

Dioxin: EPA Update

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Recent History

- ☑ Science Advisory Board (SAB) review; May 1995
- ☑ Report received from the SAB; Fall 1995
- ☑ Major SAB comments -- revision and re-review of Chapter 8: Dose-Response(D/R)Modeling and Risk Characterization; add TEF Chapter
- ☑ Internal, Inter-Agency, and External Review of D/R and TEF Chapter and revised Integrated Summary and Risk Characterization
- ☑ SAB re-review of revised D/R and TEF Chapter and Integrated Summary and Risk Characterization -- November 1 and 2, 2000
- ☑ SAB/Executive Committee review of Nov. meeting draft report and letter to Administrator -- May 31, 2001

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Very Recent History

- ☑ Revisions to 2000 Draft and Inter-Agency (IWG) Review (2002/2003)
 - ☑ IWG requests a review by the NAS to help ensure that the risk estimates contained in the draft reassessment (2003 version) are scientifically robust and that there is a clear delineation of all associated uncertainties (Oct. 29, 2003)
- Response to NAS, Finalization and Publication

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SAB Report: May 31, 2001

- Compliments on careful and thorough review of the literature
- Suggested improvements
 - More focus on non-cancer effects
 - Increased emphasis on mode of action
 - More clarification of uncertainty

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SAB Report: May 31, 2001 -- 2

- Lack of SAB consensus on several key issues
 - Cancer characterization – Carcinogen vs. Likely Carcinogen
 - Margin of Exposure and/or Reference Dose
 - Upper bound estimate of cancer risk
- Recommended Agency expeditiously move toward finalization of EPA's Dioxin Reassessment
- (www.epa.gov/science1/fiscal01.htm)

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Major Issues Identified in SAB/Public Comments Addressed

- Sparse data for national means for sources/ pathways
- More info on dioxin-like PCBs in exposure document
- State of exposure model validation
- Trends in environmental levels/ body burdens
- TEFs/ TEQs
- Human data impact on hazard and risk characterization
- Significance of enzyme induction and other biochemical effects
- Relative roles of data, scientific inference, science policy

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EPA worked with other Federal agencies to reach conclusions

- NIEHS authors Chapter 8, “Dose / Response”
- NIEHS, NIOSH, DOD contributing authors (plus EPA and non-Federal scientists)
- NIOSH scientist published key cancer dose/ response analysis (2001)
- DHHS *Report on Carcinogens 2001*, TCDD listed as “Human Carcinogen”
- USDA, FDA collaborate on food survey design and data collection

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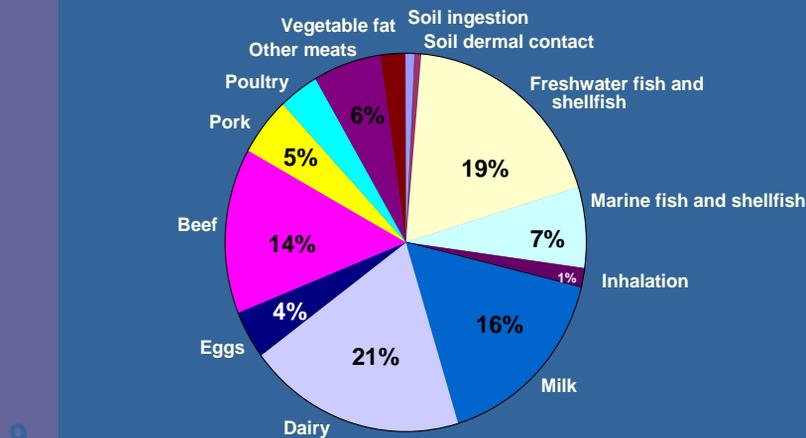
Key Findings of the Reassessment *Exposure Document -- 1*

- 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

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

2000 Draft Estimate: ~ 65 pg TEQ_{DFP-WHO₉₈}/day



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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

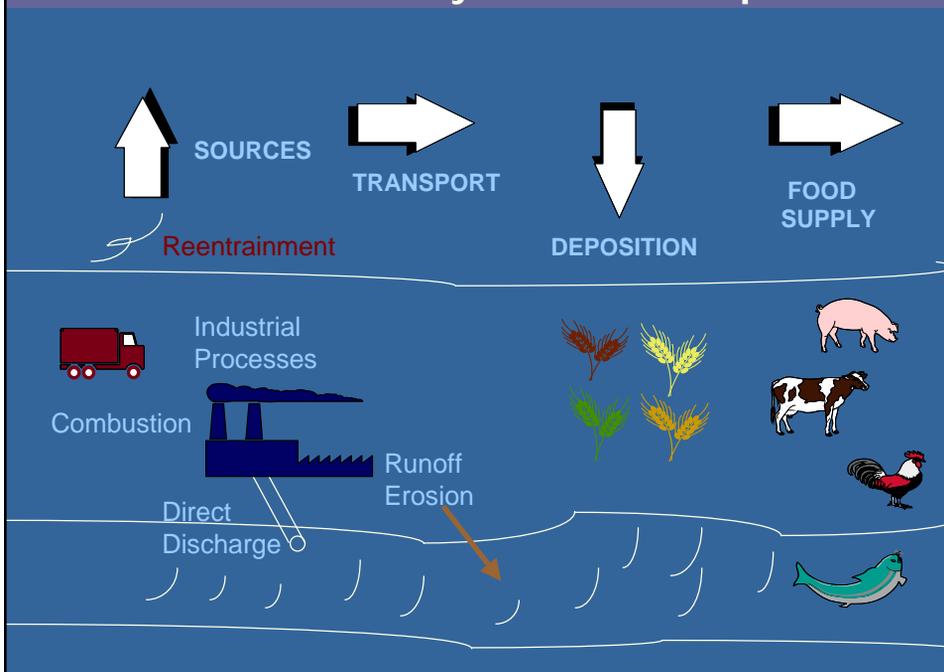
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Key Findings of the Reassessment Exposure Document -- 3

- 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
- See *Dioxins and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure*, IOM/NAS, July 2003

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Sources and Pathways to Human Exposures



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 WHO₉₈ TEFs
 - Include coplanar PCBs

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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.

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US, International Comparisons

	Body Burden L/NOAEL	Effect	Safety/ Unc. Factor	Guid.	Daily Intake (pg/kg/d)
WHO 1997	10-40 ng/kg	Several	10	TDI	1-4
ATSDR 1999	32* ng/kg	Neuro-Devel.	90	MRL	1
JECFA 2001	13/25 ng/kg	Devel.	3.2/9.6	TMI	2.3**

*Body burden from original publication; ATSDR used intake of 0.12 ng/kg/day

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Comparison with EPA

- Similarities
 - Focus on lowest adverse effects
 - Use body burden as dose metric (expect ATSDR)
 - Suggest additional decrease in intake is necessary
- Differences
 - Assume cancer will be insignificant at guidance
 - Use safety/ uncertainty factor (between 3.2 to 90) for LOAEL, pharmacodynamics, human variability
 - Safety assessment vs. a MOE / quantitative risk assessment

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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

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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.

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Summary

- Dioxin science has evolved rapidly; more data lead to better understanding ... and more questions
- Expanded human data on cancer reinforce our previous concern for the potential for human health impacts.
- Identification of non-cancer effects in animals and human are sufficient to generate a similar level of concern
- Environmental levels and human exposure are declining but are still at a level of concern
- Current source characterization is complex with uncontrolled burning and reservoir sources potentially playing a significant role.

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Further Questions?

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