 30 years and we have been involved in it since its very early stages.

Comments: The draft report presents certain recommendations concerning the analytical methodology used to determine toxaphene in real samples and other recommendations concerning toxicology of toxaphene. Our comments are restricted to the analytical chemistry aspects.

The analytical chemistry recommendations concern issues of toxaphene degradation and perceived deficiencies in the analytical methodology and a recommendation to change to the ECNIMS methodology as is currently performed throughout many parts of the world. ECNIMS has been in existence for decades and ORD has supported its inclusion in the tool kit of EPA chemists by generating the publications cited above. However, we have no official methods that use chemical ionization mass spectrometry at all, positive or negative ion. We have no GC/GC/MS or GC/MS/MS methodologies in place. We have no LC/MS methodology in place that uses ESI. Rather we have a methodology that uses Thermospray Ionization, a technique that few if any laboratories still retain in their instruments.

In the particular case of the toxaphene issue here, we support the recommendation to pursue modern methods involving ECNIMS. The complementary and screening use of GC/ECD is highly recommended along with the inclusion of the degradation products in the methodology. Cases of positive samples or indeterminate samples can be submitted for GC/ECNIMS as needed to support the findings. The basic finding of the draft report is that the science as currently practiced in this analysis is inadequate to do the task that needs to be done. We concur in this conclusion.

One issue concerns the availability of instrumentation to carry out ECNIMS. This capability is included in many instruments along with EI (Agilent instruments, for example) if the option is selected. One difficulty is that an ion source changeover is often required which is a day of down time because of equilibration and gas purging. This may be reduced on recent instruments capable of a more rapid switchover. It does imply that production laboratories would probably keep a dedicated instrument for this technique, depending on sample load. The technique is reliable, reproducible, quantitative, and practical so that misinformation that has been circulated in the past about ECNIMS should be disregarded. It is obvious that laboratories in the U.S. and throughout the world are able to perform this technique without difficulty.

Citations:

W. C. Brumley, C. M. Brownrigg, and A. H. Grange, "Determination of Toxaphene in Soil by Electron Capture Negative Ion Mass Spectrometry After Fractionation by High Performance Gel Permeation Chromatography," J. Chromatogr., 633, 177-183 (1993).

W. C. Brumley, E. Latorre, V. Kelliher, A. Marcus, and D. Knowles, "Determination of Chlordane in Soil by LC/GC/ECD and GC/EC NIMS with Comparison of ASE, SFE, and Soxhlet Extraction," J. Liq. Chromatogr., 21, 1199-1216 (1998).

OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE

ASSESSMENT AND REMEDIATION DIVISION: OSRTI agrees with the conclusion that research is needed in reproductive, mutagenic, and carcinogenic toxicity of toxaphene degradation products. However, the decision to fund this specific research should be balanced against other research needs of the Superfund program.

OFFICE OF SUPERFUND REMEDIATION AND TECHNOLOGY INNOVATION

The IG report recommends that we validate and use a particular method for testing for toxaphene degradation products. It also recommends that EPA address risk assessment related issues.

Background: The Analytical Services Branch (ASB, within Superfund) typically does not consider the kinds of issues discussed in this report (science, policy and research questions that address risk and method validation). We generally do provide services to site managers that are well established and frequently requested. As a result, from an ASB perspective, these recommendations do not affect us directly. The current Contract Lab Program does not have the capability to run the recommended analyses, nor do our non-routine analytical services contracts. However, should site managers care to request these new analyses, we might assist in finding contract vehicles that could provide these services in a cost effective manner. At the current time, in order for Remedial Project Managers or On-Scene Coordinators to conduct these kinds of analyses (or other more innovative kinds of methods), they would need to establish task orders with labs using the RAC, START or other regional contract vehicles. As a result, ASB is neutral in our reaction to these recommendations.

Discussion: However, we do have the following additional thoughts (which are touched on in this report):

Before a site manager or OSC would order this kind of work, they would need confirmation that levels of these degradation products in the environment present health (or environmental) risks of concern to our Superfund communities. This would argue that the risk questions be addressed first. Addressing the risk (associated with levels in the environment) will in part then drive the requirements for the methods.

Secondly, while the proposed method may be a reasonable means to improve recognition of the specific degradation products, it is not clear from the report whether alternative approaches have also been evaluated. It may be more cost effective (for the cleanup industry, broadly speaking) for EPA to identify methods that can be run utilizing the kinds of equipment currently available at many commercial environmental labs.

OFFICE OF SOLID WASTE

General Comments:

- While OSW concurs with the OIG Ombudsman findings and recommendations, we have some issues and concerns regarding the presentation of technical discussions which result in some incorrect statements in the report, which we will clarify in the specific comments.
- Also there appear to be some technical contradictions in statements addressing the comparison of applicability between the GC/ECD methods and the NIMS method in the sections of Appendix A.
- With the promulgation of the Methods Innovation Rule on June 14, 2005 (70 FR 34537, June 14, 2005), OSW removed the final barriers to completely allowing the use of the performance-based measurement system (PBMS) for RCRA analyses. Under PBMS, any appropriate method may be used, whether it is published in SW-846 or is from an alternative source, provided that it can be demonstrated to generate data of known and appropriate quality that can be used for its intended application. Under the PBMS paradigm, a NIMS method that can be validated for a site-specific application may be used for analyzing toxaphene degradation products for RCRA applications.
- The problems encountered with the data generated from the GC/ECD methods, (e.g., Method 8081), are not because of the method's lack of capability, but of inappropriate application of the method in the project planning process. If toxaphene degradation products are not included or requested as target analytes in the planning documents, it does not matter whether you use GC/ECD or NIMS for the analysis. These analytes will not be reported in either case.
- An additional finding and recommendation should be that "Toxaphene degradation products should be included as target analytes for analyses at toxaphene-containing sites."
- OSW agrees that the NIMS methodology would make for easier definitive identification of toxaphene degradation products and any other organochlorine pesticides than would GC/ECD because of the enhanced analyte identification capabilities of the mass spectrometer.

Specific Comments:

- At a Glance, pg. 3 of 35: In the third sentence beginning with "The analytical methods...", "are not designed to identify" should be changed to "are not normally used to identify". If toxaphene degradation products were identified as target analytes and standards obtained for them during the project planning process, then the existing ECD methods could be used to identify these degradation products. However, the results will not be produced nor reported unless specific actions to include them in the analytical planning process are done.
- Section "A Different Analytical Method Is Needed...", pg. 5: In the first sentence, please change "...do not evaluate..." to "... are not normally used to evaluate..." Please add the following to the end of the second sentence: "...mixture, 'but have not been formally validated for toxaphene degradation products'".

- Please change the title of the Topic on pg. A-8 from “EPA Method 8081 Does Not Identify Toxaphene Degradation Products” to “EPA Method 8081 Is Not Normally Used to Identify Toxaphene Degradation Products”. Figure 3A is an excellent GC/ECD chromatogram which shows clearly identified peaks for the toxaphene degradation products, Hx-Sed and Hp-Sed. Use of an appropriate standards chromatogram for comparison would result in valid qualitative and quantitative identification of these compounds by GC/ECD, which directly contradicts the statements in this section to the contrary.
- The comparison discrepancies reported on pg. A-9 between the NIMS results and the Method 8081 results were not primarily due to differences in the analytical capabilities of the methods, but due to differences in reporting requirements with respect to which compounds were actually target analytes for the application of each method. The key advantage of the NIMS method over GC/ECD for single component or congener-specific analytes is the direct definitive identification that mass spectrometry provides. Use of a non-specific GC detector, such as ECD, requires an additional confirmation step to complete the compound identification.
- On pg. A-10, in the first sentence of the Section “Gas Chromatograph/Negative Ion Mass Spectrometry Can ...”, please add the following wording, “...NIMS can definitively ‘and directly’ identify and measure...”

OFFICE OF WATER

Background

The Office of the Inspector General (OIG) has asked several EPA offices to review a draft report dated August 12, 2005 and titled More Information Is Needed On Toxaphene Degradation Products (OIG Assignment 2004-1124). The authors of this draft report describe limitations of some EPA analytical methods for determination of the insecticide toxaphene, and the lack of information on potential adverse health effects of toxaphene. The authors urge EPA to develop more sensitive and selective methods, and conduct more studies on the health effects of certain toxaphene degradates. The Office of Water, which has the responsibility for monitoring pollutants in water, is responding to the recommendations for development of better methods for toxaphene. We have identified two EPA analytical methods that can measure toxaphene degradates in water.

Discussion

Toxaphene is a complex mixture of over 200 very similar chlorinated compounds known as toxaphene congeners. Congeners differ in the number and location of chlorine atoms. In a water or soil environment the relative proportions of the individual chlorinated congeners change (i.e. weathers or degrades) as the original mixture loses chlorine. The authors note that some EPA methods do not measure seven specific toxaphene congeners that have been identified at a Superfund site in Georgia. They refer to these congeners as "degradation products", and recommend that EPA approve a method that uses a negative ion mass spectrometry (NIMS) technology to determine these products. We have evaluated this technology, and agree that it could provide another sensitive method for determination of individual toxaphene congeners. However, in addition to approved non-mass spectrometry (MS) methods EPA 508 and 608 that only determine toxaphene as mixtures of congeners, MS methods (EPA 525.2 and 1625) are capable of determining low levels of specific congeners.

Prof. Ronald Hites of Indiana University developed a NIMS method (Anly. Chem. 59, 913-917; 1987) for ORD that later was used in Region 5 to measure toxaphene degradation products in Great Lakes' sediment (J. Great Lakes 25(2): 383-394; 1999). This is the method which the authors of the OIG report attribute to a European source. Although this NIMS method will not provide a major increase in selectivity relative to the EPA MS methods, it may provide better sensitivity in "dirty" samples because interferences often do not easily ionize in the negative ion mode. The NIMS method is available for use and has been used in the Great Lakes Program though it has not yet been fully validated by EPA or published in the Federal Register.

Toxaphene is of environmental interest, but the use and production of toxaphene has been banned since 1990. Our present chemical method development efforts are fully focused on developing robust methods for determinations of complex classes of pollutants that are used in increasing amounts, and transported into our waterways. These pollutants include personal care products, pharmaceuticals, currently registered pesticides (and degradates), and other emerging pollutants. Although validation of additional methods for toxaphene is not an Office of Water priority, we are available for questions about application of the NIMS method, or our EPA MS methods to measurements of toxaphene congeners in the environment.

OIG Technical Comments on the Agency Response

OIG Draft Recommendation 1:

We recommend that the Administrator direct the Assistant Administrators for Water and for Solid Waste and Emergency Response to:

- a. Develop, validate, and approve the gas chromatograph with negative ion mass spectroscopy method to analyze toxaphene degradation products, especially p26, p40, p41, p50, p62, Hx-Sed, and Hp-Sed, and
- b. Use the new method to analyze environmental samples in their programs.

OIG Technical Comments on EPA's Response:

We agree with the comments provided by EPA's Office of Research and Development (ORD) concerning using the gas chromatograph/negative ion mass spectrometry (NIMS) method for detecting and documenting environmental contamination by toxaphene degradation products. Specifically, we want to highlight and comment on the following points in ORD's response:

- ORD states that EPA has no official NIMS method and supports including the NIMS method into EPA's "tool kit." We agree with ORD that the NIMS needs to be approved as an EPA method so that the method is readily available to EPA staff and the regulated community to evaluate and test for degraded toxaphene in the environment.
- ORD states that "... the science as currently practiced in the analysis [of toxaphene] is inadequate to do the task that needs to be done." This is consistent with our position that technical toxaphene degrades in the environment and the current use of EPA's GC/ECD method does not adequately detect potential human exposure to toxaphene's degradation products left in the environment.
- ORD states that "The [NIMS] technique is reliable, reproducible, quantitative, and practical..." We also found this to be true about the NIMS technique; no technical or practical issues prevent EPA programs from using NIMS.

We have the following comments regarding the response from the Office of Solid Waste and Emergency Response (OSWER):

- The Analytical Services Branch (ASB) within the Superfund program indicates that ASB has a "neutral" opinion on the development, validation, and approval of a NIMS method. ASB indicates it is up to the Remedial Project Manager (RPM) and On-Scene Coordinators (OSC) to conduct these "...more innovative kinds of methods." In our opinion, it is impractical to expect RPMs and OSCs to have the necessary laboratory

skills, time, and resources to develop, validate, and implement the “innovative” NIMS on a site-specific basis. RPMs and OSCs will probably continue to choose an already approved EPA method (e.g., Method 8081) from EPA’s pre-existing “tool kit” of analytical methods (even though it is not exactly what is needed), rather than validate a new NIMS method themselves.

- ASB’s comments do not address the problem of evaluating for toxaphene degradation products at Superfund sites being addressed by potentially responsible parties (PRP), which are the majority of Superfund sites. PRPs are reluctant to use an unapproved EPA method, because EPA may not accept the validity of the data from the unapproved method. Analogous to RPMs and OSCs, PRPs would prefer to continue to choose an already approved EPA method (e.g., Method 8081) to evaluate for degraded toxaphene at a Superfund site rather than have to validate an unapproved NIMS method. Hence, we insist that EPA validate and approve the NIMS method to facilitate its use by RPMs, OSCs, and PRPs instead of each user having to separately validate the NIMS method each time it is used.
- ASB expresses concern that the analytical equipment at commercial analytical laboratories is not capable of running the NIMS method. To the contrary, we found that most commercially available gas chromatograph-mass spectrograph instruments (e.g., Agilent instruments – f.n.a. Hewlett-Packard) have the capability to run the NIMS method (i.e., a lab would need to purchase the chemical ionization option for the instrument). This equipment issue is directly addressed in ORD’s comments. Due to configuration issues with the hardware of a gas chromatograph-mass spectrograph, we agree with ORD’s opinion that a commercial laboratory would probably have to dedicate a single instrument for the NIMS analyses.
- The Office of Solid Waste (OSW) indicates that the analytical procedures specified in EPA Method 8081 were not designed or validated to analyze for toxaphene degradation products. However, OSW indicates that the GC/ECD analytical technique used in EPA Method 8081 could be developed to detect toxaphene degradation products (e.g., add individual toxaphene congeners as target compounds and use the appropriate toxaphene congeners as standards). We concur with OSW that EPA Method 8081 was never designed or validated to detect degraded toxaphene. Furthermore, we conceptually agree that the GC/ECD technique could be developed to detect toxaphene degradation products, but we do not advocate this course of action because the compound identification by the GC/ECD technique is inherently inferior to the compound identification by GC/NIMS due to the presence of a mass spectrum for identifying the peaks.
- OSW indicates the problems encountered with detecting toxaphene degradation products by EPA Method 8081 were due to inappropriately applying EPA Method 8081 during the project planning process. We agree that EPA Method 8081 should not be used to evaluate for degraded toxaphene products in the environment (i.e., EPA Method 8081 does not list individual toxaphene congeners as target compounds). However, we stress that EPA’s project planning process at Superfund sites needs to recognize that technical

toxaphene degrades in the environment and that NIMS is the best available method to detect and identify the extent of degraded toxaphene.

- OSW states that under the performance-based measurement system (PBMS) for RCRA analyses, any method (EPA approved or not) can be used "... provided that it can be demonstrated to generate data of known and appropriate quality ..." Therefore, OSW defers to the site managers to validate the method for each site-specific application. As with the Superfund program, in our opinion, the expectation that site managers have the necessary laboratory skills, time, and resources to develop, validate, and implement the "innovative" NIMS on a site-specific basis is impractical. As a result, site managers will probably continue to choose an already approved EPA method (e.g., Method 8081) from EPA's pre-existing "tool kit" of analytical methods (even though it is not exactly what is needed), rather than validate a new NIMS method themselves.
- OSW suggests the following additional recommendation: "Toxaphene degradation products be included as target analytes for analyses at toxaphene-containing sites." We agree with this suggestion and have incorporated similar language into recommendation 1b.
- OSW states that "... the NIMS would make for easier definitive identification of toxaphene degradation products and any other organochlorine pesticides than would GC/ECD because of the enhanced analyte identification capabilities of the mass spectrometer." We agree with OSW that NIMS' superior identification capabilities are needed to clearly identify individual congeners from such a complex mixture of congeners and other non-toxaphene peaks found in environmental samples.

We had the following comments regarding the response from the Office of Water (OW):

- OW's response indicates that the NIMS method only provides another sensitive method for the determination of individual toxaphene congeners. Specifically, OW states that "... MS [mass spectrometry] methods (EPA 525.2 and 1625) are capable of determining low levels of specific congeners." We disagree with OW's assessment of the value and utility of the existing methods. EPA Methods 525.2 and 1625 use electron ionization mass spectrometry that is inherently less sensitive than existing methods that use gas chromatography with electron capture detectors, i.e., EPA Methods 508 and 608. The NIMS method is the only practical mass spectrometry method that has the same sensitivity as the GC/ECD methods. EPA method 525.2 lists only toxaphene (a.k.a., technical toxaphene) as a target compound. Also, EPA method 525.2 does not identify individual toxaphene congeners. Furthermore, EPA method 1625 does not even list toxaphene as a target compound for the analysis.
- OW's response does not address the continued testing of drinking water for toxaphene at public water systems, which mostly use EPA's GC/ECD Method 508. These resulting data can only be interpreted to mean that no technical toxaphene is in our Nation's drinking water. Since toxaphene has been banned since 1990 and is known to degrade in the environment, one would not expect to find technical toxaphene in our Nation's

drinking water, but would expect to find environmentally degraded toxaphene in the water. Therefore, OW's 1991 National Primary Drinking Water Regulations requiring public water systems to continue testing for technical toxaphene wastes the time and resources of public water systems. OW needs to approve and use the NIMS method to evaluate our Nation's drinking water for possible contamination by degraded toxaphene.

In conclusion, after considering EPA's response, we are committed to having EPA approve and use the NIMS to evaluate for degraded toxaphene in the environment. Furthermore, based on EPA's response, we believe that recommendation 1b needs to be revised to require EPA to evaluate sites that are known to have contained technical toxaphene to be evaluated for the presence of toxaphene degradation products by the NIMS method.

OIG Draft Recommendation 2:

We recommend that the Administrator direct the Assistant Administrators for Research and Development, for Water, and for Solid Waste and Emergency Response to arrange for specific research into the dangers of tumors (i.e., cancer) and of harm to embryos posed principally by toxaphene degradation products p26, and p50, and perhaps by p40, p41, p44, and p62.

OIG Technical Comments on EPA's Response:

We agree with the comments provided by EPA's ORD concerning the research into the human toxicity of toxaphene degradation products. ORD requests revising the wording of the first recommendation from "...posed principally by toxaphene degradation products p26, and p50, and perhaps by p40, p41, p44, and p62" to "...posed by a mixture of toxaphene congeners and metabolites found in fish." We concur with this wording change. Since the vast majority of human exposure is through eating fish, the wording change allows ORD to assess the toxicity and characterize the risk from the degradation mixture to which humans are most exposed. Furthermore, the wording change still allows ORD to study the toxicity of the individual degradation congeners that are poorly metabolized and not readily excreted from the body (i.e., p26 and p50). In short, the wording change allows ORD more flexibility in studying the toxicity of toxaphene degradation products.

We disagree with the comments provided by OSWER's ASB that the health risks from toxaphene degradation products should be addressed before developing and implementing the NIMS method. Our opinion is that the NIMS methodology is already being successfully implemented by the European Union and would require only a minimum amount of effort and resources to be validated and approved by EPA. The immediate need for an EPA-approved NIMS method is clearly demonstrated by Skidaway Institute of Oceanography's successful use of the NIMS in 2001 to document high concentrations of toxaphene degradation congeners in fish near the Terry Creek Superfund site in Brunswick, GA. By contrast, the research needed to characterize the human health risks posed by toxaphene degradation products is anticipated to take about 6 years to complete.

EPA OW's response did not specifically address the need to research the human toxicity of toxaphene degradation products. OW's MCL for toxaphene in drinking water is 3.0 ug/L. This is the regulatory limit for the acceptable human exposure to technical toxaphene in drinking water. However, since toxaphene has been banned since 1990 and is known to degrade in the environment, human exposure in our Nation's drinking water would currently be to degraded toxaphene, and not to technical toxaphene. Therefore, in our opinion, due to the lack of potential exposure to technical toxaphene in our Nation's drinking water, the OW's MCL for technical toxaphene is outdated. However, since toxaphene was a heavily used pesticide in the United States, there is a potential human exposure to toxaphene degradation products in our Nation's drinking water. Therefore, OW should be interested in ORD's research into the toxicity of toxaphene degradation products because OW will need the research if it becomes necessary to establish a health effects limit for toxaphene degradation products in drinking water.

In conclusion, after considering EPA's response, we will incorporate ORD's revised wording into the second recommendation.

Distribution

Office of the Administrator
Assistant Administrator for Solid Waste and Emergency Response
Assistant Administrator for Water
Assistant Administrator for Research and Development
Regional Administrator, Region 4
Audit Coordinator, Office of the Administrator
Audit Coordinator, Office of Solid Waste and Emergency Response
Audit Coordinator, Office of Water
Audit Coordinator, Office of Research and Development
Audit Coordinator, Region 4
Director, Waste Management Division, Region 4
Director, National Center for Environmental Assessment, Cincinnati
RCRA National Organic Methods Program Coordinator
Director, Office of Superfund Remediation and Technology Innovation
Agency Followup Official (the CFO)
Deputy Chief Financial Officer
Agency Followup Coordinator
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
General Counsel
Inspector General