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PURPOSE

Focus on how EPA's Part 503 Rule Notice of Data Availability Characterizes Risk, and Identify some Key Components of the Dioxin Reassessment that were included for Public Comment

- Comment on EPA's probabilistic risk assessment
- Identify some key dioxin reassessment concepts included in the NODA
- •How does risk compare between the Part 503 assessment compared to the dioxin reassessment approach

The Part 503 Situation

- The Round I rule from the 1993 was the major risk based regulation
 - •14 environmental pathways
 - 9 metals with concentration limits
- Round II deals with dioxins, furans and PCBs
 - EPA proposed concentration limits and monitoring requirements in 1999
 - Responding to comments, EPA conducted a new survey of dioxin levels in sewage sludge, and performed a new probabilistic risk assessment
 - •EPA publishes NODA with new information in June 2002
 - •Expected promulgation in late 2003

Part 503 Round II

- Major improvements compared to the 1999 Proposal
 - •New sample survey data on dioxin, furan and PCB levels in sewage sludge
 - Conforming use of TEF values to the WHO-TEFs 1998
 - New probabilistic risk assessment
 - •Includes a good description of the limited role spike concentrations in land applied biosolids plays in terms of increments to human body burden

Part 503 Round II

- Some problems with the risk assessment method
 - The range of risk estimates for the highly exposed farm family derived from the probabilistic assessment are exaggerated by more than an order of magnitude
 - •EPA never provides a satisfactory explanation of how dioxin, a substance widely recognized to adhere stubbornly to carbon matter, migrates from the land applied biosolids matrix

Part 503 Round III

- Highly Exposed Farm Family (adult and child)
 - 70 years at farm
 - •Farm configured so that run-off from the land applied area contaminates stream/fish
 - More than 50% of food from land applied plots
 - 20 years of sludge application in 40 years

Part 503 Round II

- Dioxin sprayed in pasture does not degrade according to EPA's risk assessment
 - •It keeps on volatilizing out to plant leaf to enter the food chain
 - Over 80% of the risk is explained by duration of exposure to beef and dairy products

Risk Estimates, $(Q*=1.56 \times 10-4/pg \text{ TEQ/kg-d})$

Percentile	Farm Adult	Farm Child		
	Risk	Risk		
50 th	1 x 10-6	1 × 10-6		
75 th	4 x 10-6	3×10^{-6}		
9 () th	1 x 10-5	7 x 10-6		
95th	2 x 10-5	1 x 10-5		
99th	4 x 10-5	2 x 10-5		

Dioxin Reassessment Components

- EPA incorporated the latest science and state of knowledge concerning dioxin characteristics and exposure pathways in the probabilistic risk assessment
- A revised cancer slope factor for calculating cancer risk from exposure to dioxins
- Approaches to evaluate risk of non-cancer health effects from exposure to dioxin

Dioxin Reassessment Components

EPA's Cancer Potency Slope for dioxin and dioxin-like compounds

 $0.1985: Q*=1.56 \times 10-4/pg TEQ/kg-d$

 $2000: Q*=1 \times 10-3/pg TEQ/kg-d$

Non-cancer endpoints and Increment to Body Burden

Risk Estimates, (Q*=1 x 10-3/pg TEQ/kg-d)

Percentile	Farm Adult	Farm Child	
	Risk	Risk	
50 th	6 x 10-6	6 x 10-6	
75 th	2 x 10-5	2 x 10-5	
90 th	6 x 10-5	4 x 10-5	
95 th	1 x 10-4	6 x 10-5	
99th	2 x 10-4	1 x 10-4	

Draft Dioxin Reassessment

Highly Exposed General Population

1 x 10-3

Studge Rule Part 503
Highly Exposed Farm Family
1 x 10-4

Part 503 Regulations Comments to EPA

- EPA's new probabilistic risk assessment has a number of major flaws that should be addressed by the Agency.
- EPA's new survey sample data document that the levels of dioxin and dioxin-like compounds have declined from 1988 to 2001.

EPA Survey 2001 Samples from 94 POTWs

Non-detects at detection limit Non-detects at zero

(in TEQ ppt)	Dioxins Furans PCBs	Dioxins Furans	PCBs	Dioxins Furans PCBs	Dioxins Furans	PCBs
Mean	36.3	21.8	14.5	29.6	21.7	5.22
Std. Dev.	52.7	47.5	22.4	49.6	47.5	10.3

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(in TEQ ppt)	Dioxins Furans PCBs	Dioxins Furans	PCBs	Dioxins Furans PCBs	Dioxins Furans	PCBs
Mean	36.3	21.8	14.5	29.6	21.7	5.22
Std. Dev.	52.7	47.5	22.4	49.6	47.5	10.3

National Estimates based on EPA Survey 1988 Samples from 174 POTWs

Non-detects at detection limit Non-detects at zero

(in TEQ ppt)	Dioxins Furans PCBs	Dioxins Furans	PCBs	Dioxins Furans PCBs	Dioxins Furans	PCBs
Mean	NA	88.2	NA	NA	46.5	NA
Std. Dev.	NA	157.0	NA	NA	153.0	/NA/

Part 503 Regulations Comments to EPA

- Use of ½ non-detects raises dioxin TEQ by 100%
- **TCDD**, (2,3,7,8-TCDD) accounts for less than 20% of TEQ
- Highly exposed farm family unrealistic
- Farm configuration with runoff unrealistic
- Biosolids volatilizes from pasture but doesn't deplete from the soil
- Risk model ignores application site setbacks, site restrictions, etc.

Part 503 Regulations Comments to EPA

In spite of the overly-conservative and exaggerated risk estimates for excess lifetime cancer for the highly exposed farm adult and child, the estimates of risk are well within what the Agency normally interprets as acceptable.

Therefore, there is no human health risk basis to impose numerical limits for dioxin and dioxin-like compounds in biosolids that are land applied in accordance with EPA rules and agronomic application rates.

Part 503 Regulations Comments to EPA

- Current decreases in dioxin levels in biosolids are related to emissions reductions from combustion sources
- There is a need to continue to monitor levels in biosolids over time
- EPA should consider use of an inexpensive bioassay screening approach (an EPA reference test method validated on sewage sludge)
- Expensive confirmatory tests (GC/MS) should be used only if a spike is detected via the bioassay test