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about 1978 Dow Chemical Co study

- multigenerational reproductive effects of TCDD at lowest dose ever tested, one trillionth of test animal's body weight per day

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28 Feb 1979

EPA emergency suspension of forestry and rights of way registration^s of 2,4,5-T (44 Fed Reg 15874, Mar 15, 1979)

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28 Feb 1979 - early 80's (2-III-5)

- Several years of legal battles due EPA emergency suspension 2,4,5-T on 28 Feb 79 with Dow leading major herbicide producers - re hazards of 2,4,5-T and particularly TCDD (consolidating in simple process in re Dow Co et al, USEPA Fifth consolidated Docket No.'s 415 et al) *5/10/91*
 - Federal Insecticide and Rodenticide Act, 7 USC §§ 136-136y required EPA demonstrate *that* risks of continued use outweighed benefits
 - EPA's posit: TCDD extremely hazardous to human and animal health, capable of causing cancer, reproductive effects and other harm at levels of chronic exposure at least as low as 1 ppt and no safe level of TCDD exposure could be demonstrated on basis of available info (44 Fed Reg, 15874 Mar 15 1979)
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15 March 1979 Fed Reg USEPA Decision and Emergency order (44 Fed Reg 15874)
Suspending Registration of 2,4,5-T

No safe level of TCDD exposure on the base of available information

Summer 1979 2-III-7-12 Reorganized EPA

- EPA preparing defend "no safe level" of TCDD posit
- thousand times greater TCDD being discovered in dumps, etc.
- VN vets filed class action against ao manufacturers
- Dow, et al named USG as third party defendant
- EPA dilemma: under pesticides law - could only cancel if risks outweigh benefits; under non-pesticide law EPA required ignore economic costs in protecting public
- Must ban where no "margin of safety"
- trash creates dioxin - no margin of safety
- EPA internal reorganization transferred action to officials more concerned with economic impacts v safety
- Steve Jellenck, EPA Asst Admin for Toxic Substance engineered Chlorinated Dioxins Working Group (CDWG) intra-EPA, to coordinate re dioxins
- Jellenck hired Dr. Donald Barnes as his special science advisor Sept 1979 - in few months co-chair CDWG - EPA dioxin policy totally reversed



- CDWG now tailoring 2,4,5-T policy to accommodate other dioxin concerns, e.g. air and water pollution standards also subject to "margin of safety" requirements
- [played into Dow strategy]

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1980

CDC Birth Defects Study Among Vietnam Vets conducted

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2 Dec 1980 Canadian ^{concern} ~~Cancers~~ 2-~~11~~-3 to 8

- USG pressured to investigate high levels of dioxin in Great Lakes when Canada released gull egg contamination *st-17*
- 2 govts agreed 'study health significant' while EPA Region 5 and Environment ~~Canada~~ investigate source and what do
- dioxin levels enough to increase risk to 1 in 100
- Fuzzed up by issuing "advisory" limiting consumption but late spring '81 EPA Region 5 draft report defied FDA "level of concern" for TCDD levels in fish-traced to Dow - recommended prohibit consumption - CC leaked Globe & Mail
- then Barnes and superior Deputy Administrator, John Hernandez, scrubbed with Dow *deletion* officials, ~~likely~~ reference to Dow
- FDA levels of concern left alone
- But Region 5 continued to warn "don't consume fish"
- *Sez ~~since~~ ppt in fish poses unacceptable hazard
Singl.

Mar 1981 Dow creates a stalemate (regulatory) 2-III 12-18

- '79-80 EPA locked into good posit - embarassed if changed
- Top Administrator - civil servants firm re risk - others opposed
- EPA researchers getting more Alsea data
- Dow's "Trace Chemistries of Fire" report - dioxin a natural product of all combustion sources: thus because large % natural and TCDD from 2,4,5-T so small, it would abuse 2,3,4-T producers to ban
- EPA rejected - only certain materials burn --> dioxins
- Barnes view won in EPA, CDWG took Dow view
- Hamptead, Long Island incinerator closed in '80 by EPA still closed awaiting EPA certification
- Regulatory paralysis resulted - Dow won
- Reagan policy - control public opinion about dioxin to relieve regulatory pressure
- Mar 1981 (2-IV-1): 1) all action on dioxin to Barnes as Co-chair CDWG 2) EPA struck deal with Dow to recess hearings to negotiate secretly out of court settlement of 2,4,5-T controversy
- tightly controlled press releases merely suggesting "levels of concern" - EPA relieved of responsibility to regulate and enforce

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1982 Times Beach

- Barnes used 1 ppb, 1000 times weaker for Times Beach residential soil as "level of concern"
- *Rita Lovelle*
~~Site levels~~ (asst administrator) a brief to her showed public not an overriding concern
- Media took up 1 ppb as safe level

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Early 1983

- Within few months of Times Beach evacuation EPA Administrator Anne Gorsuch Burford and her Asst ~~Peter~~^{Rita} Lavelle forced out for misconduct and Times Beach issues
- Shortly after Acting Administrator John Hernandez forced out for altering and suppressing Region 5 report
- Barnes escaped
- William Ruchelshaus appointed head EPA

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May 1983

CDC completed and submitted draft research protocol for scientific review and comment by:

1. OTA
2. Science Panel of Cabinet Domestic Policy Counsel AOWG
3. HHS Advisory Committee on Special Studies Relating to Possible LT Effects of Phenoxy Herbicides and Contaminants (the Ranch Hand Panel)
4. CDC's Ad Hoc Review Panel

June 1983

Ruchelshaus speech re:

1. conflicts in major laws re safety overall vs. risk/benefits
2. lack of coordination among agencies - now deal with class of pollutants impossible to establish safe level. I shouldn't be forced to assert "margin of safety" - proposed get legislation weighing risk against benefits

August 1983

- likely time to announce Dow EPA settlement on 2,4,5-T was August recess
- But on 3 Aug 2 pages of long-suppressed Alsea results of 1979 - held in EPA since 1980 inadvertently released in July 83 by contract chemist
- EPA in court had said no such study exists
- Alsea showed 5800 ppt in residential soils, in animals and baby with no brain - from routine use of chemical widely used in agriculture (5.8 ppb = 6 times Barnes)
- Dr. George Streisize (EPA Chief witness on reproductive hazard of TCDD in 2,4,5-T hearing) expressed outrage at EPA not telling him of Table VII
- EPA bait and switch story - "Dow samples"
- Dow withdrew from hearings - 2,4,5-T cancelled
- 9th US Circuit Court of Appeals banned federal use of all herbicides in Alsea Study area until adequately tested
- In FOIA lawsuit EPA still unable prove its sample mixup story 3 years later

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Nov 83

Find ²¹ protocol for PL studies published:

1. VN Experience Study - effects of military service VN (9300 VN vets vs 8500 non VN vets)
2. AO Study - LT HE exposure to herbicides in VN (Validation Study 646 AO vets vs 97 non AO - no correlation)
3. Selected Cancers Study (specific risks of cancer in VN vets)- 6: H,L,NHL,STS,nasal, nasalpharyngeal, liver

VES 4 parts: Mortality Assessment, telephone interviews, medical/psychological exam, birth outcome validation

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Based on 1983-86 (per Houk 1-p5) in June 1989

Work by Army's Joint ESG & CDC led AOWG SP conclude that scientifically valid study based on military records was impossible without independent method of exposure verification, Houk misleadingly reports

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1984 2-III-3 "level of concern"

CDC published paper justifying CDC's earlier approval of "level of concern" 1 ppb for Times Beach

Major Young, AF scientist coordinating dioxin policy for interagency working group

CDC ^{justified} ~~fuzzed~~ all data, rejecting data on reproductive and immune system effects due "lack of information"

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1984 PL 98-540²

Passed to ensure that VA disability comp is provided to vets exposed (during service in AF in VN) to herbicides containing dioxin - set up Com EH - 15 members, 11 scientists

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April 1985

VA C on EH first meeting - no studies *100% A R/*

June 1985 - 2nd - reviewed 7 studies - despite specific direction to look at PCT and chloracne as HE of dioxin, not 1 of 7 dealt with PCT. Cmtee decided DVA *reg* disallowing all diseases, except chloracne, based on sound evidence

Aug 85 - VA *regs* finalized

Spring 86 - 3rd mtg

since - 2 times per year approx

no diseases recommended until Z aboard

27 Sep 1985 API ltr Re Detection of Trace Amounts of Dioxin in Bleached Kraft Sludge

- EPA found low levels of dioxin (low ppt) in sludge at 4 bleached kraft pulp mills in Maine and in fish downstream from mills in Androscoggin R.
- Industry reps coordinating efforts to address issue and develop appropriate programs and prepare answer media
- 6 key questions - 6th "Do we need to take action to reduce these levels?"
- "Industry policy makers will be deciding whether further action is necessary"

1 ppb CDC level - Maine low ppt - better - false

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Sept 85

early 80's EPA tasked determine HE of exposure to dioxin

method quite different from C on EH - probable result several scandals

exhaustive literature search

700 chosen

authors selection - well versed

each to read 700 - then assigned a section of report

sections compiled into draft document

document thru peer review - 30 scientists from academic, industrial, political groups

peer group discussed all sections to satisfy all

Sept 85 - EPA released - dioxin is probable human carcinogen

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25 Oct 1985 NCASI Phase I Program Responding to Report of Dioxin..."

- "testing the hypothesis that dioxin formation in the pulping process is of chlorine based bleaching origin ..."
- NDS found "very low but measureable quantities of dioxin" in fish
- without information of Phase I "it would be premature to commit resources"

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4 Dec 1985 Dept of Army to Dr. Houk from Christian

CONFIDENTIAL
Army epidemiologist - a scientist and military analyst - found AOP interim report didn't
provide clear guidance in determination of possible exposure opportunity. The material and
data...are set up to demonstrate a single point of view"

Powerful proof of missed opportunity to determine exposure.

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9 Jan 1986 1 - 67

Senior statistician for AO project (Karon) warned director of project that dioxin analyses was so flawed that there was "substantial liklihood that there would be essentially no correlation "between exposure scores and blood levels (John Karon)

In ^{//} ~~W~~ July 89 hearings 1-108 Dr. Smith reports that Dr. Tavis Gordon, renowned stastician and Dr. Max Haber, preeminent statistitian, ~~and~~ agree with Karon

19 Mar 1986 Proctor & Gamble to NCASI

- summary of meeting among Dow, Syntec Inc., Proctor & Gamble, NCASI on Feb 7, 1986 in Detroit
- VSD (vertical safe dose) method of risk assessment of EPA to be challenged as unsound and unscientific by Syntec - Dow views, tied in
- Use ubiquity to calm public
- Work dioxin concerns with regulatory agencies in "make-the-EPA-look-good" way
- Dow believes labs can get produceable results in PPQaudrillion range
- Dow estimates 1 ppb of dioxin in fly ash safe at 1 in million risk level
- industry should show dioxin is widespread to popularize it

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10 April 1986 1-81

Dr. Peter Layde, acting AO project director, states exposure estimates are "meaningless" in Science article

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25 July 1986 Memo on: Trip Report to CDC for Meeting between ESG and AOP, 24 July 86
in Atlanta, GA

Re Dr. Robert Worth, Chief Scientist, CDC

Mayor Tj^{CV}imberg says "Dr. Robert Worth near the end of the meeting stated 'In my personal opinion, the results of the Blood Validation Study will not produce any substantial scientific data. He did say that the validation study should produce some scientific answers that would allow us (CDC) to get out of the main Agent Orange Study with ~~out~~ honor"

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Oct 1986

Protocol by CDC "Validation Study Comparing Military Records - based on Estimates of the likelihood of Exposure to AO with Current Serum level of 2,3,7,8-tetrachlordibenzo-p-dioxin (TCDD)" approved by AOWG & OTA

30 Dec 1986 Red Cavaney, Pres/ API, to API XTV Cmtee "Dioxin Task Group Proposal"

- Year ago EPA as part of NDS found traces dioxin in sludges of some P&P mills
 - "Although this created some activity at the state regulatory level, the industry was able to forestall major regulatory and public relations difficulties by, among other things, agreeing to cooperate in a joint study with EPA to determine the source of the dioxin if, in fact, it proved to be present"
- // With the "release of the results of the joint Industry/EPA study indicating where dioxin might be found... the potential for widespread public exposure and related regulatory pressures will be increased"
- Ltr set up 3 committees to deal with issue