

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

July 31, 1984

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

Mr. Norman H. Nosenchuck, P.E.
Director, Division of Solid Waste
New York State Department of
Environmental Conservation
50 Wolf Road
Albany, New York 12233

Dear Mr. Nosenchuck:

Your letter of May 30, 1984, to John Moore provided detail on your plans to dispose of 425 55-gallon drums of waste contaminated with 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD). We understand your department would like to dispose of the drums by burying them inside the cap at the Love Canal site.

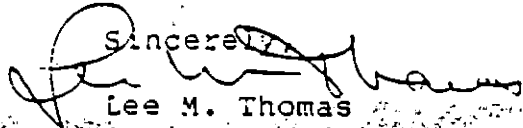
EPA's current policy is, in general, to follow technical standards promulgated under the Resource Conservation and Recovery Act (RCRA) when managing hazardous waste at a Superfund site. This policy means that those wastes generated on-site to be land disposed at Love Canal should, if possible, be managed in a unit designed, built and operated in accordance with the technical RCRA standards for a new land disposal facility. In addition, we recommend that the facility's design incorporate the considerations for special waste management plans discussed in EPA's proposed dioxin listing regulation.

You may wish to continue storage of the 2,3,7,8 TCDD contaminated wastes until a permanent method of treatment or disposal is available. The storage facility, in this case, should meet the technical RCRA requirements for a new storage facility. We recommend, in addition, that the storage facility provide secondary containment in case the drums spill or leak.

We have adopted this current policy since Don Clay's letter to you of June 14, 1983. His letter suggested that EPA would favorably consider a proposal to bury the drums in the cap if the State met several conditions. This approach will probably not be acceptable under our new policy.

Complying with our policy will likely increase the costs of waste management at Love Canal. EPA is prepared to consider a request for additional Superfund monies to cover these costs. A final decision on the specific requirements and funding must await a quick feasibility study under the auspices of our joint activities under CERCLA.

Sincerely,



Lee M. Thomas
Assistant Administrator



OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

MEMORANDUM

SUBJECT: Disposal of Wastes Containing TCDD at Region VI
Incineration Facilities

FROM: Lee M. Thomas, Assistant Administrator
Office of Solid Waste and Emergency Response

TO: Dick Whittington, P.E.
Regional Administrator (6A)

On June 14, 1984, you wrote John Moore concerning "Disposal of Wastes Containing TCDD at Region VI Incineration Facilities." This activity is regulated under the "Vertac Rule" issued under TSCA. I am responding because OSWER has assumed responsibility for the substantive review of the 60-day notifications required by TSCA's "Vertac Rule" before dioxin is removed for disposal.

In your memorandum, you state that EPA policy should require input from the involved Region before approval of Vertac notices. I agree. I have instructed my staff to ensure complete coordination with the Regions on Vertac Rule decisions. Our standard practice is to work with appropriate Regional RCRA or PCB officials. I understand that on previous occasions your staff has been consulted before notices were approved for incineration of 2,3,7,8-TCDD contaminated material at the Rollins, Deer Park facility. Consultation will now occur for each notice. If you would like to designate a specific contact for your Region, please do so. I also agree that consultation with states is desirable and I believe Headquarters should defer to Regions on how this may best be accomplished.

I share your view that dioxin contaminated waste should not go to incinerators with significant environmental problems. If, however, an incinerator has a violation of a RCRA requirement that is not serious enough to affect the Region's overall assessment of the facility's current environmental soundness and capabilities (i.e., does not effect the satisfactory operation of the facility), I believe we can approve the notice while the involved Region and State independently pursue RCRA violations. This approach would be consistent with my objectives in the evolving policy on disposal of Superfund wastes at RCRA land disposal facilities. It is also consistent with the Dioxin Disposal Advisory Group's (DDAG) approach in reviewing 60-day notifications; the DDAG review is only to ensure the technical and environmental soundness of the proposed disposal option.

The DDAG has recommended approval of the Dow Chemical (Freeport, Texas) notice, now in process, provided that the possible major RCRA environmental violations referred to in your memorandum do not affect the environmental soundness of the Rollins, Deer Park incinerator.

I understand that the possible violations related to financial requirements and are not such as to make your Region uncomfortable with the continued operation of the facility in a manner protective of the environment. Given this fact and my approach in these situations as outlined above, I understand that your Region's original concerns with Dow's proposal have been resolved.

Please advise me immediately if you have any remaining concerns with our approving Dow's notice.

Your memorandum also raised three other specific issues:

- The firm proposed to dispose of the waste need not have been notified -- The 60-day notice requirement applies to the individual wishing to dispose of the wastes. DDAG's review focusses on the technical/environmental acceptability of the planned disposal. Specific business arrangements between involved parties are not reviewed. Approval of a notice does not mean that a satisfactory business arrangement has been completed. However, should the approved disposal option not work out, EPA would have to be re-notified (the 60-day process) before another option could be implemented.
- Delegated States should be consulted -- I agree. Regional processes for consulting with States will have to be expeditious: EPA has only 60-days for its total review process. EPA's approval applies only to the Federal TSCA requirement, of course. All necessary State and local requirements also must be met. The notification rule is an interim emergency measure to give EPA time to prevent improper disposal.
- Dioxins should only be disposed of in RCRA permitted facilities that have been tested for dioxin disposal -- This issue is being addressed in the dioxin listing. Until it is effective, the 60-day notification requirement and its procedures apply. Where the DDAG has judged it prudent, EPA requests that some dioxin contaminated wastes not be incinerated until a demonstration burn is conducted. Appropriate risk analysis and public involvement may also be necessary.

Thank you for your interest in this issue. I look forward to your support as we proceed with the difficult task of resolving the dioxin problem.

METHODS FOR DECONTAMINATION, DETOXIFICATION OR
CONTAINMENT OF TOXIC WASTES/SOILS CONTAMINATED
BY PCBs, DIOXINS, AND FURANS

Paul E. des Rosiers*

ABSTRACT

The EPA Office of Research and Development currently has budgeted approximately \$1 million in 1984 for engineering investigations to support a national dioxin strategy. This paper covers projects that are either on-going or in the final planning stages, together with a review of private sector developed technologies that show merit. The EPA projects include: (a) a classical study on the sorption/desorption of 2,3,7,8-TCDD on/from contaminated soils using a variety of solvent systems historically associated with 2,4,5-trichlorophenol distillation "bottoms", namely, water, methanol, ethylene glycol, toluene, and certain surfactants; (b) an assessment of PCB transformer fires to include a characterization of soot produced, safety protocols for firemen (and protective clothing), and practical remedial methods; (c) an evaluation of a mobile incinerator; (d) an evaluation of the feasibility of UV photolysis, singly and in conjunction with chemical detoxification methods such as alkali polyethylene glycolates (APEG) for dioxin-contaminated soils; and (e) an evaluation of in-situ stabilization/fixation techniques, which will include asphaltic materials and portland cement, among others.

INTRODUCTION

On January 10, 1979, a railroad tank car carrying 75,000 liters of crude o-chlorophenol ruptured near Sturgeon, Missouri. Forty-seven workers from the Norfolk & Western Railway Company were employed to clean up the spill and in the process were exposed to a variety of toxic chemicals, including chlorinated phenols, phenol, and the toxic artifact, 2,3,7,8-TCDD. In fact, the concentration of this dioxin isomer amounted to only 22 ug/kg (ppb). As a result of alleged exposure and the manifestation of certain perceived health effects and physiological symptoms, e.g., rashes, dizziness, loss of memory, extreme fatigue, impotence, upper respiratory difficulties, and in one case, cancer of the testicles and the skin, the workers brought suit in an Illinois court against the railroad company and the manufacturers of the tank car and the faulty coupling, including Monsanto, the manufacturer of the o-chlorophenol. On August 26, 1982, the Edwardsville, Illinois jury awarded the highest monetary judgments ever made in the U.S. as a result of a single tankcar spill -- \$57.95 million. Prior to the commencement of the April 5 trial, Monsanto, General American Transportation, and Dresser Industries settled out-of-court for an estimated \$8 million. This court decision represents the first time a U.S. jury has concluded that dioxin caused permanent harm to humans and thus has highlighted

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the more than 35 waste disposal sites within the State of Missouri that contain polychlorinated dibenzo-p-dioxins (PCDDs).

Recently, in November and December of 1983, three separate suits were filed in St. Louis Circuit Court: in one case, by 57 persons who contend they suffered general systemic effects from dioxin-tainted soils at six sites in eastern and central Missouri -- for \$684 million; in a second case, by 25 dockworkers and a widow of a former dockworker of a trucking firm in St. Louis -- for \$620 million; and finally, by 183 people at Times Beach and Castlewood who assert that they suffered serious health deficiencies as a result of dioxin exposure -- for \$1.8 billion. Therefore, this situation has catalyzed an acute public and governmental awareness of the potential severity and explosiveness of the PCDD problem. PCB transformer fires, accidental spills, and inappropriate disposal have compounded the problem particularly in regards to PCDFs (furans).

On December 15, 1983, the U.S. Environmental Protection Agency (EPA) issued a national dioxin strategy for investigating, identifying and cleaning up sites contaminated by dioxin (2,3,7,8-TCDD)(ref 1). Within the framework of this strategy is a plan that calls for research to be conducted on the technical feasibility and economics of alternative methods for disposal and destruction of wastes and soils contaminated by dioxin.

To implement this strategy, EPA has established seven categories (tiers) of investigation and study ranging from the most probable contamination to the least. These are:

1. 2,4,5-Trichlorophenol (TCP) production sites and waste disposal sites.
2. Sites and associated waste disposal sites where 2,4,5-TCP was used as feedstock for pesticide products.
3. Sites and associated waste disposal sites where 2,4,5-TCP and its derivatives were formulated into herbicidal products.
4. Combustion sources such as municipal and hazardous waste incinerators, PCB transformer/capacitor fires, reactivation furnaces for spent granular activated carbon, boilers burning PCBs and pentachlorophenol (PCP)-treated wood, etc.
5. Sites where herbicides derived from 2,4,5-TCP have been and are being used on a commercial basis such as rights-of-way, rice fields, forests, certain aquatic areas, and pastureland.
6. Certain organic chemical and pesticide manufacturing facilities where improper quality control on certain production processes would have resulted in the formation of 2,3,7,8-TCDD.
7. Control sites where contamination of 2,3,7,8-TCDD is not

suspected. These will be compared with known contaminated sites to form a background level for the strategy studies.

It is expected that 80-90 percent of the 2,3,7,8-TCDD contamination will be found in the first two categories. Cleanup activities in these areas will be managed by the Agency's hazardous waste Superfund program.

Funding for efforts in the remaining categories will be undertaken from separate \$4 million appropriations for each of the 1984 and 1985 fiscal years earmarked for the National Dioxin Study. The timeframe anticipated for taking samples and conducting investigations in Tiers 3 through 7 is two years.

EPA RESEARCH AND DEVELOPMENT DIOXIN--ENGINEERING PROGRAM

Funding in the near term for the EPA ORD Dioxin--Engineering program is delineated as follows:

	<u>FY 1984, \$K</u>	<u>FY 1985, \$K</u>
Base	1145	1041
Accelerated	2400	1950
Total	3545	2991

Additionally, approximately \$1.3 million for each year is being used for health, fate and transport, and analytical quality control/quality assurance investigations. The following projects have recently been initiated and are herewith summarized:

o Sorption/desorption of 2,3,7,8-TCDD from contaminated soils. There are many inferences in the scientific literature that "...it has been demonstrated and reported ...that TCDD is tenaciously bound to soil particles and will not leach off with water ..." (ref 2), yet such a hypothesis remains to be proven by employing properly and statistically designed experiments. Data gathered in an impressive study, conducted at the Universite Catholique de Louvain in Belgium (ref 3) indicated that up to 95 percent of the lindane applied (0.1 - 6 ppm) was adsorbed by soil colloids in 42 soil samples (top and subsoil horizons). Furthermore, leaching experiments showed a low adsorption capacity, almost immediate retention, and almost complete irreversibility. Thus, migration of lindane in the soil profile appeared to be an extremely slow phenomenon and would be practically limited to the superficial layer.

Recent data from soil borings at Times Beach, Missouri (ref 4) demonstrate almost complete adsorption of 2,3,7,8-TCDD within the upper 23 cm soil thickness and an interesting chromatographic effect when concentration of 2,3,7,8-TCDD (143 - 2 ppb range) is plotted against soil depth. Total organic carbon (TOC) (117 - 6 ppm range) adsorption paralleled that of TCDD except that removal occurred in the upper 5 cm.

Because TCDD can be bound to soil colloids by any or all of the following mechanisms, namely, adsorption, absorption, chemisorption, and occlusion, it was necessary to conduct classical

scientific experiments dealing firsthand with TCDD's apparent peculiar behavior in soil. Hence, a decision was made to obtain paired samples from nine sites known historically to be contaminated by 2,3,7,8-TCDD -- six from designated sites in Missouri, one from Jacksonville, Arkansas, one from Newark, New Jersey, and finally, one from Niagara Falls, New York. Each pair would represent roughly a core of one meter depth in a known contaminated area, the other sample would comprise a clean or uncontaminated soil profile some distance away. The clean soil samples would be characterized as to pertinent parameters such as pH, percent sand, silt, and clay, organic content, moisture content, specific ion exchange capacity, etc. These samples would also be contaminated with radiolabeled 2,3,7,8-TCDD and the horizontal and vertical migration of the TCDD would be determined with time at a specified temperature. The mobility of TCDD in the nine clean soils will be measured with the aid of scintillation counters. The TCDD-contaminated soils, meanwhile, will be used in experiments designed to promote desorption. Therefore, a variety of solvents common to the production of 2,4,5-TCP will be employed, namely, ethylene glycol, methanol, water, toluene, and certain surfactants, at ambient laboratory temperature (18-20°C) and at the maximum temperature likely to be observed in the field, that is, about 40°C. The results of each study will be both internally and externally peer reviewed prior to publication in an appropriate journal.

o In-situ stabilization. The history of TCDD-contamination within the State of Missouri can be traced to 1971 when Russell Bliss, a waste oil hauler and disposer, collected 2,4,5-TCP still bottoms, mixed the latter with other waste oils such as spent automotive crankcase oils and PCBs, and applied these mixtures as dust preventatives to several unpaved roads. As a result, to date more than 35 sites within the state have been designated as highly hazardous to human health by the EPA Office of Solid Waste and Emergency Response (OWSER), in cooperation with the Centers for Disease Control (CDC) in Atlanta, Georgia, and have thus been placed on the Agency's Superfund list for remedial action. Several of these sites are located near residential communities and require temporary, if not immediate, remedial action to prevent dust emanation and soil transport due to rainfall. However, the utility of asphalt and cement for this application is unknown and has yet to be studied properly. Moreover, some members of the scientific community have raised questions as to the potential for hot asphalt to release TCDD from the soil matrix. ORD has therefore initiated a series of experiments whose purpose will be to evaluate a variety of methods for dust and erosion control. These include asphalt, portland cement, two types of geotextiles (one porous to enhance vegetative growth, one non-porous to minimize vegetative growth), and a newly developed encapsulant that may be best characterized as a sulfur-enhanced asphaltic material. These encapsulants can be employed as paving mixtures or as fixative agents, where applicable.

Since the volume of TCDD-contaminated soil within the State of Missouri is estimated at 500,000 m³, one alternative disposal method has been proposed -- that of controlled removal, transport, encapsulation with a properly designed fixating agent, and deposi-

tion of the slurry or "fixed" soil within an abandoned mine. A feasibility study is currently underway that will address the size/volume/capacity of selected mines and the geological and hydrogeological conditions with special emphasis placed on wet-dry conditions and proximity to groundwater. The study will further identify front-end preparations and failsafe backup systems necessary for fullscale implementation to include various transport options and the potential impact upon sensitive areas such as schools or hospitals. Finally, the advantages and disadvantages of the concept will be documented regarding the compatibility of the stabilized materials within the mine environment and optimization of the placement schemes.

o UV photolysis/APEG chemical detoxification. Currently, ORD is investigating the use of alkali polyethylene glycolate (APEG) reagents to treat soils contaminated by halogenated hydrocarbon wastes, including PCBs, ethylene dibromide (EDB), and 2,3,7,8-TCDD (ref 5).

Certain contaminated soils in dumpsites and horse arenas in Missouri, Arkansas, New Jersey, and New York are areas of immediate concern, however. The principal objective of this research was to evaluate initially, at the proof-of-principle level, selected APEG reagents at ambient temperatures for the destruction of TCDD and other hazardous substances in soils from two contaminated Missouri sites: Denney Farm and Timberline Arena. The total organic chlorine contents of these two soils are, respectively, 1380 and 15.3 ppm; their TCDD contents are, respectively, 330 and 277 ppb.

The experiments basically involved: (a) the preparation of soil samples and solutions; (b) the treatment of samples with APEG reagents; (c) the "quenching" of treated samples at predetermined time intervals of 7, 14, 21, and 28 days to destroy or inactivate the reagent; and (d) the analysis of samples removed for 2,3,7,8-TCDD content. In addition to the treated samples, untreated control samples were also analyzed.

The technique will be applied to small field plots (1 m x 1 m) at a designated site in Missouri this summer. Control plots will be treated with polyethylene glycol (a proton donor), using agricultural equipment for both injection and rototilling purposes, in order to discern any measurable TCDD destructive enhancement due to ultraviolet photolysis. Similar plots will be treated in a like manner with APEG reagents. Should the field trials prove successful, full field validation tests will be performed the following summer with the intent of cleaning up an entire horse arena during the evaluation.

o PCB transformer/capacitor fires. Presently, ORD is conducting research on PCB fires, which covers three areas: (a) the chemistry of PCB fires to include theoretical products of thermal stress based on composition of askarel used; (b) emergency response protocols for firemen, including protective clothing required; and (c) practical remedial measures for building cleanup (ref 6). Certain facts have become apparent as a result of ORD's investigative efforts: Given that chemical production in the U.S. no

longer includes 2,4,5-TCP manufacture (the most significant historical source of 2,3,7,8-TCDD), the soot produced as a result of PCB transformer/capacitor fires contains the highest concentrations of PCDFs and PCDDs (the latter only if chlorobenzene diluents are present in the askarel mixtures) found in the U.S. today; on a weight basis, however, municipal combustion devices account for the largest quantity of PCDFs and PCDDs produced currently. As a result, ORD is in the process of securing PCB samples from: Binghamton, New York; Chicago, Illinois; and San Francisco, California, sites of significant PCB transformer fires. The EPA analytical laboratory in Cincinnati, Ohio will conduct a chlorobenzene isomer screen on the samples together with homologue analyses for PCBs, the purpose being an attempt to correlate PCDDs and PCDFs content of soot and wipe samples (within the transformer vaults) with chlorobenzene and PCB content in the transformer fluid. The information thus gathered will be shared among the electric utilities, insurers, firemen associations, the Electric Power Research Institute (EPRI), and the National Institutes of Occupational Safety and Health (NIOSH).

o Mobile incinerator. The EPA mobile incineration system (Fig 1) is designed and constructed to provide a mobile facility for onsite thermal destruction/detoxification of hazardous and toxic organic substances. The total system consists of: (a) major incineration and air pollution control equipment mounted on three heavy-duty semi-trailers; (b) combustion and stack gas monitoring equipment housed within a fourth trailer; (c) ancillary support equipment. The mobile incineration system comprises principally: (a) a rotary kiln, with a 15 cm thick refractory-lined, direct fired, cocurrent flow unit designed to operate up to 1000°C with a nominal solids retention time of 1 hr; (b) a secondary combustion chamber, lined with 15 cm of castable refractory, designed to provide 2.2 sec of retention time and up to 1200°C; (c) a wetted-throat venturi quench elbow located on the exit that cools flue gases to about 88°C; (d) a cleanable, high efficiency air filter; and (e) a mass transfer scrubber comprising a horizontal, cross-flow irrigated, packed bed absorber tower and induced-draft fan driven by a 155 hp diesel engine. Auxiliary equipment consists of bulk fuel storage, waste blending and feed equipment, scrubber solution feed units, ash receiving drums, and an auxiliary diesel powered generator.

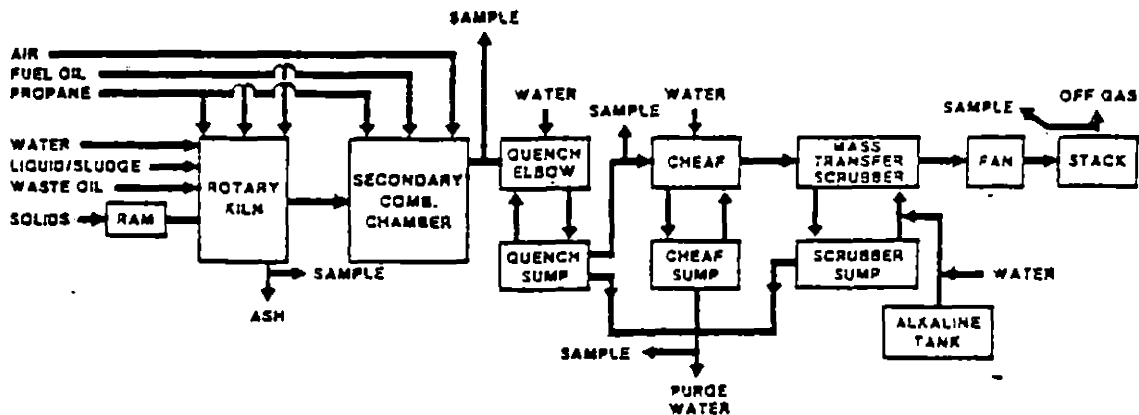


Figure 1. Block flow diagram of mobile incineration system.

The total system is controlled and monitored via electrical relay logic and conventional industrial process instrumentation and hardware. Safety interlocks and shutdown features comprise a major portion of the control system. Fuel, waste and combustion air feedrates, combustion temperatures, and stack gas concentration of CO, CO₂, and O₂ are continuously monitored, thus assuring compliance with regulatory requirements.

Several trial burns have been conducted designed to meet requirements specified by the Resource Conservation Recovery Act (RCRA), namely: (a) maximum allowable particulate matter emission rate of <180 mg/m³ corrected to 7% O₂ in the stack gas; (b) HCl removal efficiency >99% or a release rate of <1.8 kg/hr for the stack emission, whichever is greater; and (c) minimum organic destruction and removal efficiency (DRE) of 99.99%. Table 1 contains recent data obtained from test burns conducted pursuant to requirements in RCRA (ref 7).

Table 1. Operational data required for permit applications.

	Test 3	Test 4	Test 5
<u>Waste Feed, kg/hr</u>			
T ₄ CM	31.8	Trichlorobenzene: 3.8	15.1
Dichloro- benzene	43.1	Tetrachlorobenzene: 0.6	2.9
		Aroclor 1260: 6.6	22.7
<u>Stack Emissions</u>			
Flowrate, m ³ /min @STP	112	86.2	90.5
Particulates, mg/m ³ *	64.9	35.2	42.7
HCl, g/hr	18.3	1.12	1.50
HCl, RE %	99.95	99.98	99.99
T ₄ CM, DRE %	>99.99996	-	-
Dichlorobenzene, DRE	>99.99998	-	-
Trichlorobenzene, DRE	-	>99.9998	>99.99993
Tetrachlorobenzene, DRE	-	>99.994	>99.99985
Aroclor 1260, DRE	-	>99.9998	>99.99991
Total R-Cl, g/hr	<0.48	<0.39	<0.41

* Corrected to 7% O₂; T₄CM = Tetrachloromethane

Currently, a solids feed system is being installed. This will allow more flexibility within the mobile incineration system so that contaminated soils can be processed. "Cold" and "hot" tests are to be conducted using clean sand and sand contaminated with similar surrogates as employed in the liquid waste tests. It is anticipated that the mobile incinerator will be transported this autumn to the Verona, Missouri area, where trial burns will be performed on 2,4,5-TCP/hexachlorophene still bottoms and UV photolysis destruction process effluent wastes (ref 5), currently stored at the Syntex Agribusiness facility. Following these trials, TCDD-contaminated soils from the Denney Farm site will be processed. Trial data will be evaluated and, if acceptable, field tests will be conducted on the remaining liquid wastes and the

TCDD-contaminated soils and sludges. These tests will represent the first approved land-based incineration of 2,3,7,8-TCDD-contaminated liquids and soils in the U.S.

PRIVATE SECTOR DEVELOPED TECHNOLOGIES

Certain private sector developed technologies that are either under active development or show promise include:

o High temperature, fluid-wall reactor. The J.M. Huber Corporation of Borger, Texas has developed and constructed a high temperature, fluid-wall thermal process that operates in the range of 2200°C using intense thermal radiation in the near infrared (ref 8). The hazardous waste reactants, that is, the halogenated organic liquid wastes and contaminated soils, are isolated from the porous graphite reactor core walls by means of a gaseous blanket formed by flowing nitrogen gas radially inward through the porous core walls. Destruction is accomplished by pyrolysis rather than oxidation. Reactor exhaust gases are cooled and pass through a cyclone and baghouse for particulate removal. Chlorine removal and further cooling are accomplished in an aqueous caustic scrubber. The cool, particulate-free gas then passes through an activated carbon charcoal bed prior to entering the stack.

This represents the first destruction process tested using contaminated soils. Aroclor 1260 was mixed with sand to form a solid waste feed containing approximately 3000 ppm PCBs. Carbon black was also mixed with the feed at a 6.25:1 ratio to PCB oil. This was equivalent to about 2.5 percent of the total feed mass. (Carbon black is used to enhance radiant energy transfer to the feed and to reduce coagulation of the sand particles.)

A statistical analysis of the destruction efficiency data employing a Monte Carlo simulation indicates that the range of DEs for the reactor, at 95% confidence limits, is 99.9995 - 99.99995 percent. In all cases, the DREs exceeded the 99.9999 percent criterion as set forth by the Toxic Substances Control Act (TSCA) for PCB incineration. PCDDs and PCDFs were analyzed in the cyclone outlet samples by selected ion monitoring GC-MS. The results of these analyses showed that both were below detection limits of 0.03 - 0.06 ug/SCM. Current plans call for a test burn on TCDD-contaminated liquids, followed by soils, located at a plant site in Jacksonville, Arkansas. Successful demonstration of this process by Huber will result in the granting of commercial permits. Huber is presently constructing a 50,000 ton/yr unit, which will be available for use in early 1985.

o Fluidized-bed incineration. Energy, Incorporated of Idaho Falls, Idaho has developed two fluidized bed incinerator units that have been routinely used to destroy radioactive wastes (ref 9). The smaller 20 cm diameter, manually controlled unit can process 135 g/hr and is fully RCRA permitted. The 45 cm diameter unit is fully automated and contains several emission control devices including an activated carbon absorber and full radioactive iodine capture devices. Energy, Incorporated has a RCRA Part B permit pending. The larger unit has a rated capacity of 22.7 kg/hr.

o In-situ vitrification. Battelle Pacific Northwest Laboratories, Richland, Washington has developed an emerging technology for potential, in-place immobilization of radioactive and highly toxic wastes (ref 10). The contaminated soil is stabilized and converted into an inert glass form. This conversion is accomplished by inserting electrodes into the soil and establishing an electric current between the electrodes. Any contaminants released from the melt are collected and routed to an off-gas treatment system. A stable and durable glass block is produced that chemically and physically encapsulates any residual waste components. Table 2 delineates some recent data.

Table 2. In-situ vitrification data.

System Size	Power	Electrode Spacing	Block Mass	Depth
Laboratory	30 kW	30 cm	50-1000 kg	-
Pilot	500 kW	1.2 m	10 tons	-
Full-scale	3750 kW	5 m	350 tons	10-13 m

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APPENDIX

1. Example of a calculation of TCDD equivalents where isomer-specific concentrations are available.

Isomer	Concentration (ppb)	Relative Potency	TCDD Equivalents
2,3,7,8-TCDD	0.5	1	0.5
1,2,3,7,8-PeCDD	0.10	0.2	0.02
1,2,3,6,7,8-HxCDD	0.05	0.04	0.002
1,2,3,7,8,9-HxCDD	0.5	0.04	0.02
1,2,3,4,7,8-HxCDD	0.1	0.04	0.004
2,3,7,8-TCDF	10.5	0.1	1.05
1,2,3,7,8-PeCDF	0.1	0.1	0.01
2,3,4,7,8-PeCDF	0.01	0.1	0.001
1,2,3,6,7,8-HxCDF	0.01	0.1	0.001
1,2,3,7,8,9-HxCDF	0.01	0.1	0.001
1,2,3,4,7,8-HxCDF	0.01	0.1	0.001
2,3,4,6,7,8-HxCDF	0.01	0.1	0.001
Total:			<u>1.6</u>

Note that the total TCDD equivalents estimated is rounded to the nearest decimal because a more precise estimate is not warranted.

2. Example of a calculation of TCDD equivalents where only homologue-specific analyses are available.

Homologue	Concentration (ppb)	Relative Potency	TCDD Equivalents
TCDDs	0.5	1	0.5
PeCDDs	0.5	0.2	0.1
HxCDDs	13.0	0.04	0.42
TCDFs	100.0	0.1	10.0
PeCDFs	150.0	0.1	15.0
HxCDFs	10.0	0.1	<u>1.0</u>
Total:			27.0

Note that the total TCDD equivalents estimated is rounded to the nearest decimal because a more precise estimate is not warranted.

"OTHER" DIOXINS AND FURANS

Basis of Concern

- o Related chemicals sometimes nearly as toxic as 2,3,7,8-TCDD
- o Amounts generated sometimes as great or greater than 2,3,7,8
- o Relative potencies, not all in agreement

Status of Strategy

- o Tentative agreement on some approaches/issues
 - separate effort from Dioxin Strategy
 - 3 general approaches being defined:
 - 1) little additional effort
 - 2) thorough testing of "dirty dozen"
 - 3) screening of comprehensive list
 - chemicals of concern based on exposure & hazard
 - favor a bioassay battery of tests as part of strategy
 - monitoring needed for several chemicals
- o Draft available in a few weeks

Regulatory Activities on Chemicals Related to 2,3,7,8-TCDD

- o RCRA listing: tetra, penta & hexa
- o PCB fires: furans
 - Proposed Rule by October 1
- o Wood preservatives: hexa
 - PD-4 issued
- o Pentachlorophenol, non-wood uses: hexa
 - expected September 29
- o OTS is asking industry for bioassay battery on a PMN

Other Activities on Related Chemicals

- o Bioavailability Workshop in September included concerns about dioxin relatives
- o Computational Techniques Workshop in October will include dioxin relatives as a case study
- o Pesticides with possible dichloroaniline contamination (diuron, linuron, propanil)
 - Possible azo & azoxy formation in wastes & treated fields

Centers for Disease Control
Atlanta GA 30333

July 6, 1984

Mr. Morris Kay
Regional Administrator
U.S. Environmental Protection Agency
Region VII
324 East 11th Street
Kansas City, Missouri 64106

Dear Morris:

As you know we have been evaluating the health issues related to cleanup of land contaminated with 2,3,7,8-tetrachlorodibenzo-dioxin (TCDD) in response to requests from you and others in EPA. We would like to communicate to you our recommendations on several issues of importance.

We have previously stated that TCDD concentrations of one part per billion (ppb) or greater in the surface soil of a residential area constitute an unacceptable risk to human health. Adequate cleanup of residential areas, from a public health perspective, requires that the concentration of TCDD left in surface soil be less than one ppb. Although research is continuing into the health effects of TCDD, we are not currently aware of any new information that would substantially alter the reasoning behind this judgement, as expressed in the TCDD risk assessment document of Kimbrough, et al.


Acceptable remedial strategies for residential areas might include leaving TCDD concentrations of one ppb or greater in soil that is below the surface level (covered either by the surface soil or some more durable material such as asphalt or concrete) if current and future use of the land precludes the likelihood of significant future exposure to the contaminated soil. Should TCDD be left in subsurface areas, EPA, as the federal agency responsible for risk management at TCDD sites, should be able to assure that these higher concentrations of TCDD will not be disturbed during all reasonable uses of residential land. There must also be assurance that erosion will not eventually uncover these buried pockets of TCDD; the land use must also be monitored to prevent future use (e.g., construction) that might disturb the buried TCDD, causing unacceptable human exposure at a future date. In the absence of long-term monitoring of contaminated residential sites, the Centers for Disease Control (CDC) recommends that the 2,3,7,8-TCDD be removed from all contaminated areas, regardless of depth, to a level of 1 ppb. In any event, in areas with surface and subsurface contamination, we would recommend removing at least the upper layer of heavily contaminated soil (6 inches or greater) and replacing with uncontaminated soil to provide an effective barrier for ordinary residential use. Where feasible, e.g., in discrete areas of exposure, or in areas of very high levels of contamination, we would recommend removing as much of the highly contaminated subsurface dirt as feasible.

Page 2 - Mr. Morris Kay

For land where the use is going to be other than residential, a cleanup standard different from one ppb may be appropriate. Certain agricultural activities, such as raising food animals that bioaccumulate TCDD, ought to be conducted on land with far less than one ppb TCDD. For commercial or former industrial areas, where children are seldom present and where extensive human contact with soil or dust is not likely to occur, a cleanup standard less stringent than one ppb could reasonably be considered. In evaluating such non-residential areas judgement must be used as to the likelihood of significant exposure (especially to children) occurring. For example, non-residential areas such as playgrounds, parks, day-care centers, horse arenas or other settings where significant exposure to soil occurs should have limits similar to residential areas. Other areas with less likelihood of significant exposure could have clean-up standards that are somewhat higher; the levels proposed by EPA Region II of 5 ppb for such areas (with a ceiling of 7 ppb) seem reasonable to us. The same caveats noted above concerning erosion and future land use also would apply to commercial areas.

As you know, it is very important that the remedial strategies applied be consistent from Region to Region. Furthermore, although there is great variability among the sites, it is important to apply the same general set of principles so that a consistent policy is developed and implemented. We are quite willing to assist in this process, and we will be glad to review remedial action plans for conformance to accepted public health principles.

Sincerely yours,


Vernon M. Houk, M.D.
Director
Center for Environmental Health

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

FILED
U.S. DISTRICT COURT
EASTERN DISTRICT ARKANSAS

JUL 18 1984

By: CARL R. BRENTS, CLERK

DEP. CLERK

UNITED STATES OF AMERICA,

Plaintiff,

vs.

No. LR-C-80-109

VERTAC CHEMICAL CORPORATION, and
HERCULES, INC., A Corporation,

Defendants.

ARKANSAS DEPARTMENT OF POLLUTION
CONTROL AND ECOLOGY,

Plaintiff,

vs.

No. LR-C-80-110

VERTAC CHEMICAL CORPORATION, and
HERCULES, INC., A Corporation

Defendants.

ORDER

This Court approved the entry of a Consent Decree on January 18, 1982. This decree contemplated that the parties would ultimately reach a negotiated remedial plan for Vertac's Jacksonville plant site. Paragraph VI of the Consent Decree provides for dispute resolution by this court in the event the parties failed to reach a negotiated remedial plan. After exhaustive study of the plant site and protracted negotiations by the parties, no remedial plan has been approved by all of the parties. Vertac, Hercules and the State Department of Pollution Control and Ecology are satisfied with the plan prepared by Vertac's consultants. Additionally, Hercules and Vertac have entered into an agreement concerning the sharing of the cost

associated with implementing the remedial plan. However, the Environmental Protection Agency objected to Vertac's proposal and the parties have been unable to resolve their differences. Therefore, Vertac filed a petition pursuant to Paragraph VI of the Consent Decree seeking this court's intervention in the resolution of the dispute.

The history of the Jacksonville plant site as well as this litigation is fully developed in the Court's Memorandum Opinion and Order filed May 12, 1980 wherein preliminary injunctive relief was afforded the plaintiffs in these two consolidated cases. United States v. Vertac Chemical Corporation, 489 F.Supp. 870 (E.D. Ark. 1980).

Paragraph VI(A) of the Consent Decree provides as follows:

(A) In the event a dispute should arise among Vertac, EPA and the State regarding any plan, proposal or implementation schedule required to be submitted by Vertac pursuant to the terms and provisions of this Consent Decree, Vertac shall, within 45 days after the expiration of the time allowed under paragraph V(B) for response by EPA/State, file a petition with this Court setting forth the proposal in dispute. In the event of a dispute between Vertac and EPA or the State, Vertac shall also have the burden of showing that its proposal is appropriate to fulfill the terms, conditions, requirements and goals of this Consent Decree. In resolving any dispute, the Court shall consider the nature of any endangerment, and the cost-effectiveness of alternate proposals which satisfy the goals of this Decree.

Vertac has the burden, under this dispute resolution procedure, of showing that its remedial proposal is appropriate to fulfill the terms, conditions, requirements and goals of the Consent Decree. The issue before this court is whether or not Vertac has met this burden and in

making this determination the Court is required under the Consent Decree to consider:

- 1) the nature of any endangerment to human health or the environment,
- 2) the extent to which the various proposals would reduce any endangerment to human health or the environment; and
- 3) the cost-effectiveness of alternative proposals which would satisfy the goals of the Consent Decree.

The goal of the Consent Decree is the protection against endangerment to human health or the environment arising from present or prior operations or conditions at the Jacksonville plant site; provision for orderly and systematic storage, transfer, disposal or treatment of chemical wastes at the Jacksonville plant site; protection against migration of pollutants from the Jacksonville plant site into the environment; implementation of plans and remedies for restoration and/or containment of any contaminated ground water; the study of the condition of Rocky Branch Creek, the drainage ditch running from the east side of the plant site to Rocky Branch Creek, and Bayou Meto; and the study of Lake Dupree for potential remedial measures. (See Paragraph IV of Consent Decree).

Approximately two weeks of testimony was presented by the parties at the dispute resolution hearing and the Court is now prepared to make its Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

1. The alternative remedial plans address three basic sources of potential endangerment to human health and/or the environment.

- a) barrelled wastes containing up to 100 parts per million dioxin which are buried in the "North Burial Area".
 - b) contaminants other than dioxin in the wastes buried on-site such as chlorinated phenols, anisoles, chlorinated benzenes, 2,4-D, 2,4,5-T in the "North Burial Area" and aldrin, dieldrin and DDT in the "Reasor-Hill Burial Area".
 - c) low level concentrations of dioxin and chlorinated phenols in the East Ditch, Central Ditch and Cooling Pond.
2. There is not a serious danger of the dioxin, contained in the barrels in the "North Burial Area", moving off-site underground. Samples from the wells on-site demonstrate that it is very unlikely that dioxin will move subsurface in the groundwater even when a liquid organic solvent component such as toluene is present.
 3. The non-dioxin wastes are more soluble in water than dioxin and are therefore more readily mobile in subsurface groundwater. However, the non-dioxin wastes are much less toxic than dioxin, and the monitoring wells in place and proposed provide adequate warning of any such groundwater transportation of wastes.
 4. Vertac's negotiated remedial plan provides for on-site containment of the contaminants in a manner which prevents the fractures in the underlying bedrock from increasing the mobility of the contaminants off-site.
 5. The negotiated remedial plan which Vertac seeks court approval of in the instant dispute resolution proceeding calls generally for permanent closure of the cooling water pond formed by Rocky Branch Creek near the western boundary of the site; solidification and encapsulation of cooling pond sediments in clay vaults at designated locations on the

plant site; improving and extending the clay caps over the buried wastes, including 12 inches of topsoil on all caps and establishment of vegetative cover thereon; constructing additional slurry barrier walls in trenches dug into weathered bedrock in such a way as to divert the flow of groundwater away from the waste burial areas; construction of approximately 3,000 feet of additional French drains, together with a leachate collection and treatment system designed to prevent the escape of any contaminated groundwater off-site and to allow disposal of water in compliance with strict federal and state standards; a detailed monitoring and maintenance program to determine the continued effectiveness of the Vertac Plan; and the undertakings of Vertac and Hercules to remedy any defects which might become apparent in the future to assure that the Plan continues to meet the goals of the Consent Decree until such time as the Jacksonville plant should be closed as an active manufacturing facility, and for thirty years thereafter.

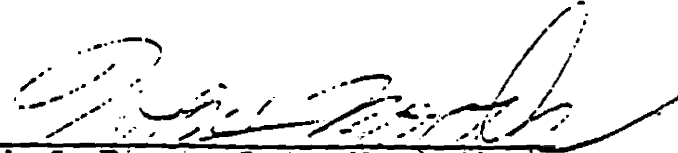
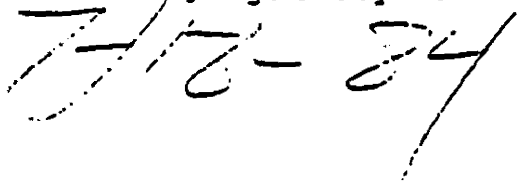
6. The Environmental Protection Agency's alternative remedial plan is described in Alternative IV of the report of CH2M Hill attached to the Environmental Protection Agency's response to Vertac's Petition for Dispute Resolution. Generally, this alternative calls for excavation and reburial. This proposal lacked in many respects as far as specific plans and specifications are concerned. While reburial in a Resource Conservation and Recovery Act site as suggested by the EPA has advantages over the current burial sites, the Court is convinced that any additional safety to human health and the environment achieved by this procedure is far exceeded by the risks of exposure from excavation.

7. The EPA proposal is inadequate in its provision for monitoring the possible off-site movement of contaminants.
8. Vertac's negotiated remedial plan is superior to the EPA alternative proposal in its protection of human health and the environment and is far more cost-effective.

CONCLUSIONS OF LAW

1. The Court has jurisdiction over the parties and the subject matter of this suit, pursuant to the provision of 28 USC §1331 and of the Consent Decree entered herein on January 18, 1962.
2. In resolving the dispute between EPA, on the one hand, and Vertac, Hercules and the ADPCE, on the other, the Court must consider the nature of any endangerment to human health or the environment that is involved, the extent to which the various proposals would reduce any such endangerment, and the cost-effectiveness of alternative proposals which satisfy the goals of the Consent Decree.
3. The Court concludes that the Negotiated Remedial Plan in the form attached as Exhibit A to Vertac's petition for dispute resolution herein, together with the supplemental financial assurance agreement in the form attached to the response filed by Hercules, is appropriate to fulfill the terms, conditions, requirements and goals of the Consent Decree, and that it is superior to the alternative proposed by the EPA in terms of safety and cost-effectiveness.
4. Considering the nature of potential endangerment to human health or the environment involved; the extent to which the Vertac Plan would reduce any such potential endangerment; the extent to which the implementation of alternatives proposed by EPA could increase such

- endangerment; and the relative cost-effectiveness of the alternative proposals, the Negotiated Remedial Plan is far superior to any alternative proposal submitted on behalf of EPA and should be approved.
5. EPA's claim for recovery of costs and expenses, as to Vertac, as asserted in the proposed amended and supplemental complaint which it seeks to file herein, was satisfied and merged into the terms of the Consent Decree itself pursuant to the provisions of paragraph XIV(A).
 6. At this time, EPA's attempt to amend its complaint to seek a judgment for costs and injunctive relief against Hercules appears to be moot and without merit in view of the approval of the Vertac Plan.
 7. For the foregoing reasons, EPA's petition for leave to file its amended and supplemental complaint herein is denied, but without prejudice to the right of either EPA or State to renew such a petition as was contemplated in paragraph XIV(C).
 8. While the conduct of the EPA has been somewhat inconsistent and disconcerting, the court concludes that the defendants have failed to prove entitlement to an award of fees and costs in this case.
 9. It is therefore ordered that Vertac begin immediate implementation of its remedial plan.


U. S. District Judge Henry Woods




Memorandum

Date April 11, 1984

From Chief, Superfund Implementation Group

Subject Review and Comments on Toxicity of 2,3,7,8-Tetrachlorodibenzofuran
(2,3,7,8-TCDF)

To Joel D. Mulder
Public Health Advisor
EPA Region IX

As requested we have had members of the Center for Environmental Health and National Institute for Occupational Safety and Health (NIOSH) staff review the findings of 2,3,7,8-TCDF at the Neville Chemical site in Santa Fe, California and comments regarding potential action levels for the site as it relates to initiation of a response, analysis of samples, and health concerns.

As you are aware, we have been working with EPA on a Task Force to develop suitable criteria for QA/QC for environmental toxicant measurements. Many of these recommendations have been included in the most recent EPA laboratory services contract negotiations for dioxin. They include:

- o Reporting requirements for deliverables
- o Analytical methods
- o QA/QC requirements
- o Chain-of-custody and document control procedures

In addition, we recommend an externally operated quality assurance program, analogous to the one in operation for dioxin, consisting of:

- o A performance audit sample for furans in every analytical run
- o A blank control sample in every analytical run

This type of program will insure that numbers generated by laboratories for furans will be of "known quality" and that an estimate can be made of a lower cutoff value for considering a sample as positive (i.e., equal to or greater than the threshold level) with an established false negative confidence level.

Any action at the site will of course be predicated upon the laboratory results. It was not clear to the reviewers whether or not proper QA/QC procedures were in effect and if the laboratory did in fact have standards for the individual isomers of TCDF. It was also not clear if the laboratory was able to confirm their results.

On a qualitative basis, the 2,3,7,8-tetrachlorodibenzofuran has similar toxic effects as the 2,3,7,8-tetrachlorodibenzodioxin. Although there are some animal studies available, the long-term chronic toxicity has not been studied. However, from reviewing the available results, it appears that 2,3,7,8-tetrachlorodibenzofuran is at least five times, and in some instances 20 times, less toxic than the 2,3,7,8-tetrachlorodibenzodioxin.

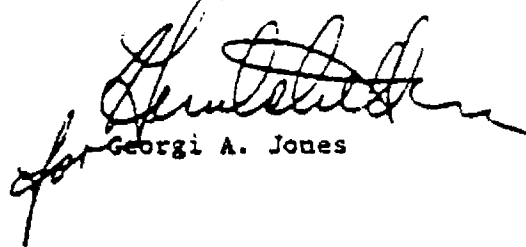
It is presently not known how persistent this particular compound is in the environment. However, based on available information, particularly the Japanese Yusho episode (which demonstrated that this isomer in humans was excreted relatively rapidly), one of the reviewers concluded that levels below 10 ppb in residential areas should not cause any concern. In industrial and commercial areas, this level could be higher since exposures such as gardening and children playing in dirt would not occur. Levels below 25 ppb in commercial and industrial areas should not give rise to major concern. Levels above 10 ppb in residential areas and above 25 ppb in commercial and industrial areas should be reviewed.

If other congeners of PCDF are also present, lower levels could well be required because of a potential additive effect.

In general the reviewers felt that it is not possible at the moment to make a detailed risk analysis due to a lack of data. It is dangerous to simply use 2,3,7,8-tetrachlorodibenzodioxin and build in a "fudge" factor. General environmental contamination with furans may be quite high, based on recent fish data, and thus, until we know more about background levels it is premature to set clean-up levels in the ppb range.

As you requested, we will review the proposed sampling protocol as soon as it is received from your office, and will review the subsequent analytical results. We should then be in a better position to render site specific recommendations. Major remediation activities at the site should be held in abeyance until these results are back and until an appropriate site safety plan is developed.

If we can provide any additional assistance please contact me.


for Georgi A. Jones

Mr. Chairman:

The Food and Drug Administration (FDA) appreciates the opportunity to testify on the human health effects resulting from exposure to 2, 3, 7, 8-tetrachlorodibenzodioxin (TCDD).

Since the Subcommittee is familiar with FDA's responsibility and jurisdiction over food products containing environmental contaminants, including dioxins, I will try to give primary emphasis to issues raised by the Subcommittee in its letter of invitation.

As we have heard from scientists from the National Institute of Environmental Health Sciences and the Centers for Disease Control, TCDD is a highly toxic compound which in certain animals causes birth defects, cancer, immunotoxicity, and a variety of biochemical and physiological alterations. Most of what is known about TCDD's toxicity derives from animal studies, particularly studies in rats, mice, and guinea pigs. It is evident that the sensitivity of different rodent species to TCDD varies greatly, perhaps by as much as a thousandfold. This information is important to keep in mind, since our ultimate task is to estimate safe levels of exposure to human populations.

Unfortunately, based on current information, it is not possible to determine whether humans are more sensitive or less sensitive than the highly susceptible rodent species. The reason for this is that the exposure level to humans is very difficult to estimate accurately.

While there have been accidental exposures to TCDD, such as the Seveso, Italy incident, the actual levels of exposure to humans is unknown. There are scientists who have argued that humans are relatively insensitive to the effects to TCDD based on studies with



O. B. Vawter
11-83

STATEMENT

BY

SANFORD A. MILLER, PH.D.

DIRECTOR, BUREAU OF FOODS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE
RESEARCH AND ENVIRONMENT

COMMITTEE ON SCIENCE AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

JUNE 30, 1983

FOR RELEASE ONLY UPON DELIVERY

cohorts of individuals accidentally exposed to dioxin who have subsequently developed chloracne--the argument being that systemic exposure must have been significant for chloracne to have developed. The counter-argument states that chloracne might have been the result of topical exposure only where little of the compound penetrated the skin to expose the individual systemically. Hence, systemic effects would not be expected to be seen. Based on present knowledge, we cannot reliably state whether humans are more or less sensitive than the animal models that have been used to explore the toxicity of TCDD. Nevertheless, in recommending the concern levels for TCDD in Great Lakes fish at 25 and 50 parts per trillion (ppt), FDA has in effect acknowledged the extremely potent toxicity of TCDD as determined experimentally using animal models.

FDA's actions on another toxic substance, aflatoxin B₁, illustrates our concern for TCDD. Aflatoxin B₁, which is a metabolite of the mold Aspergillus flavus, has always been considered an extraordinarily toxic and carcinogenic substance. Because this mold grows naturally on peanuts and corn, particularly corn in the Southeastern United States, toxic levels of aflatoxin are impossible to avoid entirely. Consequently, the FDA, under the authority of section 406 of the Federal Food, Drug, and Cosmetic Act, has established an action level for the presence of aflatoxin in food commodities and finished food products. The point here is that the action level established for aflatoxin is approximately 1,000 times higher than the concern level that FDA recommended to the Great Lakes States for TCDD residues in carp and catfish. It should be emphasized that prior to the findings on TCDD, aflatoxin was generally regarded as the most carcinogenic substance known to science.

In establishing either an action level or recommending a level of concern, FDA is both guided and constrained by its statutory authority. Under section 402(a)(1) of the Act, food is regarded as adulterated if it bears an added poisonous or deleterious substance at a level which may render that food harmful to human health at the levels consumed. If the substance in question is unavoidable by good manufacturing practice, section 406 provides for establishing a level which must protect the public health, while at the same time avoid needless reduction of the available food supply.

The Delaney clause, which states that no substance may be approved as a food additive if it is shown to induce cancer in man or animals, is a provision of section 409 of the Act and thereby applies to food additives, not to unavoidable contaminants in food. TCDD, in this instance, is not a food additive, but rather is an added poisonous or deleterious substance which cannot be completely avoided by good manufacturing practice. Therefore, TCDD in fish is subject to sections 402(a)(2) and 406 which do not contain a provision similar to the Delaney clause. Section 406 requires that the extent to which the poisonous or deleterious substance is unavoidable under good manufacturing practice be considered in setting a tolerance. Thus, in this sense FDA must determine the balance between health effects and the results to the consumer of removal of a food product from the market. This balancing is particularly difficult in the face of as much uncertainty as exists with TCDD. However, at the time we developed our recommendations, we were confident that they met both the requirement for public health protection, as well as avoided the needless reduction of part of the food supply.

We recognized then and recognize now, that there would be critics who would argue that the uncertainty of TCDD's health effects in humans and the knowledge of its high toxicity in laboratory animals would dictate that any level at which TCDD could be detected would be too high and that such food should be banned. This approach would, in fact, result in the banning of most bottom-feeding fish in the Great Lakes and possibly other species of fish, such as smelt. If the analytical methodology used for detecting TCDD improves by an order of magnitude, the likelihood is that still more species of fish would be found contaminated, resulting in the closing of those fisheries as well. Based on our evaluation of the available data, we felt that such action was not warranted and in our advisory stated that fish containing more than 50 ppt should not be consumed and those containing more than 25, but less than 50 ppt should not be consumed more than twice a month. We further stated that, based on fish consumption data, we saw no public health problem below 25 ppt.

It should be recognized that these values are not tolerances or action levels, but instead are levels of concern requested by several of the Great Lakes States affected by this problem. Since the Great Lakes are shared with Canada, we attempted to harmonize our concern with those of the Canadian Health Protection Board. We did not attempt to establish a tolerance for TCDD in fish as that would force FDA to formally prepare and defend the level. Such formal action on the part of FDA would be challengeable in the courts and we would need to defend the proposition that the fish were adulterated at the tolerance level by a poisonous and deleterious substance which may have rendered it harmful to human health under ordinary conditions of use.

On the other hand, FDA would also have to defend the proposition that below the action level there is no public health concern whatever.

Since there is considerable uncertainty about TCDD's effects on humans, particularly with regard to the question of the sensitivity of humans to various levels of TCDD, the Agency believed that any effort to set an action level or tolerance would be premature and possibly counterproductive. The concern level, which was developed primarily to provide guidance to the individual States that are confronted with the problem, reflected the apparently restricted nature of the food contamination in that it did not appear to be a national problem. For these reasons, the level of concern was believed preferable to an established action level or tolerance. It is important to note that this level was established only for the specific situation in fish in the Great Lakes, and does not apply to other foods or areas.

We arrived at the level of 25 ppt by examining the distribution pattern of TCDD in Great Lakes fish and then determined the risk associated with various levels of contamination. From our examination of the distribution of TCDD in fish in the affected area we concluded that, for the most part, the species of most concern were the bottom-feeding fish such as carp and catfish. Looking at the level of contamination and keeping in mind our statutory requirement to consider both public health and the availability of food, we evaluated several possible levels of concern ranging from 10 ppt to 100 ppt. We determined that 25 ppt represented a level of risk acceptable to the public health while resulting in a minimal impact on the availability of Great Lakes fish as a food source.

Let me now describe the basis for the Agency's conclusion that catfish and carp from the Great Lakes do not pose an unacceptable risk to the public health at a level of 25 ppt. According to the information available to us from food consumption surveys, the upper 90 percentile of fresh water fish consumption in the Great Lakes States is 15.7 grams of fish per day. For the United States as a whole, total fish consumption is about 28.1 grams per day. Most of this is marine fish which, insofar as is known, does not contain TCDD. Moreover, bottom feeders, such as carp and catfish, make up only a fraction of all fresh water fish.

Using the worst-case assumption that all exposed individuals consume high levels of fish (at the 90 percentile of fish consumption), that all the fish consumed are fresh water fish from contaminated areas in the Great Lakes, and that these fish consist exclusively of bottom feeders such as catfish and carp having exactly 25 ppt of TCDD, we calculated a daily exposure to TCDD of 392.5 picograms from such fish.

It should be kept in mind, however, that these exposure estimates are based on several assumptions that are most unlikely to hold true for even a single individual. For example, it needs to be recognized that to assure that no sample exceeds a 25 ppt residue level, the average limit imposed on any given fishery must be well below this and statistically would probably not exceed 1/3 of that amount. Thus, no individual would, on a consistent basis, consume fish at 25 ppt. Assuming that the individual consumed only bottom fish from the

Great Lakes fisheries, that person would probably consume fish with dioxin on the average of approximately 8 ppt. This then reduces the estimate of exposure to 130.8 picograms/day from such fish. Further, the average individual would not exclude consuming bottom fish from uncontaminated areas or surface-feeding fish with nondetectable levels of TCDD. In all likelihood, no more than 10 percent of the fish in the average individual's diet within the affected States is likely to be composed of bottom-feeding fish from contaminated areas. Taking this correction into account, the estimation of consumption is reduced to 13.1 picograms/day.

To determine the risks of cancer from this exposure, we utilized the best animal data available for the purpose which was developed by Kociba and his colleagues. We regarded these data as the best for the purpose of risk assessment, as this work provided the most information on the relationship of dose or exposure to response. Since the mechanism by which TCDD induces cancer in rodents is unknown, it is not possible to say which of the standard mathematical models are appropriate for use. We do assume, however, that most of these models are far more likely to overestimate risk, rather than underestimate it. Further, risk in this context says only that the data are consistent with the probability that the risk level could occur, not that it necessarily will occur. It also must be kept in mind that the relative sensitivity of humans to the animal models is not known and there is considerable controversy in scientific circles on this point.

With these caveats in mind, the risk levels represented by a 25 ppt maximum residue level representing a predicted exposure to an 80 kg

individual of approximately 13 pg/day is calculated as approximately 3 cancers out of a million or 3×10^{-6} lifetime risk using the linear model. Given the fact that the Agency viewed these "concern levels" as interim statements, it is important to consider what the lifetime risk of cancer might be for a specific increment of time. For a period of 1 year, the risk is 4 in 100,000,000 or 4×10^{-8} using the linear model. It should again be emphasized that these calculations make no pretense of representing an actuarial risk. The intent of the exercise is to obtain an estimate of the upper bound or upper limit of risk that a particular agent poses to exposed human beings. In this case, whether or not it represents an upper limit depends upon whether humans are less sensitive or more sensitive than the rodent models on which these estimates are based. Only time and the gathering of additional information will provide the insight necessary to adjust these estimates in whatever direction appears appropriate.

A further point needs to be made. At the present time, the concern level set at 25 ppt is consistent with the demands and the constraints imposed by the sensitivity of the analytical method used to detect TCDD. While there are analytical screening procedures which can detect TCDD at levels at approximately 1 ppt, these methods do not specifically identify TCDD. Confirmation that the chemical entity detected is in fact TCDD requires the use of specific mass spectroscopic techniques. In order to both detect and confirm TCDD, residue levels must be at least 10 ppt or higher. Therefore, in setting a level of concern, it was necessary that our chemists who monitor and analyze fish taken from the Great Lakes fisheries be able

to detect levels that were significantly below the level of concern in order to demonstrate the nature of the distribution of contamination in fish. As indicated earlier, to assure that fish containing levels of TCDD which exceed 25 ppt are not present, it is necessary to detect and measure with accuracy and precision, levels that are roughly 70 percent lower. In other words, the 25 ppt level of concern for Great Lakes bottom fish requires that the most sensitive method for detection and confirmation be used. This methodology is expensive. We estimate that it costs about \$1,000 per sample. To set the concern level much lower than 25 ppt would be in fact be forcing the technology beyond its current state-of-the-art and would not provide a rigorous scientific basis for legal actions that might be taken.

I would like to provide for the record a description of the analytical methodology and some points about its difficulties that are relevant here. I would also like to submit some data on the levels of TCDD found in fish and other foods analyzed by our various laboratories.

As mentioned earlier, we indicated that should samples of fish exceed 25 ppt, such fish should not be consumed any more frequently than twice a month. We were asked for an advisory because of the possibility that people living along the Great Lakes might depend on these fish to provide a significant portion of their diet. At 50 ppt or over, we advised that there be no consumption. This statement is based on estimates of monthly exposure and is consistent with and does not exceed the estimates of the upper limit of risk calculated for 90 percentile consumption of fish at 25 ppt.

It is important to emphasize that any estimate of an acceptable level of exposure to TCDD by human populations is clouded by the following uncertainties: the relative sensitivity of human populations to TCDD as compared to the animal species tested and the possibility that certain individuals within the exposed population are unusually susceptible to the adverse effects of TCDD. Such unusual susceptibility could derive from a host of factors including genetic background, dietary or nutritional status, exposure to other halogenated aryl substances, such as other dioxins and dibenzofurans, disease, and possibly other predisposing factors. In this case, as in the case with many chemicals, the total information available does not provide full confidence for setting levels of concern or action levels. We are therefore compelled to rely upon the best data available and to make the most reasoned judgments possible within the framework of existing legislation. The decisions on TCDD are an example of this, but it is important to keep in mind that as new information becomes available, the decisions will change accordingly.

Mr. Chairman, in your letter of invitation you also asked what kind of information was required to increase the certainty of our regulatory judgments. Clearly, as we have indicated several times in our remarks, we need to know with much greater confidence the relative sensitivity of humans to TCDD. This controversy has split the scientific and medical communities and its solution is essential to any rational regulatory action. To accomplish this task, the scientific community in general needs not only to expand, focus and refine our epidemiologic efforts, but also needs to better understand the mechanism by which

TCDD exerts its effects. With such data, we can then determine the relationship of the involved metabolic pathways to those in man and should be able to identify specific metabolic endpoints with which the toxicity of TCDD can be monitored in man at levels of exposure that may not lead to overt chronic responses.

The scientific community also needs to develop more rapid and specific methods of analysis that can accurately and precisely identify TCDD at levels of concern. This would permit not only easier identification of products of concern, but more importantly, would allow many more analyses of a greater variety of food products obtained from a large number of markets.

In conclusion, Mr. Chairman, this example in regulatory decisionmaking illustrates FDA's role in protecting public health by ensuring a safe and nutritious food supply. This responsibility is exercised by individuals who call upon science, law, and the regulatory process to accommodate the demands of safety, contamination, food requirements, Congress, consumers, and the courts. Although the regulatory process has often been criticized, on the whole it has provided effective public health protection for the millions who consume food in the United States.

Mr. Chairman, this ends my formal statement. My colleagues and I will be happy to answer any questions you may have.