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THE TOXIC SUBSTANCES CONTROL ACT: A CHEMIST'S VIEW

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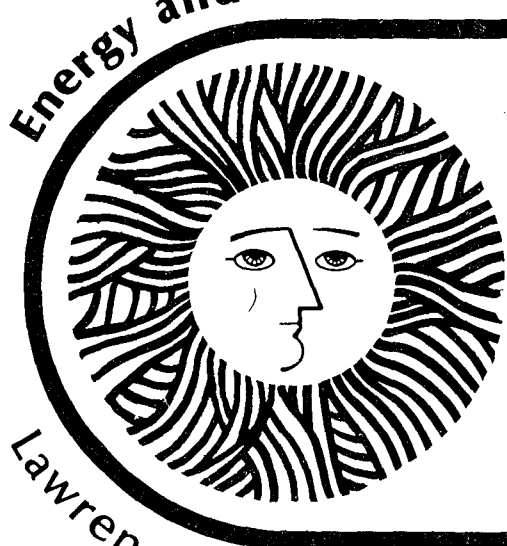
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The Toxic Substances Control Act:
A Chemist's View

Mathilde J. Kland

June 16, 1978

Lawrence Berkeley Laboratory University of California/Berkeley

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THE TOXIC SUBSTANCES CONTROL ACT:
A CHEMIST'S VIEW

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Presented before Section K
AAAS Pacific NW Meeting
Symposium on Environment and Society
University of Washington, Seattle
June 16, 1978

THE TOXIC SUBSTANCES CONTROL ACT: A CHEMIST'S VIEW

THE WIDESPREAD USE OF PETROCHEMICAL DERIVATIVES IN FOODS, DRUGS, COSMETICS AND CONSUMER GOODS, AND THE PRESENCE OF TOXIC AND CARCINOGENIC POLLUTANTS IN AIR AND WATER HAS BEEN SUFFICIENTLY WELL DOCUMENTED BY NOW TO BE THE CAUSE OF DEEP CONCERN (1). AS THE BACKGROUND LEVELS OF THESE ENVIRONMENTAL POLLUTANTS INCREASES, IT BECOMES PROGRESSIVELY MORE DIFFICULT TO PINPOINT THE CONTRIBUTION OF INDIVIDUAL POLLUTANTS TO THE INCREASING INCIDENCE OF CERTAIN FORMS OF CANCER, HEART AND OTHER CIRCULATORY AND RESPIRATORY AILMENTS, NOT TO MENTION A GROWING SUSCEPTIBILITY TO ALLERGIC, CENTRAL NERVOUS SYSTEM (CNS) AND EMOTIONAL DISORDERS.

WITH EXPANDING AWARENESS IN THE PUBLIC SECTOR IT IS BECOMING MORE DIFFICULT TO SATISFY THE LAY PERSON WITH THE ARGUMENT THAT THE INCIDENCE OF THE SO-CALLED "DEGENERATIVE DISEASES" - E.G., ARTHRITIS, DIABETES, CANCER AND OTHER METABOLIC PATHOLOGIES, ARE ONLY THE CONCOMITANTS OF A GROWING LIFE EXPECTANCY -- TOO OFTEN IT IS THE CHILD OR YOUNG PERSON WHO IS AFFECTED BY A LEUKEMIA, AN ALLERGEN INDUCED ASTHMA, OR SOME SERIOUS METABOLIC OR CNS DISORDER, AND OUR MORTALITY RATES FOR THE VERY YOUNG ARE EMBARRASSINGLY HIGH FOR A MEDICALLY AND TECHNOLOGICALLY ADVANCED SOCIETY (2).

BECAUSE OF THEIR RELATIVELY LOW LEVEL AND THE MULTIPLICITY OF TOXICANTS IN AIR AND WATER, IT IS NOT SURPRISING THAT OUR EARLIEST

PAGE TWO

AWARENESS OF THE EFFECTS OF SUBSTANCES SUCH AS CHIMNEY SOOT, RADON EMANATIONS FROM COAL, THE COAL TAR DYES, CHLORINATED HYDROCARBONS, AND ARSENIC, FOR EXAMPLE, STEMMED FROM THE OBSERVATION OF OCCUPATIONALLY RELATED DISEASES (3) SUCH AS LUNG AND BLADDER CANCER, EMPHYSEMA, HEART DISEASE, ASTHMA AND CONTACT DERMATITIS, RATHER THAN FROM ENVIRONMENTAL OBSERVATIONS.

UNFORTUNATELY THESE HEALTH HAZARDS ARE RAPIDLY OUTSTRIPPING THE WORKPLACE AND BEING CARRIED INTO THE HOME AND COMMUNITY. WITNESS THE HIGHER INCIDENCE OF STILL-BORN AND MISCARRIAGES AMONG THE WIVES OF VINYL CHLORIDE WORKERS (4), AND OF CANCER IN THE FAMILIES OF ASBESTOS WORKERS, WHO BRING THE FINE FIBERS HOME ON THEIR CLOTHING, HAIR, ETC. ASBESTOS INSULATION IS UBIQUITOUS OUTSIDE OF THE WORKPLACE, AS ARE THE VINYL CHLORIDE BASED PRODUCTS (E.G., PVC PIPE, PLASTIC WRAP, VINYL TILE, UPHOLSTERY AND CARPETING).

HOW DOES SOCIETY PROTECT THE PUBLIC HEALTH IN A HIGH TECHNOLOGY ENVIRONMENT, ECONOMICALLY COMMITTED TO, AND INCREASINGLY DEPENDENT ON, PETROCHEMICAL - BASED FERTILIZERS, FABRICS, FOOD ADDITIVES, PHARMACEUTICALS, FURNISHINGS AND GOODS IN EVER EXPANDING ARRAY?

BY THE BEGINNING OF THE 70'S POLLUTION PROBLEMS HAD BECOME SUFFICIENTLY PRESSING TO TRIGGER A SPATE OF ENVIRONMENTAL LEGISLATION PROTECTING OUR AIR AND WATERWAYS (5). THE LAST ENVIRONMENTAL BASTION TO FALL WAS THE CHEMICAL INDUSTRY WHICH HELD OUT FOR FULLY 5 YEARS AGAINST THE GROWING PRESSURE FOR GOVERNMENT REGULATION OF THE PROLIFERATION OF CHEMICALS WHOSE ADVERSE BIOLOGICAL

PAGE THREE

AND ECOLOGICAL EFFECTS WERE BECOMING INCREASINGLY EVIDENT (6). WITNESS THE PERSISTENT PESTICIDE DDT, THE TRANQUILIZER THALIDOMIDE (A TERATOGEN WHICH RESULTED IN DEFORMED CHILDREN, WITH FLIPPERS FOR HANDS), VINYL CHLORIDE (A CARCINOGEN), THE PHOSPHATE BASED (NERVE POISON) PESTICIDES, THE NEMATOCIDE DBCP (A SUSPECT CARCINOGEN, JUST RECENTLY ASSOCIATED WITH STERILITY IN MALE WORKERS) -- TO LIST BUT A SAMPLING.

(S-1) INEVITABLY, INDUSTRY DID SUCCUMB, AND THE TOXIC SUBSTANCES CONTROL ACT (TSCA) WAS ENACTED INTO LAW OCT. 11, 1976 (7). IN THE REMAINDER OF THIS PAPER I SHALL ATTEMPT TO COVER SOME OF THE SALIENT FEATURES OF PUBLIC LAW 94-469, EPA'S APPROACH TO IMPLEMENTATION OF ITS PROVISIONS, AND SOME OF MY PERCEPTIONS (AS A CHEMIST) OF TSCA'S PROSPECTS OF SUCCESS.

PUBLIC LAW 94-469: THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

AS OF JANUARY 1, 1977 THE TOXIC SUBSTANCES CONTROL ACT REQUIRES THAT "INDUSTRY MUST PROMPTLY NOTIFY EPA OF ANY INDICATION OF SUBSTANTIAL RISKS FROM COMMERCIAL CHEMICALS..." (GLEN E. SCHWEITZER, EPA/OTS (8)).

GOAL OF TSCA

(S-2) THE GOAL OF THIS LEGISLATION IS "PROTECTION AGAINST UNREASONABLE RISK". SECTION 2 OF TSCA PLACES SPECIFIC RESPONSIBILITY ON INDUSTRY TO GATHER INFORMATION APPROPRIATE TO THE PURPOSE OF THE CHEMICAL.

Public Law 94-469
94th Congress

An Act

To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes.

Oct. 11, 1976
[S. 3149]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

This Act may be cited as the "Toxic Substances Control Act".

Toxic Substances
Control Act.
15 USC 2601
note.

TABLE OF CONTENTS

- Sec. 1. Short title and table of contents.
- Sec. 2. Findings, policy, and intent.
- Sec. 3. Definitions.
- Sec. 4. Testing of chemical substances and mixtures.
- Sec. 5. Manufacturing and processing notices.
- Sec. 6. Regulation of hazardous chemical substances and mixtures.
- Sec. 7. Imminent hazards.
- Sec. 8. Reporting and retention of information.
- Sec. 9. Relationship to other Federal laws.
- Sec. 10. Research, development, collection, dissemination, and utilization of data.
- Sec. 11. Inspections and subpoenas.
- Sec. 12. Exports.
- Sec. 13. Entry into customs territory of the United States.
- Sec. 14. Disclosure of data.
- Sec. 15. Prohibited acts.
- Sec. 16. Penalties.
- Sec. 17. Specific enforcement and seizure.
- Sec. 18. Preemption.
- Sec. 19. Judicial review.
- Sec. 20. Citizens' civil actions.
- Sec. 21. Citizens' petitions.
- Sec. 22. National defense waiver.
- Sec. 23. Employee protection.
- Sec. 24. Employment effects.
- Sec. 25. Studies.
- Sec. 26. Administration of the Act.
- Sec. 27. Development and evaluation of test methods.
- Sec. 28. State programs.
- Sec. 29. Authorization for appropriations.
- Sec. 30. Annual report.
- Sec. 31. Effective date.

SEC. 2. FINDINGS, POLICY, AND INTENT.

(a) **FINDINGS.**—The Congress finds that—

- (1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures;
- (2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and
- (3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) **POLICY.**—It is the policy of the United States that—

- (1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environ-

15 USC 2601.

INDUSTRY'S RESPONSIBILITIES

I CHEMICAL ASSESSMENTS

- Complete and current records
- Data base adequate for assessment
 - (a) Existing data (literature and in house)
 - (b) Additional research data generated
- Expertise
- Risk assessment

II PRESENTATION OF INFORMATION

- Risk assessments must:
 - (a) Have adequate documentation
 - (b) Address environmentally significant issues
 - (c) Be easily understood
- Data submitted must:
 - (a) Have adequate quality control
 - (b) Be timely
 - (c) Follow prescribed format

PAGE FOUR

THE LAW ALSO REQUIRES RECORD KEEPING ON ALL COMMERCIAL CHEMICALS, WITH SELECTIVE REPORTING.

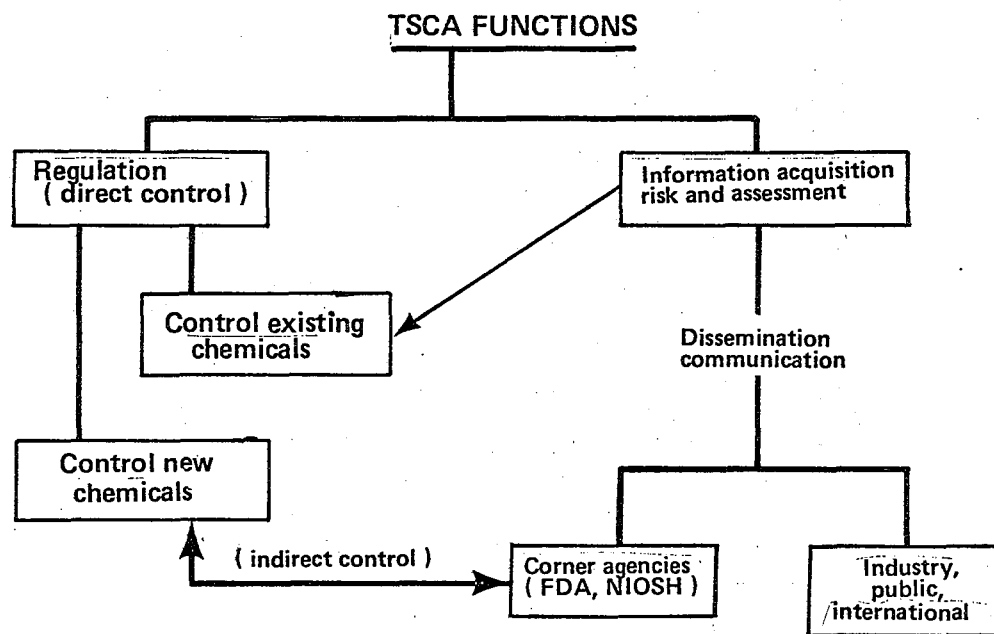
MAJOR FUNCTIONS OF TSCA

(S-3) THE MAJOR FUNCTIONS OF PL 94-469 (TSCA) ARE DELINEATED IN THE NEXT SLIDE. THEY MAY BE DIVIDED INTO A REGULATORY FUNCTION (LEFT SIDE OF CHART) AND AN INFORMATION FUNCTION, ESSENTIAL TO IMPLEMENTING THE DIRECT CONTROL OF EXISTING CHEMICALS AS WELL AS THE CONTROL OF NEW CHEMICALS, EITHER DIRECT OR INDIRECT, VIA OTHER AGENCIES (FDA, HEW, ETC.)

OF THE 31 SECTIONS WHICH CONSTITUTE TSCA, PERHAPS THE MOST CONTROVERSIAL AND DIFFICULT TO IMPLEMENT ARE THOSE DEALING WITH TESTING (SEC. 4) AND CONFIDENTIALITY (SEC. 8 - REPORTING AND RETENTION OF INFORMATION.)

(S-4) CONDITIONS FOR CONFIDENTIALITY AND TESTING REQUIREMENTS ARE SHOWN ON THE NEXT SLIDE.

THE LAW "PROVIDES FOR FUNDS TO PUBLIC INTEREST GROUPS WHICH CANNOT OTHERWISE AFFORD TO PARTICIPATE IN IMPLEMENTATION ACTIVITIES..." AND ALSO MAKES "PROVISION FOR REIMBURSEMENT WHEN ONE COMPANY TESTS A CHEMICAL AND ANOTHER WANTS TO USE THAT TESTING" (SCHWEITZER). UNDER THE LAW, CITIZENS HAVE THE RIGHT TO PETITION THE EPA TO TAKE SPECIFIC ACTIONS WITH REGARD TO A CHEMICAL (SEC. 21).



TSCA INFORMATION ACQUISITION

GENERAL POLICY

- Purposeful information ("no fishing expeditions")
- Quality control of information (reliability)
- Coordination of Agency reporting requirements (to avoid duplications)

CONFIDENTIALITY

- Segregate confidential information
- Notify before releasing it
- Release ALL test data

TESTING

- By category
- By hierarchical scheme
- For bio-effects and exposure factors
- EPA guidelines/industry protocols

REPORTING AND RECORDKEEPING

- Records on all chemicals
- Selective reporting

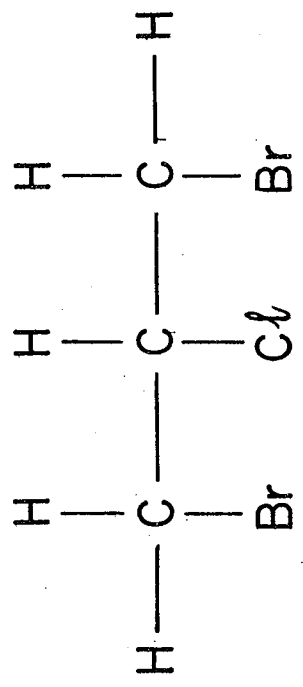
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PRIORITIES

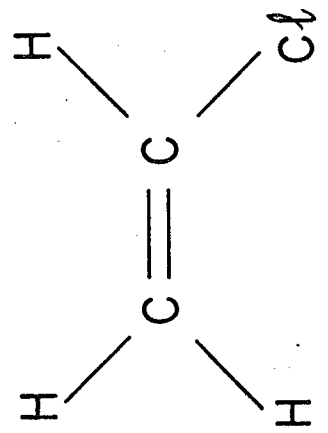
(S-5) EPA HAS SELECTED 4 HIGH PRIORITY AREAS IN IMPLEMENTING TSCA: 1) ESTABLISHMENT OF A PREMARKET REVIEW SYSTEM; 2) DEVELOPMENT OF INITIAL TESTING REQUIREMENTS; 3) REGULATORY ACTIONS (LIMITED, OF NECESSITY), AND 4) RESPONSE TO "UNANTICIPATED PROBLEMS". IN THE PAST THE AGENCY HAS BEEN CRITICIZED FOR REACTING TO CRISES RATHER THAN ANTICIPATING SERIOUS ENVIRONMENTAL PROBLEMS (VINYL CHLORIDE, KEPONE, DBCP, ETC.) IT WOULD THEREFORE APPEAR TO BE DESIRABLE TO LAY GREATER EMPHASIS ON THE KINDS OF BASIC RESEARCH INTO CHEMICAL STRUCTURE-TOXICITY RELATIONSHIPS WHICH WOULD FACILITATE THE A PRIORI PREDICTION OF CHEMICAL BEHAVIOR. THE RECENT DBCP INCIDENT IS A CLASSIC EXAMPLE. HALOGENATED ORGANICS HAVE LONG BEEN SUSPECT (9) -- YET IT TOOK THE CHANCE DISCOVERY OF STERILITY OR LOW FERTILITY AMONG MALE WORKERS THIS PAST YEAR TO ACTIVATE CONTROL OF A STERILANT WHICH IS ALSO A MUTAGEN AND POTENTIAL CARCINOGEN.

THE PRESENT PRIORITIES ALSO PLACE ON THE "BACK BURNER" OUR INCREASING CONCERN WITH HIGH VOLUME INDUSTRIAL PETROCHEMICALS AS CARCINOGENS. NO DOUBT YOU'VE HEARD OF THE SO CALLED "CANCER MAP" OF THE U.S., SHOWING THE DENSITY DISTRIBUTION OF CANCER INCIDENCE AS A FUNCTION OF LOCATION. WELL, NEW JERSEY, WITH A HEAVY PETROCHEMICAL INDUSTRY AND MY OWN CONTRA COSTA COUNTY IN CALIFORNIA, WHICH IS STRONG ON OIL REFINERIES, APPARENTLY SHARE THE DUBIOUS DISTINCTION OF RATING HIGH ON THE CANCER INCIDENCE LIST, ACCORDING TO EPIDEMIOLOGIC STUDIES. A FURTHER STUDY IS PLANNED FOR CC COUNTY. MEANWHILE,

S-5



DBCP



VC

PAGE SIX

ONE CAN ONLY HOPE THAT THESE SUSPECT POINT SOURCES OF POLLUTION WILL COME UNDER MORE STRINGENT FUTURE SURVEILLANCE AND CONTROL, SINCE THE CONTROL TECHNOLOGY IS ALREADY AVAILABLE.

(S-4)* INFORMATION ACQUISITION

EPA STRESSES THE NEED FOR SELECTIVITY IN REQUIRING INFORMATION ("NO FISHING EXPEDITIONS"!); A SECOND CONSIDERATION FOR THE AGENCY IS THE INFORMATIONAL NEEDS OF OTHER PROGRAMS AND PARTIES, AND EPA'S FUNCTION IN DISSEMINATING SUCH INFORMATION.

CONFIDENTIALITY IS UNDERSTANDABLY A SORE POINT WITH THE CHEMICAL INDUSTRY -- BUT IT MUST LEARN TO LIVE WITH THE CONGRESSIONAL DECISION (TSCA, SECTIONS 2 AND 8) THAT ALL HEALTH AND SAFETY (H&S) INFORMATION BELONGS IN THE PUBLIC DOMAIN.

TESTING

AS TO TESTING, WITH OVER 4 MILLION LISTINGS ALREADY IN CHEMICAL ABSTRACTS (CA) THE NEED FOR PROCEEDING BY CATEGORY OR CHEMICAL CLASS IS APPARENT, NOTWITHSTANDING BEHAVIORAL VARIABILITY WITHIN A CLASS. SIMILARLY, CONSIDERATION OF PRODUCTION VOLUME, USE, AND LEVELS OF EXPOSURE OF THE POPULATION AT LARGE MUST BE FACTORED INTO THE PRIORITIZATION PROCESS.

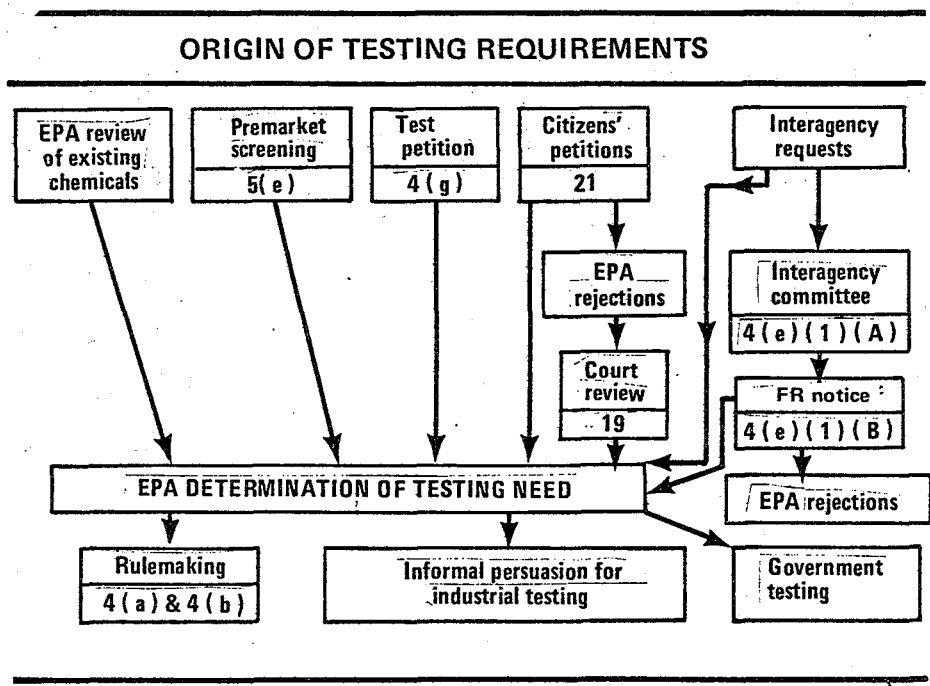
FINALLY, THE EPA HAS PROPOSED THAT PRESCRIBED MINIMUM TOXICOLOGICALLY

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POSITIVE TEST LEVELS BE USED TO TRIGGER FURTHER TESTING. THESE FACTORS COMPRISE WHAT IS KNOWN AS A HIERARCHICAL SCHEME AND MERELY SERVE AS GUIDELINES TO AGENCY DECISION - MAKING, WITH INDUSTRY RETAINING RESPONSIBILITY FOR DEVELOPING THE INDIVIDUAL TEST PROTOCOLS APPROPRIATE TO EACH CHEMICAL.

TESTING SHOULD DO MORE THAN REVEAL BIOLOGICAL EFFECTS. RATHER, IT SHOULD SERVE AS A TOOL FOR SETTING PERMISSIBLE EXPOSURE LEVELS, SO THAT MEANINGFUL RISK ASSESSMENTS CAN BE MADE. AT LEAST, SUCH IS THE PHILOSOPHY OF THE EPA. HAVING STATED AS MUCH, I FEEL OBLIGED TO ADD THAT REDUCTION OF THE EXPOSURE LEVEL OF AN INDIVIDUAL CHEMICAL TO SOME "ACCEPTIBLE" VALUE STILL LEAVES OPEN THE QUESTION OF SYNERGISTIC EFFECTS BETWEEN CHEMICALS WHICH FREQUENTLY ENHANCE TOXICITY OR CARCINOGENICITY ("PROMOTERS"). NOR ARE THE WIDE INDIVIDUAL VARIATIONS IN SENSITIVITY, WHETHER FOR GENETIC OR HEALTH REASONS, ADDRESSED BY TSCA. PERHAPS THIS IS EXPECTING TOO MUCH FOR THE PRESENT.

(S-6) THE NEED FOR TESTING A CHEMICAL UNDER TSCA IS DETERMINED BY EPA BASED ON PRIOR ACTIONS SHOWN ON THE NEXT SLIDE. IT MAY STEM FROM THE PREMARKET SCREENING; FROM A REVIEW OF EXISTING CHEMICALS; FROM AN INDUSTRIAL TEST PETITION, CITIZENS' PETITIONS OR FROM INTERAGENCY REQUESTS.



PAGE EIGHT

(S-7) RECORD KEEPING

RECORD KEEPING IS VIEWED AS THE FOUNDATION OF THE DATA BASE. A CHEMICAL PLANT OR COMPANY IS EXPECTED TO UPDATE ITS ARCHIVES ON EVERY CHEMICAL WHICH IT PROCESSES AND TO MAINTAIN THE DATA IN AN EASILY RETRIEVABLE FORM, QUICKLY ACCESSIBLE TO A GOVERNMENT AGENCY

(S-8) ON REQUEST. THE NEXT SLIDE ILLUSTRATES IN MORE DETAIL THE KINDS OF INFORMATION LIKELY TO BE REQUIRED BY THE EPA.

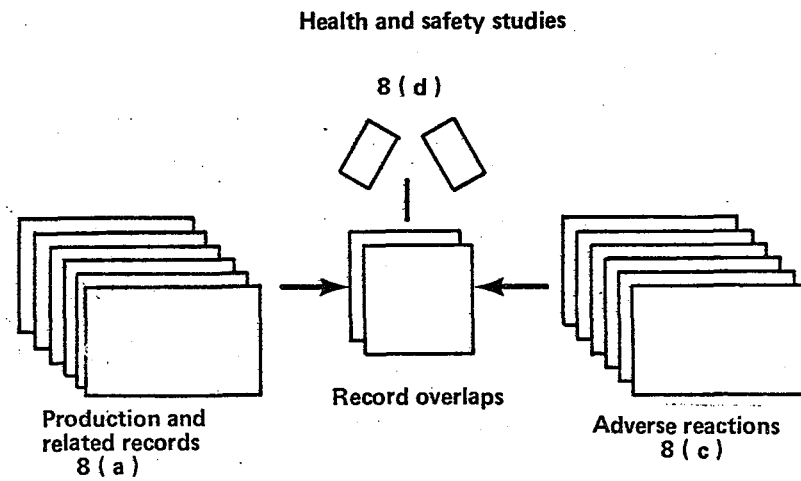
THE PHILOSOPHY THAT THE INDIVIDUAL COMPANY SHOULD BE THE REPOSITORY OF THIS DATA, BUT THAT THE GOVERNMENT SHOULD BE AWARE OF ITS EXISTENCE AND HAVE READY ACCESS, IS AN UNDERSTANDABLE SORE POINT WITH INDUSTRY, BOTH FROM THE STANDPOINT OF COST AND JEOPARDY TO PROPRIETARY INFORMATION.

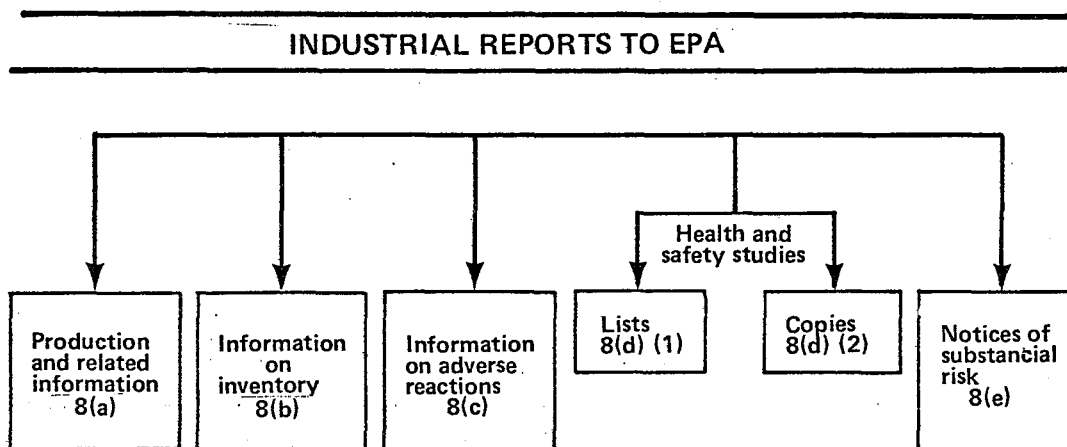
PREMARKET REVIEW

(S-9) THE PREMARKET REVIEW PROCESS FOR A NEW CHEMICAL IS SHOWN ON THE NEXT SLIDE, AND IS REASONABLY SELF-EXPLANATORY. AN INCOMPLETE NOTIFICATION WILL BE REJECTED BY THE AGENCY. TECHNICAL REVIEW

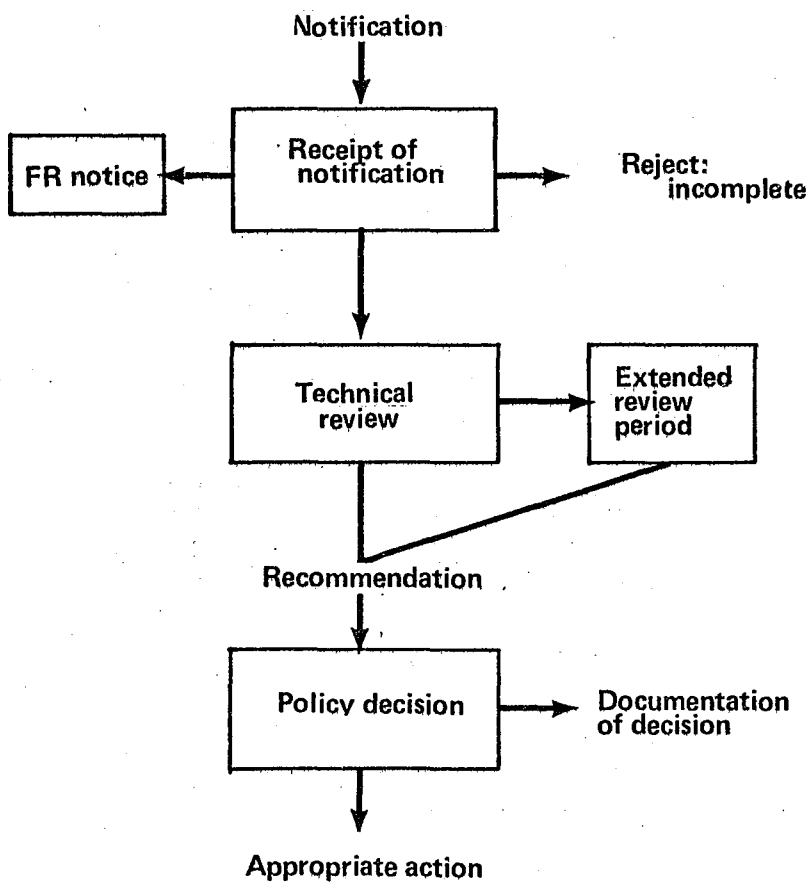
(S-10) MAY TAKE UP TO 30 DAYS AND IS SUBJECT TO A 90 DAY EXTENSION UNDER APPROPRIATE CIRCUMSTANCES. THE QUESTION OF RISK ASSESSMENT AT THIS STAGE IS CONTROVERSIAL, ALTHOUGH FAVORED BY THE EPA, ALONG WITH A LITERATURE SEARCH ON RELATED COMPOUNDS. OTHER PROPOSALS ARE MORE RELEVANT TO THE ECONOMIC RAMIFICATIONS OF TSCA: NAMELY THAT INVOLVING PAYMENT OF A FEE, AND THAT NOTIFICATIONS OF INTENT

INDUSTRIAL RECORD

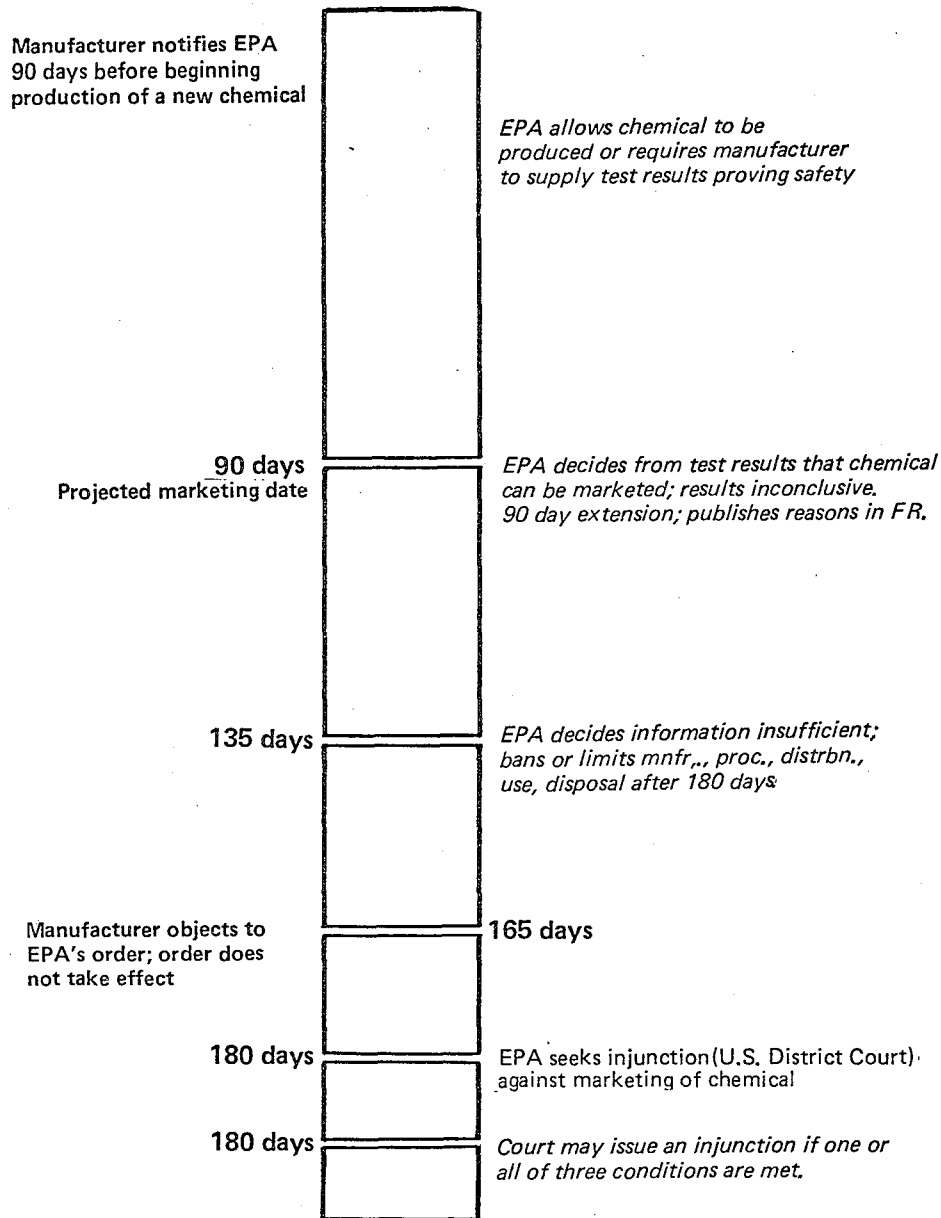




PREMARKET REVIEW STEPS



NEW CHEMICAL NOTIFICATION PROCEDURE



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REMAIN VALID FOR ONLY ONE YEAR, AFTER WHICH RENEWAL WOULD BE REQUIRED.

CONTROL OF EXISTING CHEMICALS

IN PROCESS, PENDING, OR RECENTLY COMPLETED CONTROL ACTIONS ON EXISTING 'BAD ACTORS', SUCH AS THE PCB'S (WIDELY USED AS ELECTRICAL INSULATORS) OR SOME OF THE CHLOROFLUOROCARBONS, ARE SHOWN ON THE
(S-11) NEXT SLIDE.

AVAILABILITY OF TSCA DATA

UNDER THE LAW, THE EPA IS LEGALLY REQUIRED TO PROVIDE ACCESS TO H&S DATA. THE MANNER IN WHICH THIS IS ACCOMPLISHED IS ILLUSTRATED
(S-12) ON THE NEXT SLIDE. THE FIRST 3 ITEMS ARE MANDATORY; THE FOURTH IS A PART OF THE DISSEMINATION PROGRAM FOR RAW DATA. THUS, WITH TOXICITY DATA WHICH SHOULD BE IN THE PUBLIC DOMAIN, NLM OR NTIS ARE FURNISHED COPIES OF ANY TEST RESULTS PROVIDED EPA.

INTERNATIONALLY THE EPA EXCHANGES DATA WITH OECD AND UNEP THROUGH APPROPRIATE CHANNELS.

DATA SYSTEMS

THE COMPLEXITY AND SHEER QUANTITY OF THE CHEMICAL DATA REQUIRING

CONTROL OF EXISTING CHEMICALS

IMMEDIATE ACTION

- PCBS
- Selected chlorofluorocarbons

NEAR-TERM ACTION

- Pesticides, Herbicides

CHEMICAL REVIEW AND PRIORITY SYSTEM

- Screening
- Selection for regular attention
- Regulatory package development
 - Hazard assessment
 - Source assessment
 - Alternatives assessment
 - Control options & impacts

RESPONSE TO UNANTICIPATED PROBLEMS

- Citizens petition
- Notice of substantial risk
- Results of laboratory & field studies

MAKING TSCA DATA AVAILABLE

- (1) Mandatory FR notices of receipt of data**
- (2) Annual report to congress**
- (3) Responses to requests for data**
 - (a) Freedom of information**
 - (b) Other**
- (4) EPA dissemination program**
 - (a) Multiple copies of test data submissions**
 - (b) Periodic catalogs of data submissions**
 - (c) Analyses of data received**
 - (d) International data exchange**

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PAGE TEN

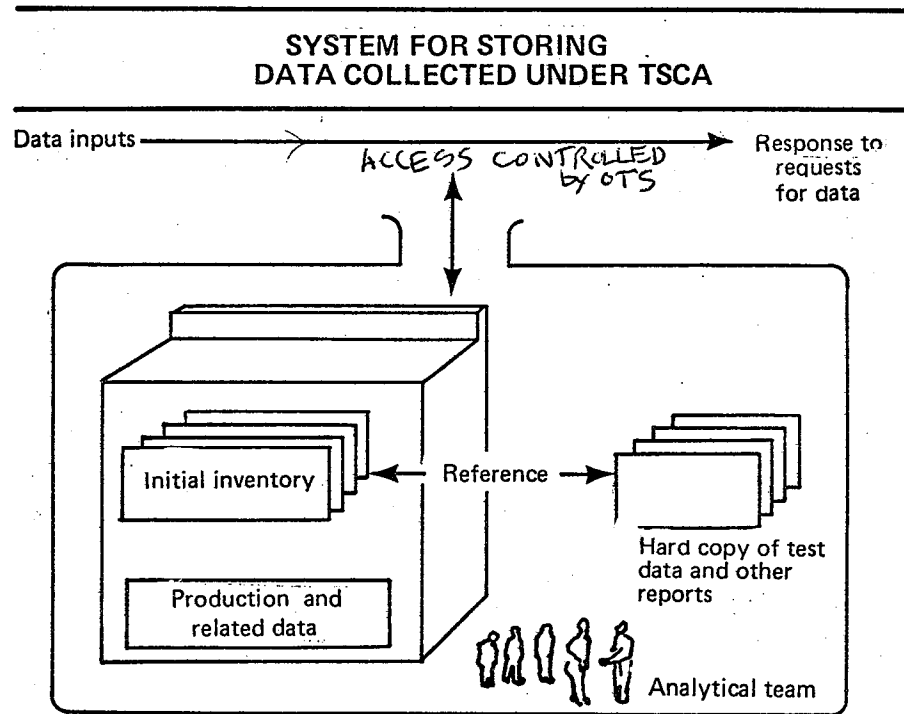
(S-13) PROCESSING TO IMPLEMENT TSCA, THE NEED FOR PROTECTING INDUSTRIAL PROPRIETARY INFORMATION WHILE SIMULTANEOUSLY PROVIDING THE REQUESTED HEALTH EFFECTS INFORMATION TO OTHER AGENCIES, TO INDIVIDUALS, AND INTERNATIONALLY TO THE WHO, ETC., PLACES A HEAVY ADMINISTRATIVE BURDEN OVER AND ABOVE THE REGULATORY ONE ON THE EPA. THE NEXT SLIDE DEPICTS WHAT WAS CURRENT THINKING LATE LAST YEAR: A CENTRAL DATA BANK LOCATED IN WASHINGTON, D.C., UNDER CONTRACT TO AND CONTROLLED BY EPA, SO THAT ALL ACCESS AND EGRESS OF INFORMATION WOULD BE CENTRALIZED. SUCH A CENTER WOULD REQUIRE APPROPRIATE STAFFING TO HANDLE DATA REQUESTS, WHETHER RAW, IN THE AGGREGATE OR OF THE ANALYZED VARIETY.

(S-14)

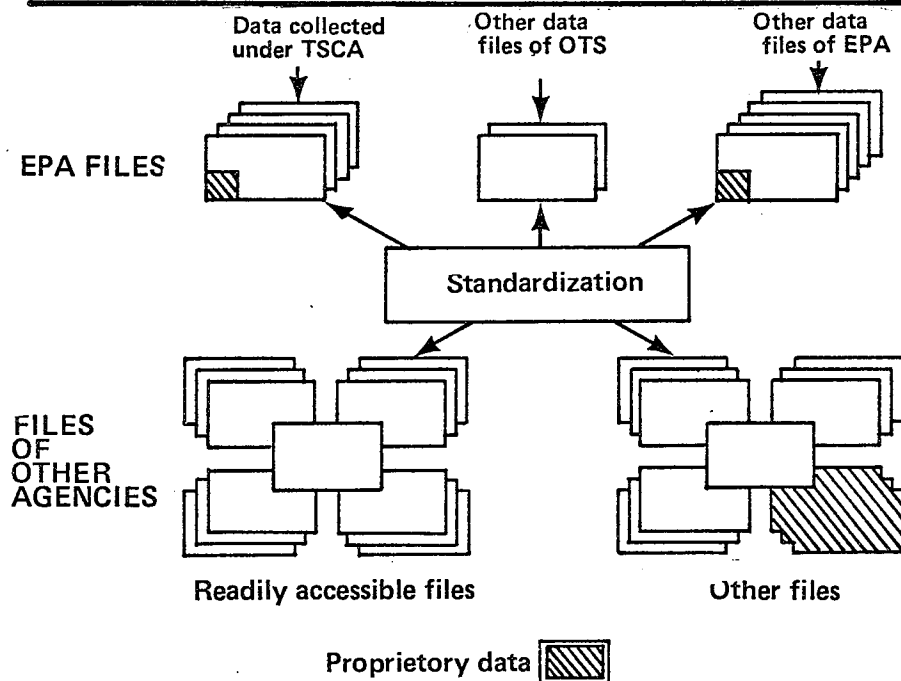
AN ESSENTIAL COMPONENT OF THIS GOLIATH IS ALREADY IN PLACE, IN THE FORM OF CAS, WHOSE LISTING OF CHEMICAL COMPOUNDS WAS A PRIME SOURCE OF MUCH OF THE CHEMICAL INFORMATION IN THE ORIGINAL TOXIC SUBSTANCES AND SUSPECT CARCINOGENS LISTINGS (1973, 1975) PUBLISHED BY NIOSH, AND THE LATER (1977) SO-CALLED CANDIDATE LIST (10), INITIALLY CONTAINING DATA ON SOME 30,000 CHEMICAL COMPOUNDS. ADDITIONS TO, AND UPDATES OF, THE CANDIDATE LIST ARE CONTINUALLY BEING COMPILED FOR LATER PUBLICATION.

WILL IT WORK?

WELL, YES - AFTER A FASHION! WHILE INDUSTRY GRUMBLES AT THE PAPER WORK, THE CUMBERSOMENESS, THE COST OF TESTING, DETECTION AND CONTAINMENT OF CHEMICALS, AND OF THE GREATER PROTECTION AFFORDED THE CHEMICAL WORKER BY REDUCING EXPOSURE LIMITS, THE FACT REMAINS THAT



ESTABLISHING AND STRENGTHENING DATA SYSTEMS



PAGE ELEVEN

WE'VE A LONG WAY TO GO -- THOUGH ALREADY WE HAVE MADE MEASURABLE PROGRESS (WITNESS THE VINYL CHLORIDE AND POLYACRYLONITRILE RULINGS (9, 11).

EPA HAS FINALLY ISSUED THE RULES ORDERING CHEMICAL COMPANIES TO REPORT EVERY PRODUCT THEY MADE IN 1977 TO THE AGENCY BY MAY 1 (ES&T, FEB. 1978, P. 129) (12). THESE RULES ARE THE FIRST TO BE ISSUED UNDER TSCA AND ARE ESTIMATED TO AFFECT SOME 5400 DOMESTIC CHEMICAL MANUFACTURERS AND PETROLEUM REFINERIES PRODUCING BETWEEN 50,000 - 70,000 CHEMICALS. THOSE WITH SALES EXCEEDING THE \$5 MILLION MARK MUST ALSO REPORT THE QUANTITY PRODUCED AND THE LOCATION OF THE OPERATION. STEVEN JELLINEK, WHO IS THE EPA ASSISTANT ADMINISTRATOR FOR TOXIC SUBSTANCES, BELIEVES THAT THE NEW RULES WILL ENABLE THE AGENCY TO KEEP PACE WITH THE ANNUAL REVIEW-AND-RULE PROCESS ON ALL CHEMICALS, ESTIMATED AT ABOUT 1000 PER YEAR.

A SERIES OF EPA/INDUSTRY SEMINARS WERE HELD THROUGHOUT THE COUNTRY THIS YEAR TO REVIEW THE RULES AND REPORTING REQUIREMENTS. NEEDLESS TO SAY THEY WERE WELL ATTENDED!

BUT HOW ABOUT THE 'OLD' CHEMICALS -- THOSE ALREADY ON THE MARKET? AND WHAT ABOUT AN INTRODUCTION RATE OF 1000/ANNUM OF NEW 'TESTED' CHEMICALS -- LARGELY NONBIOLOGICAL, AND AN INCREASING BURDEN ON HUMAN AND ECO-SYSTEM DETOXIFICATION RESOURCES? WHAT ABOUT POTENTIALLY DELETERIOUS ENVIRONMENTAL SYNERGISMS BETWEEN THE NEW AND THE OLD CHEMICALS OR, FOR THAT MATTER, AMONG THE OLD CHEMICALS THEMSELVES?

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CLEARLY, WITHOUT A SYSTEMATIC, INTEGRATED PREDICTIVE APPROACH IN PLACE FOR ASSESSING THE INTERACTIVE EFFECTS AND TOXIC POTENTIAL OF CHEMICALS IN THE ENVIRONMENT, WE ARE FIGHTING AN UPHILL BATTLE -- AND MYSTERIOUS AILMENTS OF MAN, ANIMALS AND ECO-SYSTEMS (SUCH AS THE NOW FAMOUS "LEGIONNAIRES' DISEASE") WILL CONTINUE TO PLAGUE AND PUZZLE US. LIKE ALICE IN WONDERLAND, THE FASTER WE RUN, THE FARTHER BEHIND WE FALL...

THANK YOU FOR YOUR ATTENTION.

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