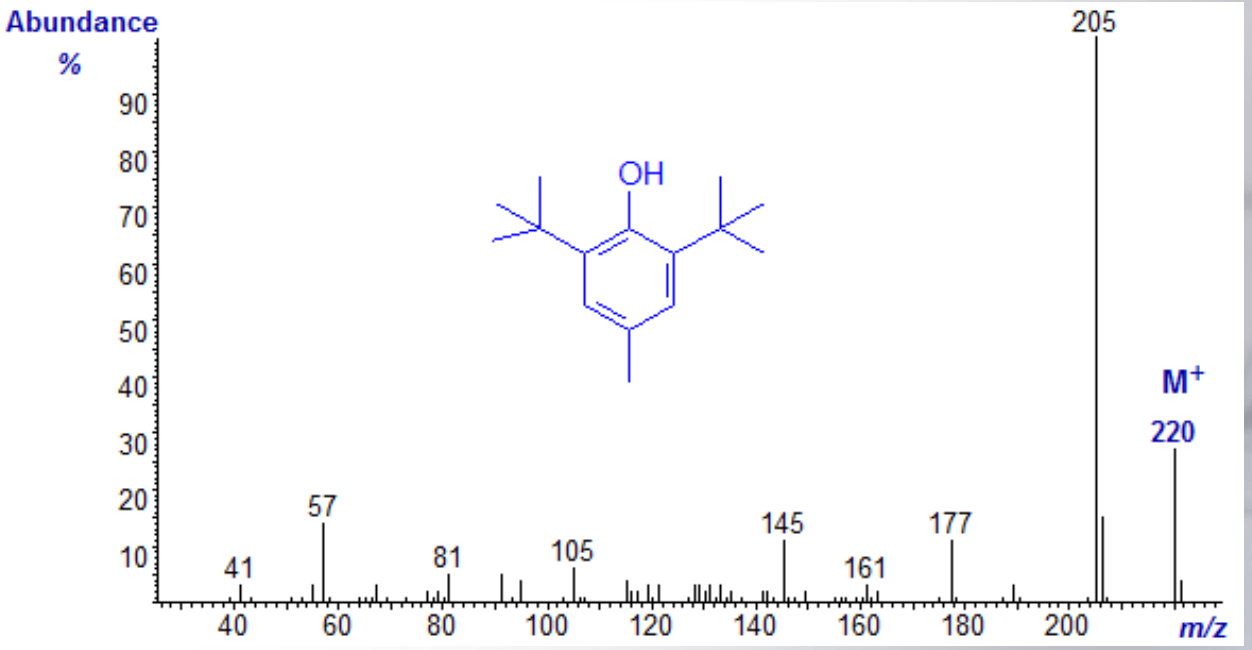
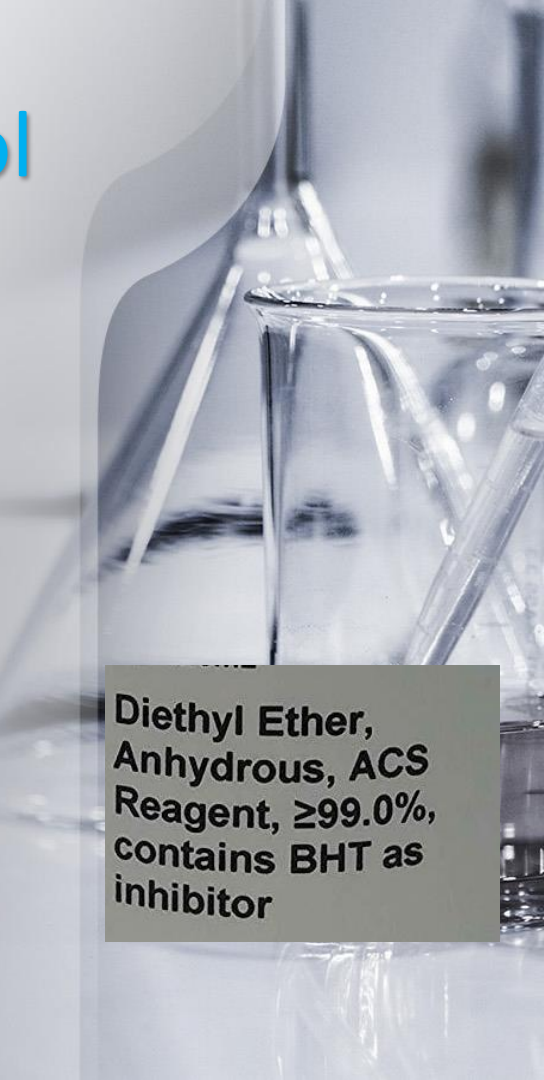
History of EPA Regulations and How They Created the Environmental Testing Industry

Jerry Parr, The NELAC Institute and
Judy Morgan, Pace Analytical

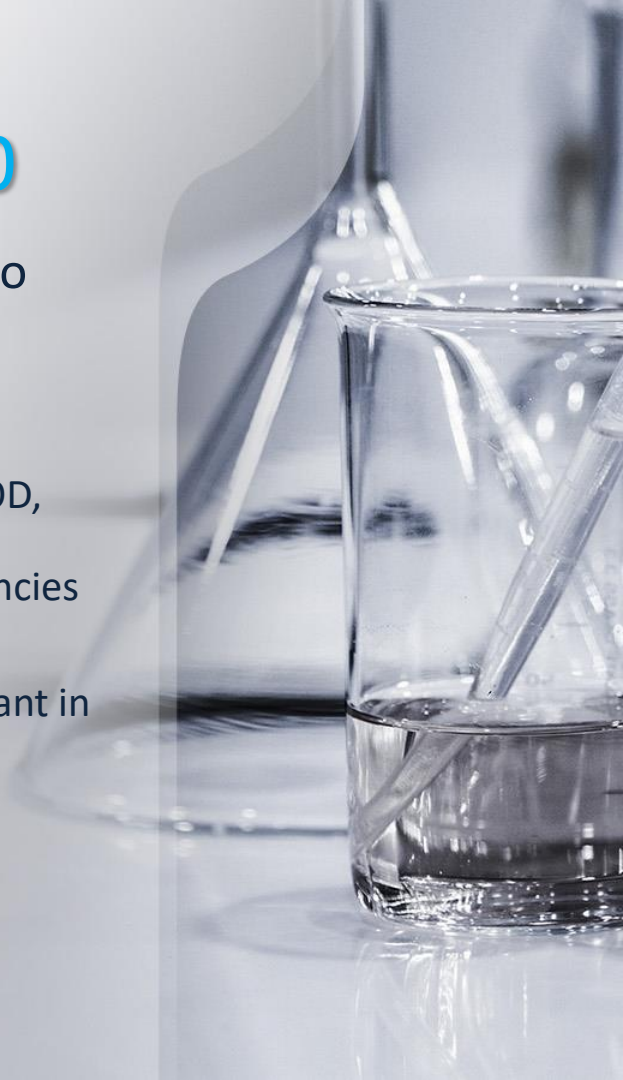
My First Compound: t-Butylcresol





Environmental Monitoring in 1970

- No EPA methods; no analyte lists; no cleanup limits; no compliance monitoring
- Testing Performed
  - Academic research; e.g., mercury in apples
  - Some wastewater testing for operational parameters (e.g., BOD, Nitrate)
  - Some ambient water quality monitoring by Public Health Agencies
- New Methods in *Analytical Chemistry*: One
  - Square-wave, polarographic determination of lead as a pollutant in river water
- 50 Finnigan GC/MS Systems world-wide (xx environmental?)
- First Computer-controlled GC/MS described



Environmental Laboratories in 1970

- Flowers Chemical
  - Jefferson Lee Flowers
- Lancaster
  - Earl Hess
- PanAmerican
  - John Lipps
- Research Organizations
  - Battelle Memorial Institute
  - Midwest Research Institute
- Other
  - Robert A. Taft Center in Cincinnati
  - State Public Health Laboratories

Organic Chemical Compounds in Raw and Filtered Surface Waters

HARRY BRAUS, F. M. MIDDLETON, AND GRAHAM WALTON

U. S. Public Health Service, Cincinnati 2, Ohio

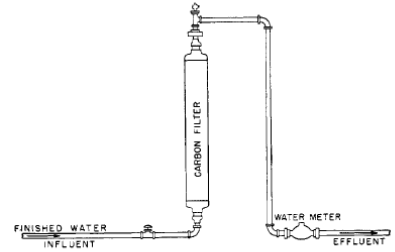


Figure 1. Carbon Filter Installation
Used for sampling filtered water for trace quantities of organic chemicals

Analytical Chemistry, 1951

A Price List from 1955

PRICE LIST EFFECTIVE JANUARY 1. 1955
Subject To Revision

DUSTS AND CLAYS

In addition to the analyses for active ingredients, we also offer analyses of the materials to be used as carriers in pesticide and other formulations.

pH	1.50
pH, HYDROXIDE, CARBONATE, AND BICARBONATE	2.00
PERCENT PASSING A 325 MESH SCREEN	2.00
BULK DENSITY, FLUFFED AND TAMPED	1.00
QUANTATIVE DETERMINATION OF THE PRINCIPAL CHEMICAL CONSTITUENTS	12.00[1]

[1] Price varies slightly depending on the actual chemical constituents present.

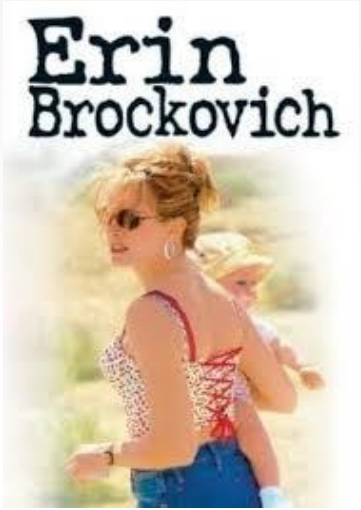
FERTILIZERS

NITROGEN, PHOSPHORUS, AND POTASSIUM	10.00

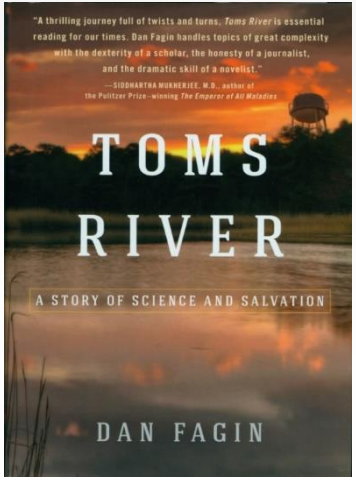
PESTICIDES

ALDRIN	$ 8.00
GAMMA-BHC	8.00
CALCIUM ARSENATE	
TOTAL ARSENIC	5.00
WATER SOLUBLE ARSENIC	5.00
BOTH ON SAME SAMPLE	8.00
CHLORAMINE T (SODIUM)	5.00
CRYOLITE (FLUORINE)	8.00
DIELDRIN	8.00
DDT	8.00
DDT AND ALDRIN	12.00
DDT AND GAMMA-BHC	12.00
DDT, BHC, AND SULPHUR	14.50
DDT AND DIELDRIN	12.00
DDT, DIELDRIN AND SULPHUR	14.50
DDT AND METHYL PARATHION	14.00
2,4-D (DUST)	10.00
2,4-D (SPRAY)	5.00
ENDRIN	10.00
METHOXYCHLOR	10.00
METHYL PARATHION	8.00
METHYL PARATHION AND CALCIUM ARSENATE	12.00
PARATHION	8.00
PYRETHRINS	9.00
SULPHUR (TOTAL, IN A MIXTURE)	2.50
TEPP (TEP)	8.00
TOXAPHENE	6.50

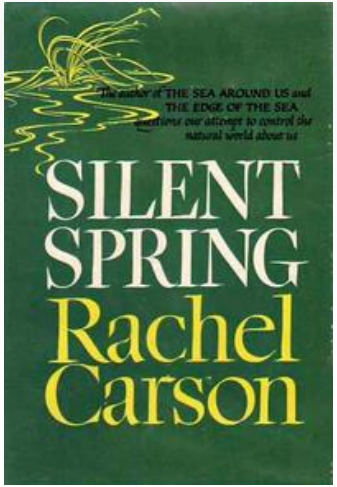
Environmental Disasters



Cr+6 Discharged into ponds 1952-1966 by **Pacific Gas and Electric**



Organic waste piped to the Atlantic and waste dumped into pits by **Ciba Geigy** and **Union Carbide** from 1952 - 1990



1962 - The book revealed the tragic effects of pesticides and fuel oil on the environment and animals.

Regulations, Laws and New Agencies…

Starting in 1877, multiple regulations and programs had been created to address specific issues, but comprehensive programs had not been developed.

By the end of the 1960's

- Independent studies were taking place
- News and specialty groups were publishing horror stories regarding industrial waste
- Environmental activists were visible in many of the issues
- Epidemiology had not fully entered into the job safety considerations
- Certain chemicals had not been officially tied to particular health conditions.
- Private citizens were spending time trying to figure out why certain illnesses were occurring

1969-70 Major Agencies Established

President Nixon:

1969 – National Environmental Policy Act redirected the government's role to protect the **earth, air, land, and water**.

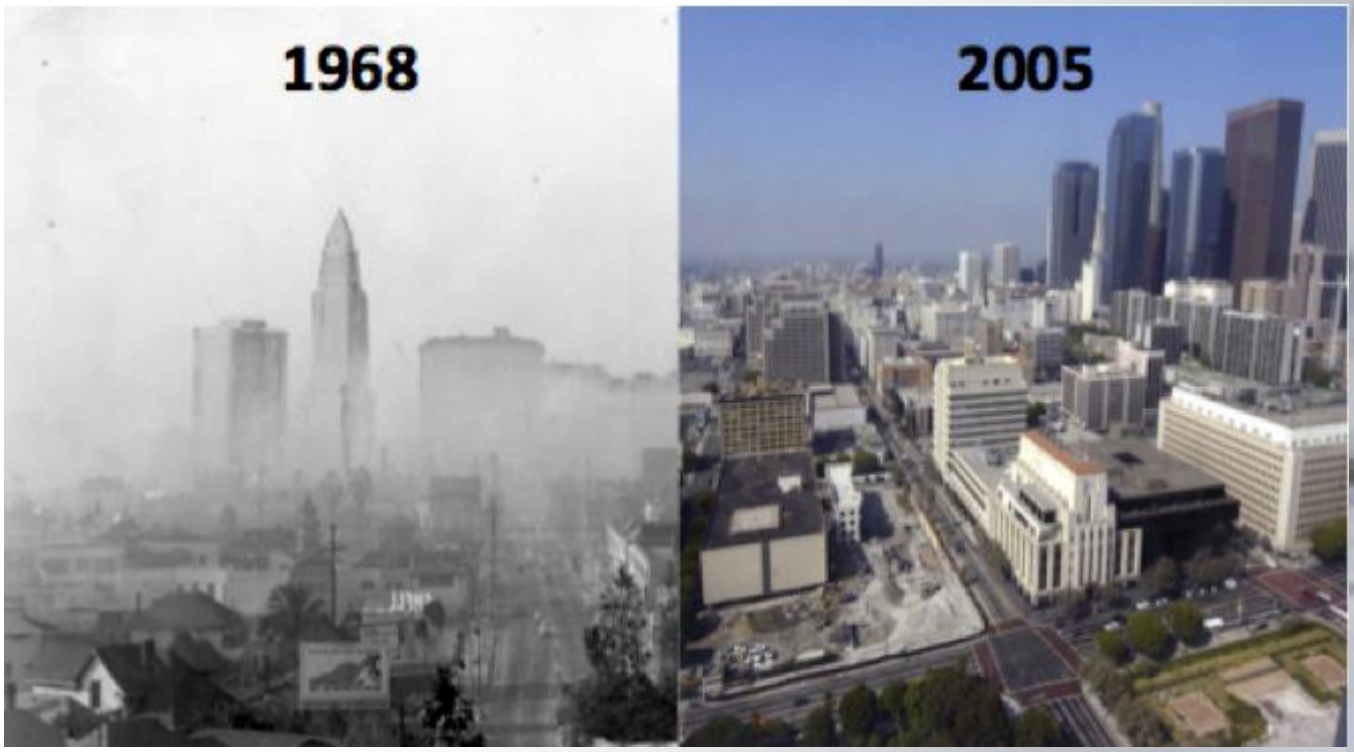
1. **Dec. 2, 1970** - signed the approval to establish both the **Environmental Protection Agency (EPA)** and the **National Oceanic & Atmospheric Administration (NOAA)**

2. **December 29, 1970 -** Signed OSHA into law at a time where approximately **14,000** occupational **fatalities** were being reported each **year** as well as **2.5 million job-related disabilities** and **300,000 new cases** of job-related **illnesses**.

Major Environmental Legislation: 1970 -1980

- 1970 – Clean Air Act
- 1972 – Clean Water Act Amendments
- 1973 – Lead Phaseout in Gasoline (CAA Amendments)
- 1974 – Safe Drinking Water Act
- 1976 – Resource Conservation and Recovery Act
- 1976 – Toxic Substances Control Act
- 1980 – Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)

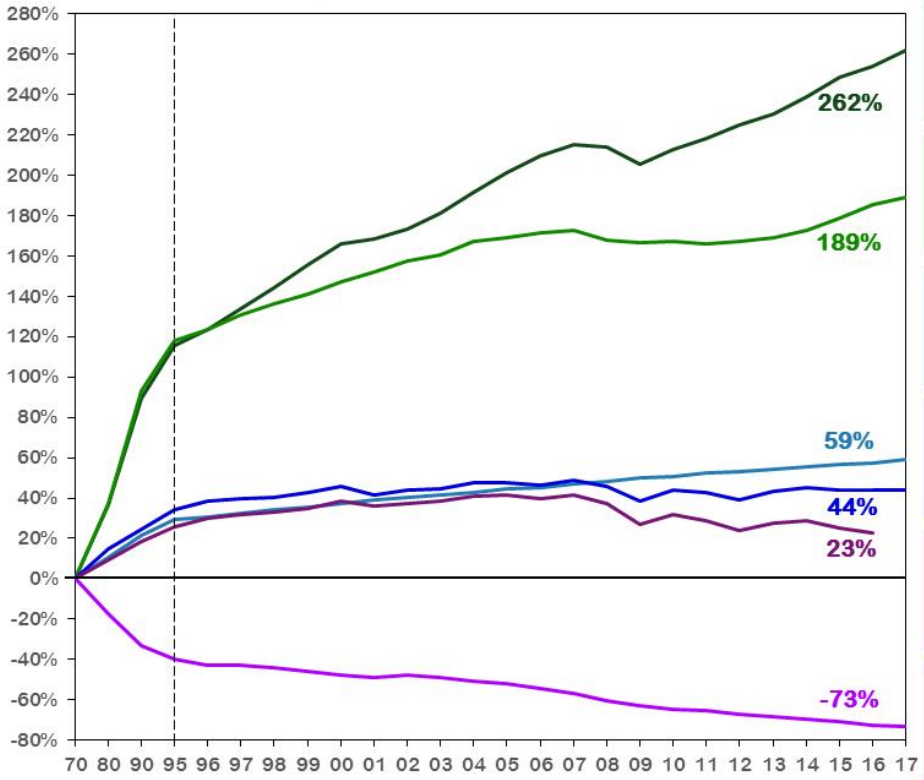
1970: Clean Air Act



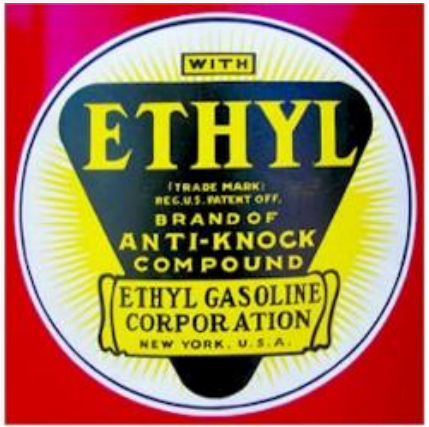
Socks, Knocks, and Rocks

- Criteria Pollutants
  - SOx
  - NOx
  - Particulate matter
  - Carbon monoxide
  - Lead
  - Ozone

Comparison of Growth Areas and Emissions, 1970-2017




240
LUBRICA


WITH
ETHYL
(TRADE MARK)
REG. U.S. PATENT OFF.
BRAND OF
ANTI-KNOCK
COMPOUND
ETHYL GASOLINE
CORPORATION
NEW YORK, U.S.A.

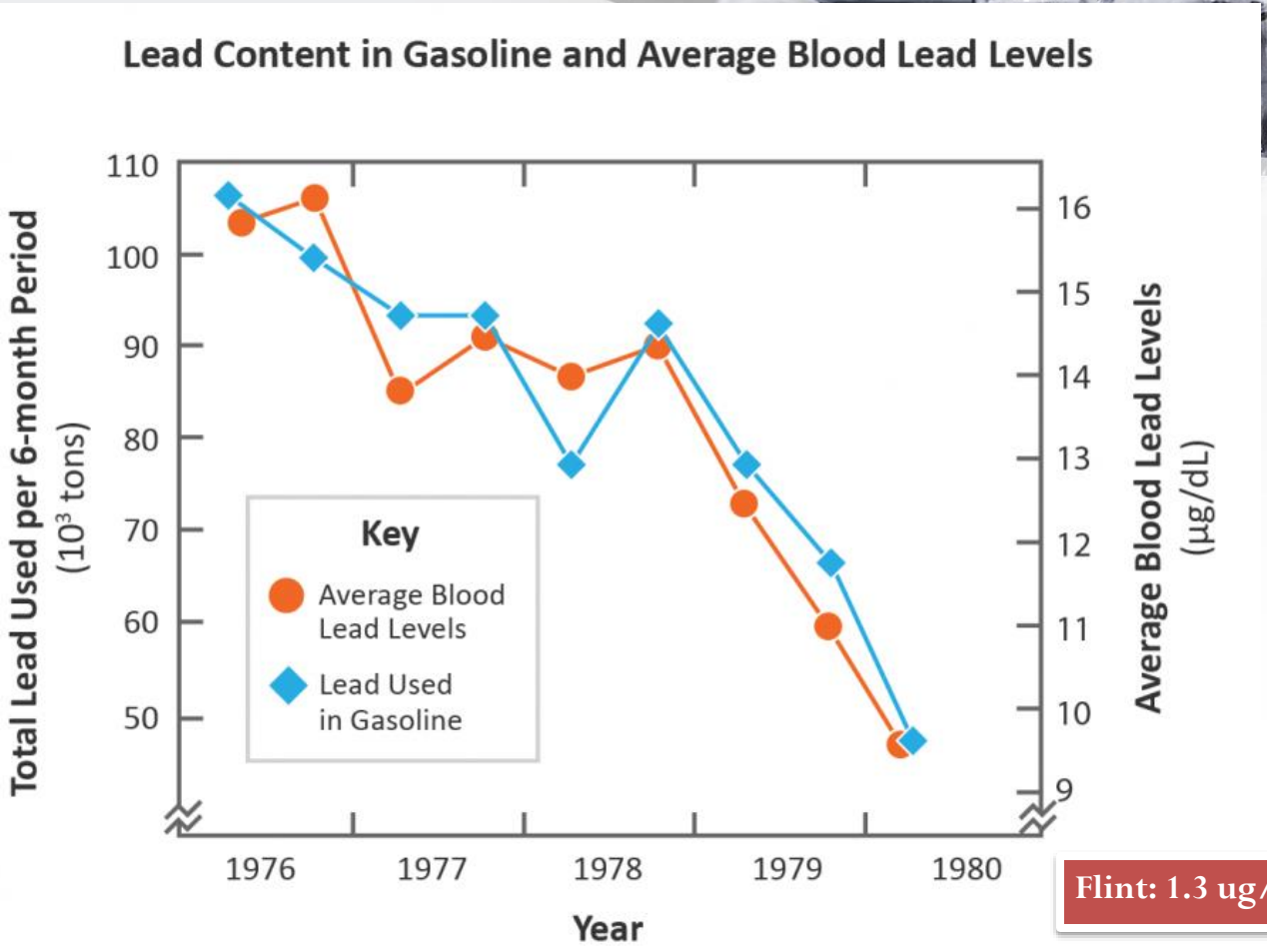

FOR USE AS A
MOTOR FUEL ONLY
CONTAINS
LEAD
(TETRAETHYL)

Phase-out of Lead

1973: EPA Requires Phase-Out of Lead in All Grades of Gasoline

January 1, 1996: Lead is prohibited in gasoline in US

No testing required; regulation implemented by controlling amount of TEL added at the refinery



Flint: 1.3 ug/dl

Air Toxics

- The 1990 CAA amendments added the regulation of emissions of air toxics (Section 112)
  - EPA must set technology-based standards for achieving emissions reductions from point sources.
  - EPA may then issue risk-based standards if the technology-based standards do not eliminate health risk.
  - The technology-based standards are called “Maximum achievable control technology [MACT] standards)”; these are reviewed every 8 years to assess “residual risks”

Air Testing Methods

Source Testing 40 CFR Part 60

Air Emission Measurement Center

- Methods 1 through Method 325B

Ambient Monitoring Technology Information Center (AMTIC)

AMTIC - Air Monitoring Methods

- Criteria Pollutants
- Air Toxics - Monitoring Methods
- Inorganic Compendium
- Toxic Organic Compendium
- Open Path Monitoring
- Passive Monitoring


1969

1970 Clean Water Act

- Objective: the restoration and maintenance of the chemical, physical, and biological integrity of the Nation's waters.
- Goals: zero discharge of pollutants and water quality that is both fishable and swimmable.
- Regulatory Controls:
  - NPDES Permit
  - Effluent Guideline Limitations
  - Mandated test methods, QC, sample preservation

Monitoring under the Clean Water Act

- NPDES outfall monitoring
  - Routine analytes as specified in permit; analytes defined in industry-specific categories, e.g., Part 405: dairy farming
  - Priority pollutants

The 129 Priority Pollutants (1976)

- Listed in Part 122
  - Appendix D; Tables 2 and 3
- 3 removed: 2 freons and bis(2-chloromethyl ether)
- 2378-TCDD only if manufacturer of specified materials
- History and background at:

http://www.epa.gov/waterscience/methods/

- Volatile Organics
- Semivolatile Organics
- Pesticides and PCBs
- Metals, Cyanide and total phenolics

The first comprehensive survey list with organic compounds

Part 136: Test Procedures

- Lists of analytes and approved test procedures for use the Clean Water Act programs
- Sample preservation and holding times
- First GC/MS procedures
- Method Detection Limit procedure

OST Test Method Philosophy

- An interlaboratory validated Reference Method should exist for every analyte
- Mandatory QC embodied in the method
- Laboratories must use the Reference Method and comply with the method QC
- Extensive ability to modify the method added in 2007

Discovery of contamination from organic chemicals in public water systems and the lack of enforceable, national standards persuaded Congress to take action.

NEW ORLEANS AREA WATER SUPPLY STUDY

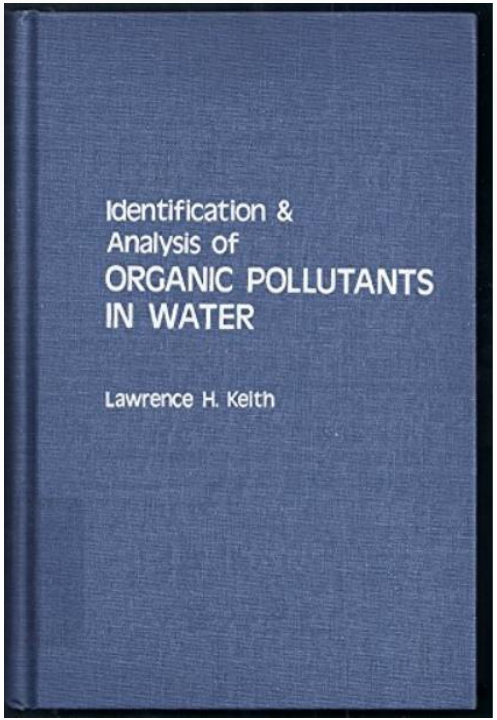
UNITED STATES · ENVIRONMENTAL PROTECTION AGENCY

PREPARED AND SUBMITTED BY
LOWER MISSISSIPPI RIVER FACILITY
SLIDELL, LOUISIANA
SURVEILLANCE AND ANALYSIS DIVISION
REGION VI
U. S. ENVIRONMENTAL PROTECTION AGENCY

1974

1976 Publication ($5.00)

- The Foundations of Organic Pollutant Analysis: 1950 - 1975 (Rosen)
- GC/MS Analysis of Volatile Organics for the National Organics Reconnaissance Survey
- Development of Computerized GC/MS Techniques within the US EPA
- 33 Other Articles



1974 Safe Drinking Water Act

- Authorizes EPA to set health-based standards to control contaminants in drinking water
- Used to be very simple:
  - Part 141: Primary Drinking Water Regulations
  - Part 143: Secondary Drinking Water Regulations
- Has become very complex:
  - UCMR
  - IESTRW
  - LT2ESWTR
  - CCR
  - DBR
  - GWR

Primary Drinking Water Regulations

- Part 141: Subparts A through G, L
  - Maximum Contaminant Levels (MCL)
  - Maximum Contaminant Level Goals (MCLG)
  - Regulated analytes
  - Required methods
  - Required laboratory practices, **including laboratory certification**

Regulated DW Analytes

- 15 inorganics (includes asbestos)
- 21 volatile organics
- 33 synthetic organics (primarily pesticides and PCBs)
- Total coliform
- 4 disinfection by-products
  - Includes THMs and HAA-5
- 3 disinfectant residuals
- 4 radionuclides
- Arsenic and turbidity

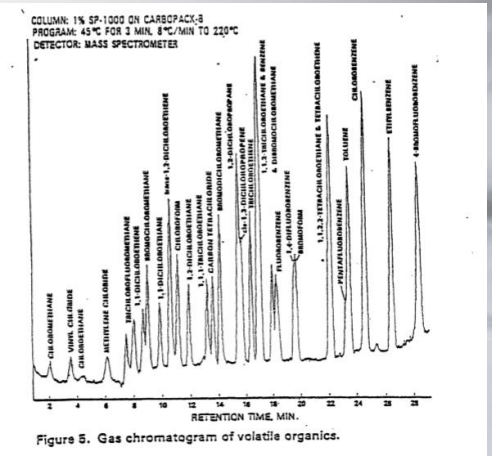


Figure 5. Gas chromatogram of volatile organics.

Monitoring for Regulated Analytes

- Requirements to monitor and frequency contingent on:
  - Population served
  - System type
  - System vulnerabilities
  - State discretion
- Key document not in regulations
  - Technical Notes on Drinking Water Methods
- Methods and Analytes in Subpart C
  - Footnotes to tables extremely important
  - Includes sample preservation and holding times
  - Includes acceptance limits for PE samples

Part 143: Secondary Contaminants

- Relate to aesthetic qualities of water:
  - Aluminum
  - Chloride
  - Color
  - Copper
  - Corrosivity
  - Fluoride
  - Foaming agents
  - Iron
  - Manganese
  - Odor
  - PH
  - Silver
  - Sulfate
  - Total dissolved solids (TDS)
  - Zinc

Unregulated Contaminant Monitoring Rules

- Used to evaluate potential new contaminants
- UCMR 1: 2001-2005, Completed
- UCMR 2: 2007-2010, Completed
- UCMR 3: 2012-2015, Completed
- UCMR 4: 2016-2020, Completed
- UCMR 5: Expected to begin in 2021
- EPA research studies, not a compliance monitoring program
- Used to identify possible additions to Part 141

OGWDW Test Method Philosophy

- A Reference Method must exist for every analyte
- Mandatory QC embodied in the method
- Supplemental details contained in Technical Notes on Drinking Water Methods
- Laboratories must use the Reference Method and comply with the method QC and Technical Notes
- Very prescriptive and little method flexibility
- New process for “equally effective” methods


1975: Increased knowledge about waste disposal

1976 Resource Conservation and Recovery Act

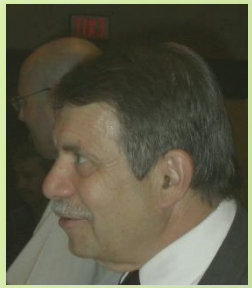
- Solid Waste Program: Subtitle D
  - manages nonhazardous waste, sets criteria for landfills and other disposal facilities, and prohibits open dumping
- Hazardous Waste Program: Subtitle C
  - controls hazardous waste from “cradle to grave”
- Underground Storage Tank Program: Subtitle I
  - regulates underground storage tanks containing hazardous substances and petroleum products.

RCRA and Superfund

- Both address legacy issues
- Superfund more comprehensive
- Superfund tends to focus on imminent danger
- Comparable approaches to cleanups, but different terminology
- Groundwater monitoring not automatic for Superfund, but always required for RCRA TSDFs

260.11: SW-846

- SW-846 no longer referenced in the RCRA regulations
- 17 SW-846 methods are referenced for specific applications



First Annual

United States

Environmental Protection Agency

Symposium

On

Solid Waste Testing and Quality Assurance

PROCEEDINGS

July 23-26, 1985
Washington, D.C.
Vista International Hotel

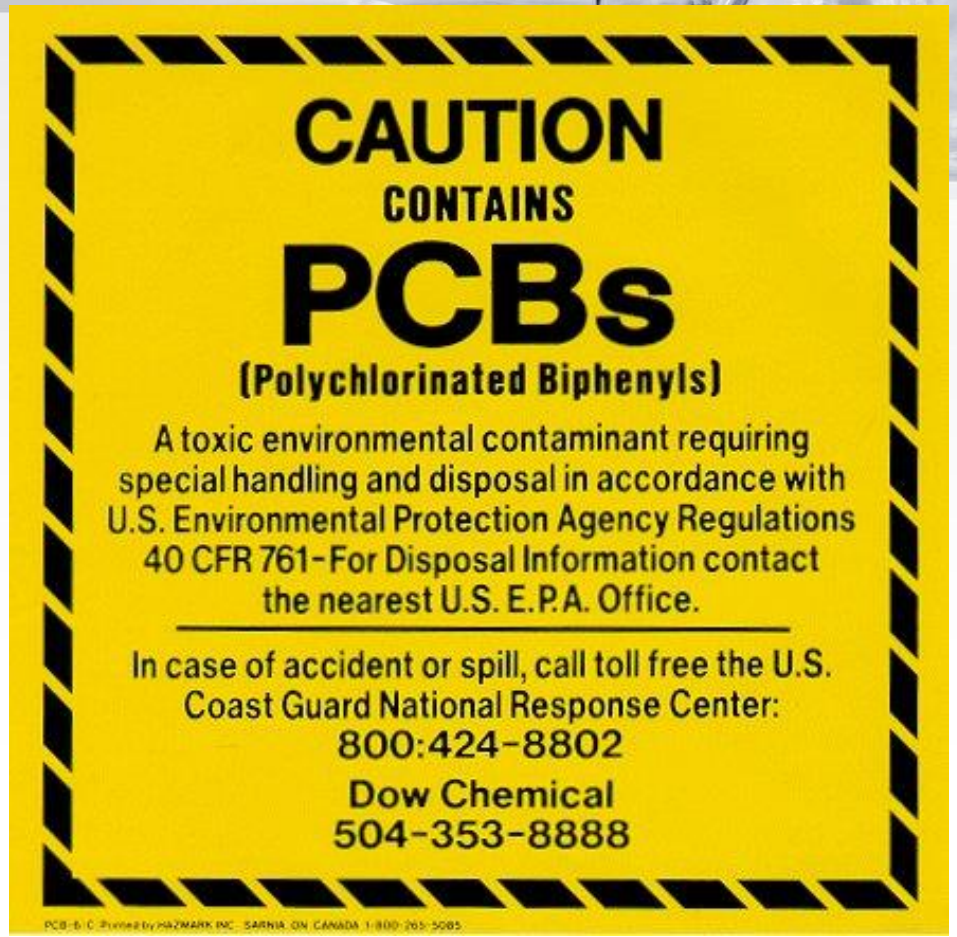
ORCR Test Method Philosophy

- Laboratories may use any method
- Extensive ability to modify the method
- QC included in Chapter 1 of SW-846
- "QA Project Plans govern all details"
- Analytes listed are conceptually measurable
  - e.g. methanol by 8260; phthalic anhydride by 8270

Caution: Some states still mandate SW-846 methods.
DOD/DOE require SW-846 methods with explicit instructions.

Part 270 Underground Storage Tanks

- Management and reporting requirements
- Leak detection, tank construction, etc.
- No discussion of testing requirements
  - owners and operators must assemble information about the site and the nature of the release
- UST testing tends to be governed at the state level


CAUTION
CONTAINS
PCBs
(Polychlorinated Biphenyls)
A toxic environmental contaminant requiring special handling and disposal in accordance with U.S. Environmental Protection Agency Regulations 40 CFR 761-For Disposal Information contact the nearest U.S. E.P.A. Office.
In case of accident or spill, call toll free the U.S. Coast Guard National Response Center:
800:424-8802
Dow Chemical
504-353-8888

1929 to 1979

1976 Toxic Substances Control Act

- Regulation of chemicals used in commerce
- Excludes food, drugs, cosmetics regulated by FDA
- Excludes pesticides regulated by FIFRA
- Includes specifically asbestos, lead-based paint and PCBs

Part 761: The PCB Regulations

- PCBs banned in 1979
- Present in many products
  - Transformer oil, hydraulic oil, adhesives, caulk, …
  - Gas pipeline liquids
- Extensive requirements for sampling procedures
- Comprehensive cleanup levels for all type of media
- Virtually no requirements for analytical methods
- Some remediation wastes require use of SW-846 methods 3500B/ 3540C or 3500B/3550B and 8082, or an alternate method validated according to Subpart Q

1978: Valley of the Drums

1980 Superfund

- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- Part 300
  - Also includes oils spills
- Process
  - Site Assessment
  - Listing in National Priority List (NPL)
  - Site Investigation
  - Remedial Action
  - Closure/Post closure

The Contract Laboratory Program

- Not required by regulation
- Established to provide cost-effective survey of some common contaminants
- Original list was Priority Pollutants plus chemicals from Love Canal (C-55, C-56)
- List and methods modified from time to time to reflect new interests and technology improvements

The Contract Laboratory Program

- Introduced Tentatively Identified Compound (TIC) concept
- Pioneered data validation as a means of reviewing laboratory data.
- Pioneered electronic data deliverables.
- Now expanded to include “Special Analytical Services.

Summary of EPA Organization and Regulations

- EPA created “Program Offices” for each major statute.
  - Air and Radiation (OAR)
  - Water (OW)
  - Solid Waste and Emergency Response (OSWER)
  - Chemical Safety and Pollution Prevention (OCSPP)
- Each Program Office develops its own constituents of concern, data quality objectives, QC requirements and test methods.
- Some laws require EPA to consider cost-effectiveness or related issues in establishing regulated limits; others do not.

Proliferation of Test Methods

- OW/OST 624
- OW/OGWDW 524
- OSW 8240 → 8260
- CLP SOW for Volatile Organics
- OAR TO-15

Improved coordination is needed in the Agency's methods development program to avoid duplication in the development and standardization of test procedures and inconsistencies in quality assurance and quality control guidelines.

EPA Report to Congress, 1988

Using the Methods

SDWA

- Promulgated methods must be used
- Laboratories cannot deviate from the promulgated method without prior EPA or State approval.

CWA

- Lab must use the methods that have been promulgated.
- Lab may make changes in the method.
- Chemistry of the method must not be changed and the performance of the modification must be documented to show that equivalence in accuracy, precision, and sensitivity with the promulgated method.

RCRA

- Lab can use any SW846 method as long as the performance of the method meets the requirement
- SW-846 methods are considered as guidance.
- For method defined parameters, the methods specified in the regulations must be used.

CAA

- Promulgated methods must be used
- Lab may make changes in the method provided that the chemistry is the same and performance of the modification is documented to show equivalence in accuracy, precision, and sensitivity with the promulgated method.

Beyond the Approved Methods

Methods are not the final resource for requirements

Standards and Accreditation Requirements (Typical, not all inclusive):

- TNI Standard 2016
- DoD Quality Systems Manual 5.3
- Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition (and supplements and Technical Notes)
- Client Technical Specifications documents
- State-specific certification rules

Methods and Regulations supersede TNI and other Standard requirements where they are more stringent.

Considerations

Program and/or Accreditation standards contain additional requirements that may be more strict than the approved method.

Where the method is more strict, follow the method ….. Where the standard is more strict, follow the standard.

Beyond the Approved Methods

Methods are not the final resource for requirements

Additional Quality Control requirements may be found in:

- Standard Methods - QC sections per group of methods.
- SW-846 - Chapters or in the General Method preceding groups of methods (i.e., 8000, 5000, 4000, 3600, 3500, etc).
- Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition (and supplements)
- 40 CFR Parts 136 and 141 - Tables and Footnotes (Footnotes are easily forgotten or overlooked)
- State Regulations for accreditation or compliance program may have additional requirements that are more strict than the Federal Regulation, Standards or Methods. (Primacy vs Non-Primacy, etc)
- Other programs or method manuals related to approved methods

Methods and Regulations supersede NELAC/TNI and other Standard requirements where they are more stringent.

Considerations

Regulations and Method related documents contain additional requirements that may be more strict than just the method.

Where the method is more strict, follow the method ….. Follow the regulation or related document where it is more strict.

Example decision tree:

Lab A is TNI accredited and DoD accredited and needs to determine requirements for Cyanide by SM4500CN-E:

- Review Method 4500CN for method requirements.
- Review SM Table 4020:I as referenced in the method for QC requirements
- 40 CFR Part 136 – Most current version includes most recent MUR. Review to make sure sample handling requirements are being met (preservation, holding time, bottles, etc.).
- Ensure that applicable TNI Standard requirements are met regarding quality systems associated with Method 4500CN-E (documentation, standard traceability, calibration requirements, SOP requirements, PT requirements, etc.).
- Ensure that additional requirements in the current DoD QSM are met for quality systems (in addition to TNI Standard).
- Ensure that SOP has all of the QC requirements per the accreditation standards, method and MUR (i.e., calibration, batch QC, etc.)

Example decision tree:

Lab B is accredited by their home state for DW and has TNI accreditation and needs to determine requirements for EDB by Method 504.1:

- Review Method 504.1 for method requirements.
- Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition and Supplements
- 40 CFR Part 141 – Review to make sure sample handling requirements are being met (preservation, holding time, bottles, etc.).
- Ensure that MDL has been determined – 40 CFR Part 141 references the MDL procedure in Part 136 Appendix B
- Ensure that TNI Standard requirements are met regarding quality systems (documentation, standard traceability, calibration requirements, SOP requirements, PT requirements, etc.).
- Assuming that the sample was collected in their home state, review additional requirements in the State regulations for both DW analysis and lab accreditation to ensure that requirements are met for quality systems (in addition to TNI Standard).
- Ensure that SOP has all of the QC requirements per the accreditation standards, method and Part 141 (i.e., calibration, batch QC, etc.)

The Past

- Every EPA program has their own unique and ever-changing test method requirements.
- State and EPA regions frequently override the federal regulations.
- Learn the regulatory process and track changes as they evolve

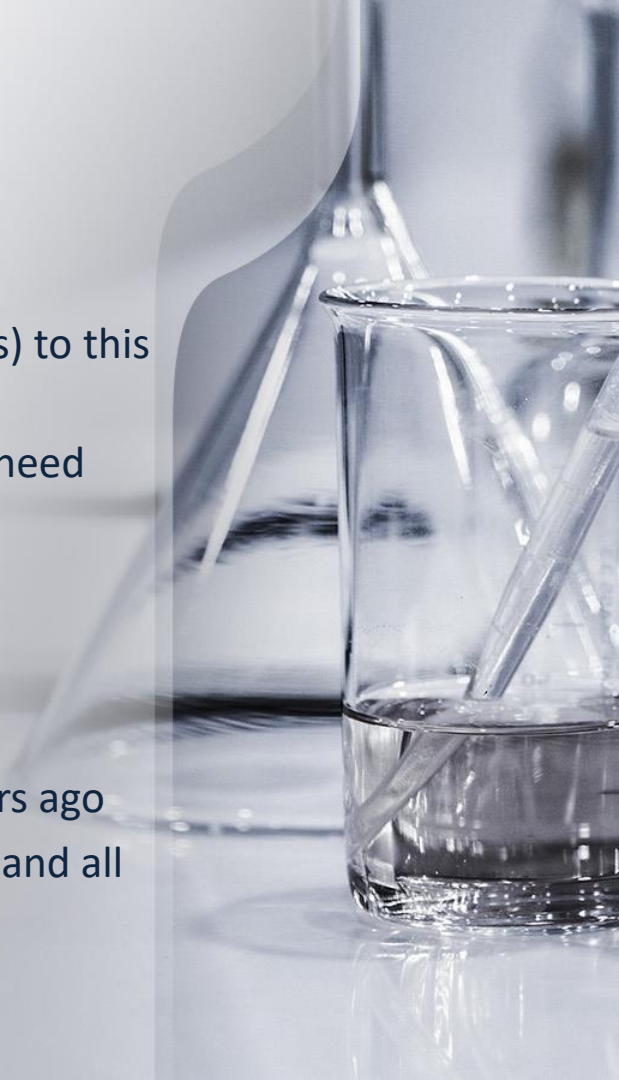
The Present

- If nothing is done to change the current process:
  - Each program will continue to work independently.
  - Program-specific analyte lists and program-specific methods will continue to proliferate (e.g., PFAS).
  - VCSB methods will continue to be considered second-class.
  - Little to no emphasis on non-target analysis.

The Future (10-15 years)

- Create a Center of Excellence for Methods
  - Each program office would send their method needs (MQO's) to this Center
  - The Center would evaluate existing methods relative to the need
  - The Center would reach out to VCSB's for new methods in accordance with OMB A-119
- Change the regulatory paradigm
  - Move away from target lists to non-target screening
  - Focus on emerging contaminants, not those banned 50 years ago
  - Mandate a national program for accreditation for all media and all laboratories

Would require legislation and major EPA reorganization



THANK YOU!

Jerry Parr

Executive Director

The NELAC Institute

jerry.parr@nelac-institute.org

817-594-7204

Judy Morgan

Chief Compliance Officer

Pace Analytical

Judy.morgan@pacelabs.com

615-347-5418