

EPA's Draft Dioxin Reanalysis

Comments to the EPA Science Advisory Board Dioxin Panel

Mark Harris, PhD • ToxStrategies, Inc. • October 27, 2010

Comments prepared on behalf of Tierra Solutions, Inc.

Point 1: NIOSH Cohort – Confounding Exposures

Fingerhut et al. (1991)

“...our study did not directly assess the effect of exposure to TCDD alone. The workers were exposed concurrently to the chlorophenols and phenoxy herbicides that were contaminated with TCDD. In addition, they may have been exposed to numerous other chemicals while employed at the plants.”



Steenland et al. (2001)

“Besides dioxin, only one known occupational carcinogen has been identified in this cohort, present at a single plant and affecting a single, relatively rare cancer (bladder).”



EPA Draft Reanalysis (2010)

“This study meets the epidemiological considerations noted previously as there is no evidence that the study is subject to bias from confounding due to cigarette smoking or other occupational exposures”

Point 1: NIOSH Cohort – Confounding Exposures

The NIOSH cohort (used for derivation of the OSF) was exposed to known and potential carcinogens*:

2,3,4,6-Tetrachlorophenol	Dieldrin	Nitrobenzene
2,4-Dichlorophenol †	Dioxane	<i>o</i>-Toluene †
2,4,5-Trichlorophenol †	Ethyl acrylate	<i>o</i> -Toluidine
2,4,6-Trichlorophenol	Ethylene dichloride	<i>p</i> -Aminobiphenyl
2,5-Dichlorophenol	Ethylene oxide	<i>p</i>-Dichlorobenzene †
Acetaldehyde	Hexachlorobenzene †	Parathion
Aldrin	Hexachlorobutadiene	Pentachlorophenol
Aniline	Methylene chloride †	Petroleum polymer resins
Benzene †	Monochlorophenol	Polychlorinated biphenyls
Carbon tetrachloride	<i>n</i> -Butyl benzyl phthalate	Sulfallate
Diamine	<i>N</i> -Nitrosodimethylamine	Sulfuric acid
Dichlorodiphenyltrichloroethane †	<i>N</i> -nitrosomorpholine	Trichloroethylene

*see NIOSH Plant reports (January 1984 – January 1991)

†Chemicals identified in soil and/or groundwater at Plant 1 – documentation that these were released into work environment

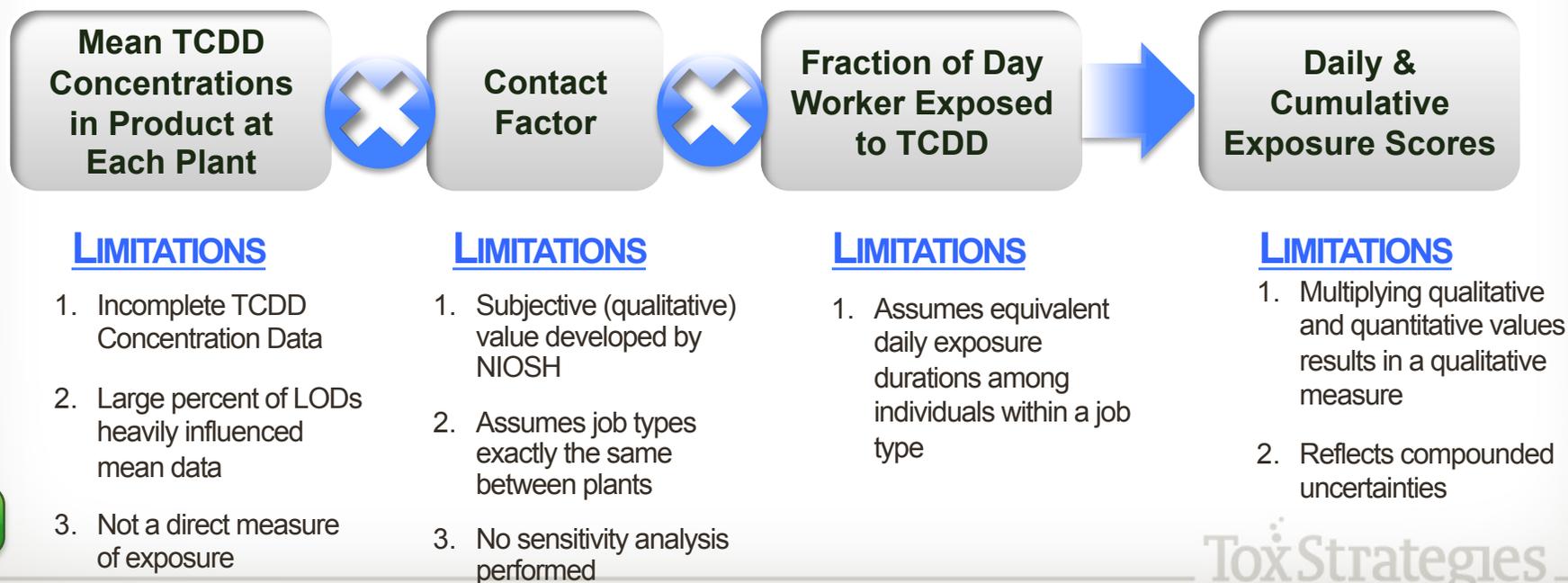
The EPA inconsistently excluded studies using confounding exposures as a rationale (e.g., Michalek and Pavuk 2008 excluded for inability to control for 2,4-D exposures)

Point 2: Qualitative Job Exposure Matrix

NIOSH Cohort exposure estimates (e.g., dose) were based on a job exposure matrix that is subjective and qualitative

Actual measurements of TCDD serum concentrations limited to 170 of 3,538 workers

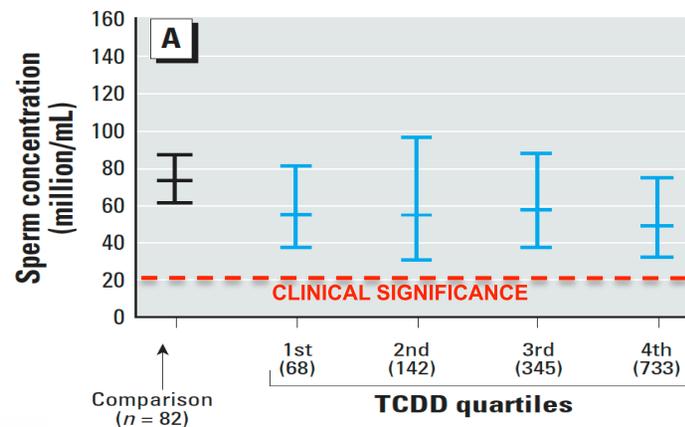
Qualitative JEM used for dose estimation:



Point 3: RfD – Study Selected Not Appropriate

The critical noncancer effect selected by the EPA was based on data that:

1. Were not clinically significant (see figure below)
2. Were not actually reported by the authors of the study
3. Did not demonstrate a dose-response relationship (see figure below)
4. Were not supported by a discussion on biological plausibility
5. Were insufficient to determine if effects were associated with TCDD exposures
6. Did not include other PCDD/Fs or other chemicals that were likely present as a result of the explosion



Point 4: Implications

1. The draft RfD and OSF suggest that the U.S. food supply may be unsafe for human consumption

Risk-based concentrations calculated using EPA's proposed toxicity factors exceed average concentrations reported by EPA scientists for beef, milk, and fish

2. The current intake of TCDD from breast milk far exceeds the RfD

Typical background intake from breast milk reported by EPA scientists is 242 pg TEQ/kg-day (Lorber and Phillips, 2002) vs. the RfD of 0.7 pg/kg-day

3. Use of the RfD and OSF indicate that soils in urban areas contain unacceptable levels of PCDD/Fs

Use of the draft RfD and OSF will cause significant resources to be allocated to site investigation/remediation with little or no apparent public health benefit