

# Dioxin Assessment Update

National Forum on Contaminants  
in Fish

Portland OR, 11/03/09

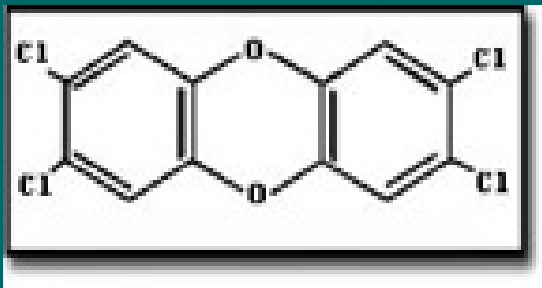
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# Disclaimer

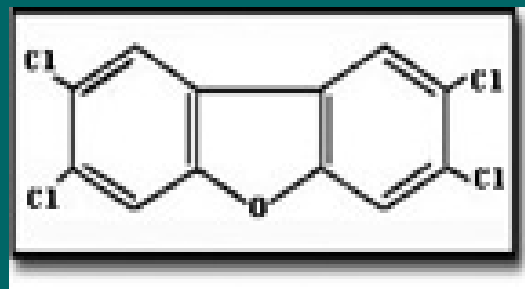
- The views expressed in this presentation are those of the author and do not represent the policy of the U.S. EPA.

Some of this is EPA policy

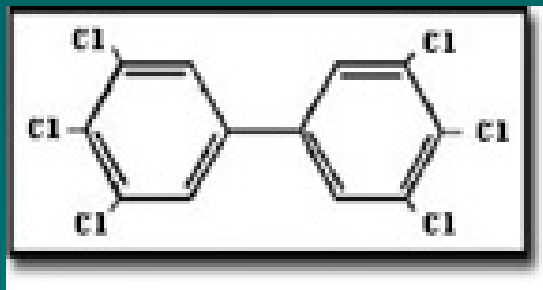
# Dioxin(s)



2,3,7,8-Tetrachlorodibenzo-p-dioxin



2,3,7,8-Tetrachlorodibenzofuran



3,3',4,4',5,5'-Hexachlorobiphenyl

<http://cfpub.epa.gov/ncea/CFM/nceaQFind.cfm?keyword=Dioxin>



# Ancient History

- EPA Health Assessment Document for Polychlorinated Dibenzo-p-dioxins: 1985 TCDD B2
- Dioxin reassessment actually started around 1986
- 1987 IRIS files for Hexachlorodibenzodioxin
  - No RfD or RfC
  - Cancer: B2, probable human carcinogen; slope factor of  $6.2 \times 10^3$  per (mg/kg)/day
- RAF purple books
  - 1987 Interim Procedures for Estimating Risks Associated with Exposures of Mixtures of Chlorinated Dibenzo-P-Dioxins and-Dibenzofurans (Cdds and Cdfs)
  - 1989 Adopt the WHO TEFs





# Less Ancient

- Charge from Administrator: 05 /91
- Chapter development, peer review: 91-94
- Science Advisory Board review: 95
- Peer review, public comment on draft Dose Response Modeling chapter (per SAB); 06/97.
- Revision, internal & inter-agency review: 95-00
- SAB re-review: 00-01
- Revision, internal & inter-agency review: 02-04



# This is What We Said in 2003

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=87843>

# Key Findings of the Reassessment *Exposure Document* -- 1

- Environmental levels have declined since the '70s
- Current US regulatory efforts have addressed most of the known large industrial sources
  - ~80% reduction between '87 and '95; further reductions anticipated)
- Open burning of household wastes is the biggest unaddressed contemporary source identified so far.
- There remain many uncharacterized sources that could be significant
  - e.g.. burning, ceramics, forest fires, secondary steel, reservoir sources
- Exposure to general population has declined but currently averages ~1pg/kg/day

# Latest and Greatest

## ➤ From Matt Lorber

## ➤ Background intake

- 2004 reassessment: 61.0 pg / day
- Lorber et al 2009: 40.6 pg / day

## ➤ Body burden

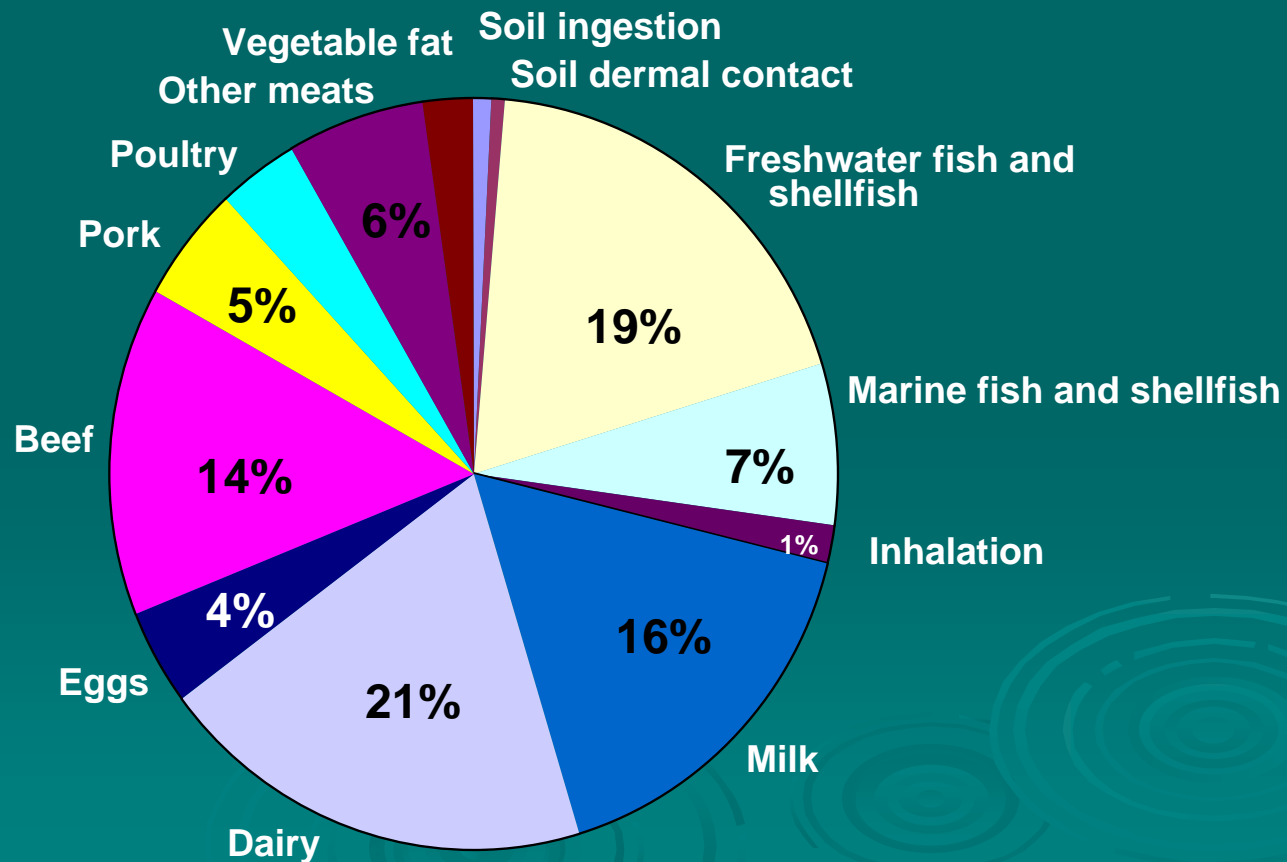
- Surveys mid '90s: 22.9 ppt lwt
- NHANES 21.7 ppt lwt



# Key Findings of the Reassessment *Exposure Document* -- 2

- General Population Exposure is from animal fats in the commercial food supply
  - Local sources make little contribution to most peoples' exposure
  - Environmental levels in meat & dairy production are major contributor
- Air deposition onto plants consumed by domestic meat and dairy animals is the principal route for contamination of commercial food supply

# Adult Average Daily Intake of CDDs/CDFs/dioxin-like PCBs



# Key Findings of the Reassessment *Exposure Document* -- 3

- Reservoir sources are a significant component of current exposure and may dominate future exposure
  - accounts for most coplanar PCB exposure
  - unknown contribution for Dibenzofurans
- Special populations may be more exposed but prevalence is not well substantiated

# Key Findings of the Reassessment *Health Document* -- 1

- Variety of noncancer effects in animals & humans
  - Developmental Toxicity
  - Immunotoxicity
  - Endocrine Effects
  - Chloracne
  - Others
- Toxic equivalents (TEQ) provide the best means for evaluating mixtures
  - Use WHO<sub>98</sub> TEFs
  - Include coplanar PCBs

# Key Findings of the Reassessment *Health Document* -- 2

- Body burden is the best dose metric for estimating risk
- Environmental mixtures of dioxin-like compounds are likely to be carcinogenic to humans; 2,3,7,8-TCDD is carcinogenic to humans.



This was before the 2005 Cancer Guidelines but reflected a lot of the thinking.

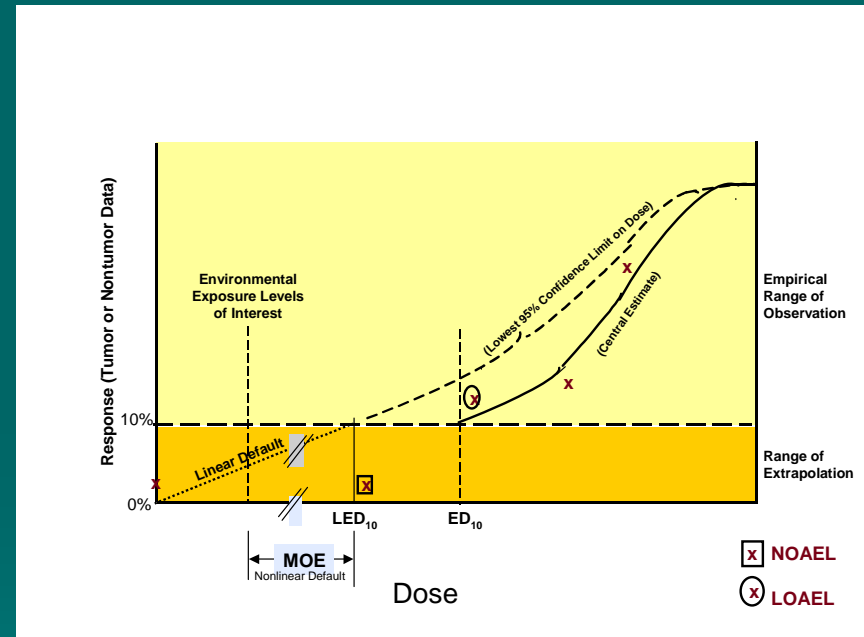
# Key Findings of the Reassessment *Risk Characterization* -- 1

- Cancer slope factor
  - Based primarily on recently published analyses of human data
  - Revised upward by factor ~ 6 from 1985 value (based on 1978 rat study)
- Cancer risk to general population from background (dietary) exposure
  - May exceed  $10^{-3}$  (1 in 1000)
  - Likely to be less and even zero for some individuals

# Key Findings of the Reassessment

## *Risk Characterization -- 2*

- Non-cancer effects observed in animals and humans at levels within 10X background
- Likely that part of the general population is at or near exposure levels where adverse effects can be anticipated.



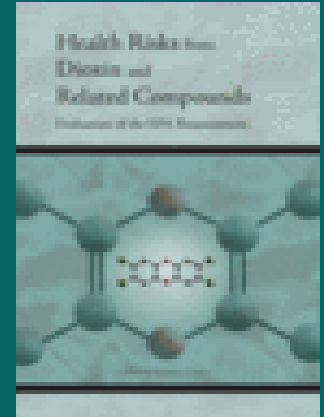
# Then What?

- National Academy of Sciences review: 04-06
- NAS report 07/11/06
- Administrator Jackson releases EPA's Science Plan for Activities Related to Dioxins in the Environment: 05/26/09



# NAS 2006

- “Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment.
- Three focus areas
  - Better justification of approaches to dose-response modeling for cancer and non-cancer endpoints
  - Increased transparency and clarity in the selection of key data sets for analysis
  - More transparency, thoroughness and clarity in quantitative uncertainty analysis.



# NAS Recommends

- NRC was OK with TEF, body burden
  - But should use PBPK for animal data.
- Cancer
  - Split re “human carcinogen” for TCDD
  - “likely carcinogen” OK for others
  - May want to call mixtures “human carcinogen”
- Want more on repro and developmental
- And immunotoxic effects
  - Want estimate of risk

# NAS on Dose Response

- Wants RfD
- Cancer
  - EPA did not adequately characterize the POD; needs rationale for BMR
  - Should do both linear and non-linear extrapolation
    - MOA is receptor binding; thus, should be non-linear
    - But POD is close to environmental levels so do linear
- Want quantitative uncertainty analysis, and probabilistic approaches for PODs

# *EPA's Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds*

## **“DIOXIN REASSESSMENT”**

EPA will release a draft report that responds to the recommendations and comments included in the National Academy of Sciences' (NAS) 2006 review of EPA's 2003 draft dioxin reassessment by December 31, 2009.

- *The draft response will be provided for public review and comment and independent external peer review.*
- *The peer review will be conducted by the EPA Science Advisory Board*

# EPA's Dioxin Science Plan

- U.S. Environmental Protection Agency is currently addressing several issues related to dioxins and dioxin-like chemicals in the environment.
- <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=209690>



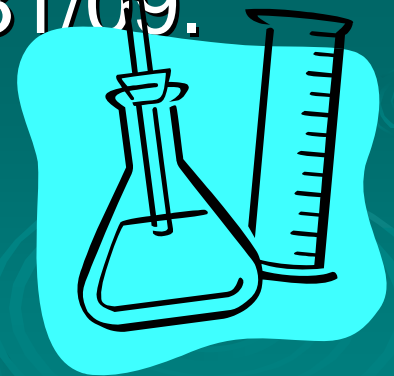
# EPA's Science Plan for Activities Related to Dioxins in the Environment

“We are...redoubling our efforts to provide guidance on the science of dioxin health effects to inform cleanup decisions at this site and protect other communities, in Michigan and across the country, facing dioxin contamination.”

*EPA Administrator Jackson  
May 26, 2009*

# Components of Science Plan

- May or may not revise sections of the 2003 document
- Review info on exposure study by U. Michigan by 09/30/09 (?).
- Evaluate information on basis for soil clean up levels; to OSWER 12/31/09.



# DIOXIN Dose-Response Assessment

EPA will release the final response to comments report and focus on completion of the dioxin reassessment.

- *By the end of 2010, EPA will release the **final response to comments report**.*
- *By the end of 2010, EPA will complete the **final dioxin human health and exposure assessment** and release it to the public, subject to further consideration of the science.*



# EPA will release the final report on Dioxin Toxicity Equivalency Factors (TEF).

- EPA will complete its Risk Assessment Forum report entitled, “Recommended Toxicity Equivalency Factors (TEFs) for Human Health Risk Assessments of Dioxin and Dioxin-Like Compounds.”
- EPA’s updated approach for evaluating the human health risks from exposures to environmental media containing dioxin-like compounds.
  - Basically says to use the WHO 2005 approach
  - This approach uses factors of ten or half logs
- A draft document released for public comment and external peer review in October, 2009
- Report will be completed by December 31, 2009.

