DETERMINING THE "MARGIN OF INCREMENTAL EXPOSURE": AN APPROACH TO ASSESSING NON-CANCER HEALTH EFFECTS OF DIOXINS

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INTRODUCTION

U.S. Environmental Protection Agency (EPA) guidance issued in April 1994 for performing screening level risk analyses of emissions from facilities that burn hazardous waste does not address the evaluation of non-cancer health effects from dioxin emissions (1). Historically, EPA has evaluated the carcinogenic risks from exposures to dioxins, but has not considered their potential non-cancer health effects because reference dose (RfD) values do not exist for any congener of polychlorinated dibenzo(p)dioxin or dibenzofuran (PCDD/PCDF). EPA's Draft Dioxin Reassessment (2) concluded, "...calculation of an RfD based on human and animal data and including standard uncertainty factors to account for species differences and sensitive subpopulations would likely result in reference intake levels on the order of 10 to 100 times below the current estimates of daily intake in the general population". Rather than compare a site-specific incremental dose of dioxin to an RfD, which is traditionally done in non-cancer exposure and risk assessments, the Draft Reassessment recommended that the potential for non-cancer effects for dioxin and related compounds should be evaluated using a "margin of exposure" analysis, considering both background and any additional, site-specific incremental exposure. It is EPA policy not to use the Draft Reassessment as a basis for making policy decisions until it has been made final. However, based upon public concerns about potential non-cancer health effects of dioxins emitted during combustion of hazardous wastes, the EPA Office of Solid Waste and Emergency Response (OSWER) independently decided, in 1995, to assess the Margin of Incremental Exposure (MOIE) to dioxins on a provisional and site-specific basis, pending the development of Agency-wide policy on the issue. The MOIE is defined as the ratio of a hypothetical individual's exposure to dioxins from a given source - in this case, a facility that burns waste - to the average background exposure of dioxins for the general U.S. population. This paper evaluates the methodologies used to calculate MOIEs in the risk assessments of five different waste combustion facilities, indicating similarities and differences, and areas in which further MOIE methodology development would be useful.

METHODS

Four hazardous waste combustion facility risk assessments, completed after issuance of OSWER's 1994 implementation guidance, were selected for evaluation. They all estimated the potential non-cancer health effects from exposure to dioxin emissions using an MOIE approach. The four risk assessments are for a commercial hazardous waste incinerator, Facility #1 (3), two mobile soil-burning incinerators used at Superfund hazardous waste sites, Facilities #2 (4) and #4 (5), and a sulfuric acid regeneration boiler unit at a chemical manufacturing plant, Facility #3 (6).

A fifth incinerator added to this group was a solid waste-to-energy facility. The screening risk assessment conducted for this facility (7) did not follow EPA's 1994 implementation guidance. It was added to this group because extremely high dioxin emissions led to estimates of incremental exposures which were very much higher than background exposures; it provides a contrast to the four hazardous waste incinerator risk assessments. The risk assessment for this facility compared incremental exposures to background exposures, but did not calculate MOIEs (7).

The risk assessments for Facilities #1, #2, and #3 covered the projected (or anticipated) period of operation of the facility starting with the trial burn period. The duration of operations for facilities # 1 and # 3 was 30 years, for #2 the duration was 0.35 years. The risk assessment for Facility #4 was performed prior to start-up of the incinerator and applied only to operations during the trial burn period; the duration was 0.16 years. The risk assessment for Facility #5 covered the period from the start of facility operations in 1983 until an anticipated time of shutdown, followed by post-shutdown impacts from residual dioxins in soil. The total duration for exposures in this risk assessment was 70 years. Since the decision was made to close the facility in late 1994, this analysis utilizes results from the risk assessment which pertain to the 11.5 year period of operation from 1983 through 1994.

Data for this analysis were taken directly from the results of the risk assessments for Facilities #1 - #4. MOIEs were calculated for Facility #5 specifically for this analysis.

PCDD/PCDF emissions for Facility #1 were measured on multiple occasions, including two trial burns, and represent the average of 26 separate runs. Emissions of PCDDs/PCDFs were obtained from actual trial burn data for Facilities #2 and #3. For Facility #4, PCDD/PCDF emissions were calculated on the basis of an emissions limit of 30 nanograms of total dioxins per dry standard cubic meter (ng/dscm) established by the State permit for the incinerator. Total emissions for Facility #5 were calculated based upon emissions data from a stack test of one of the facility's three stacks in 1992, as well as upon historical stack usage and other operating and design data. The total dioxin TEQ stack concentrations for the five facilities ranged from 0.04 nanograms per dry standard cubic meter (ng/dscm) at Facility #3 to 140 ng/dscm at Facility #5. For all facilities, emission measurements for all 17 dioxin-like PCDD/Fs were available; Table 1 summarizes pertinent stack results for dioxin toxic equivalents (TEQs).

The scenarios and exposure pathways of the five risk assessments differed, generally to meet site specific concerns. An adult subsistence farmer scenario was employed in Facility #1.

These "subsistence farmer" scenarios are characterized by the consumption of beef and/or milk produced at the farm site. Other pathways considered for subsistence farmer scenarios include inhalation, soil-related (ingestion, dermal contact), and other pathways. Three exposure scenarios were evaluated for Facilities #2 and #4: subsistence farmer, resident and recreational fisher. The typical "resident" scenario does not include home-produced animal food products, but often does include home-grown vegetable consumption, inhalation, soil-related pathways, and other pathways specific to the home environment. The "recreational fisher" scenario is used when a water body used for fishing could be impacted by incinerator emissions. Individuals consume fish that originate from that water body, and consumption rates are based on recreational fishing behaviors. A recreational fisher scenario often also considers inhalation and other pathways. Two scenarios were modeled for Facility #3: the resident (adult, infant) and recreational fisher (child). A subsistence farmer scenario was evaluated for Facility #5, with adult (beef and milk ingestion), child (soil ingestion), and infant (breast milk) exposures considered. Facility #2 was the only facility that evaluated children within two different age ranges - 1 to 6 years (child) and 7 to 18 years (school age child). Overall, the range of pathways evaluated for the facilities was from seven for Facility #2 to eleven pathways for Facility #4.

The MOIE results were calculated as a percentage; specifically, as one hundred times the ratio of the daily dose attributed only to the facility, to the national background dose (both expressed in pg TEQ dose/kg body weight/day, or simply, pg/kg/day). The background dioxin TEQ dose was given in the 1994 Draft Dioxin Reassessment (2) as a range for adults, 1-3 pg/kg/day, and as 60 pg/kg/day for nursing infants. Both of these background estimations include chlorinated dioxins and furans only; chlorinated dioxin-like PCBs would roughly double the background dose of TEQs (2). Calculation of the MOIE in the risk assessments for Facilities #1- #4 used the lower end of the range for background exposure for adults, 1 pg/kg/day, in order to be more protective of public health. To be consistent, the MOIEs for Facility #5 were calculated using the same assumed general background doses for adults and infants. MOIEs calculated for the child scenarios in the risk assessments for Facilities #2 and #5 utilized the same daily background dose of 1 pg/kg/day as was employed for the adult.

The derivation of the incremental exposure level used to generate the MOIE varied among the five sites. Facilities #1 and #4 used the lifetime average daily dose, LADD, of dioxins; the LADD is the dose experienced during the pertinent exposure while the facility is operating averaged over a lifetime - the averaging factor is equal to the exposure duration (e.g., 30 years) divided by a lifetime (70 years). Facility #3 used the average daily dose (ADD); the ADD is the dose experienced only during the pertinent exposure period while the facility is operating. Facilities #2 and #5 calculated MOIEs using both the LADD and the ADD.

Further details on the site-specific assessments can be found in their respective citations (3-7).

RESULTS AND DISCUSSION

The MOIE results for the five facilities are shown in Table 2. The highest MOIEs by far were those from Facility #5. For example, the MOIE values for the adult subsistence farmer were 950% and 170%, using the ADD and LADD, respectively. The MOIE for the nursing infant of the subsistence farmer, using only the ADD, was 500%. The next highest MOIE among the other four sites was 10%, for both the recreational fisher and the child of the subsistence farmer at Facility #2, calculated using the ADD; MOIE values were 0.2% and 0.1%, respectively, when the LADD was used. The MOIEs for all exposure scenarios at Facility #2 were less than 1% when the LADD was used as the daily dioxin dose. The MOIEs at the three other facilities were all less than 1%. The MOIE for the adult subsistence farmer ranged from 0.02% to 170% among the four facilities that used the LADD value; the MOIE for this same scenario was 2% for Facility #2 and 950% for Facility #5, when the ADD was used.

The risk assessments for Facilities #1 through #4 concluded that the potential non-cancer health effects and cancer risks associated with dioxin stack emissions would not be significant and hence that no further analyses or regulatory activities would need to be considered. In contrast, EPA's Region 5 determined that the weight-of-the-evidence, including the high dioxin emissions and the results from the risk assessment, was sufficiently compelling for EPA's Region 5 to issue an Emergency Order under Resource Conservation and Recovery Act (RCRA) Section 7003, requiring the facility to install Maximum Achievable Control Technology (MACT) over a specified time period (8). For reasons unrelated to the Emergency Order, Facility #5 terminated operations on December 31, 1994.

Since 1995, a number of risk assessments have been performed as part of the permitting process for RCRA facilities and prior to the operation of mobile incinerators at Superfund sites. As evidenced by the current review of five combustion risk assessments, significant variations exist in terms of the exposure scenarios evaluated, the exposure pathways considered, and the exposure doses selected for determining the MOIE - LADD versus ADD.

As stated in the introduction to this paper, a Reference Dose (RfD) is used as a tool in establishing concern for non-cancer effects of exposure to a chemical. An RfD is not by itself an action level; it does not establish an acceptable daily dose, nor does it establish a danger level. Rather, it is a risk descriptor which is intended to serve as a common reference point from which risk managers can make decisions regarding the acceptability of a given exposure. Depending, of course, on many factors such as the specifics of the site being assessed, the contaminant being considered, and the non-cancer effect for which the RfD was calculated, risk managers at EPA have often considered incremental doses equal to or greater than the RfD to be of sufficient concern to warrant additional consideration.

An RfD has not been established for any dioxin congener, however, because background exposures are already an order of magnitude or more higher than an RfD that would be calculated. This does not imply that adverse health effects occur at background levels for dioxins. In its Draft Dioxin Reassessment, EPA concluded that some adverse non-cancer impacts may be occurring at one order of magnitude of average background TEQ intake or body-burden levels (2). Therefore, background TEQ intakes appear to be between the levels of potential RfDs that could be calculated and the levels at which adverse impacts may be occurring.

Since the RfD is not a practical benchmark to evaluate incremental impacts from site-specific sources of dioxin, the MOIE is a useful alternate approach. A number of technical and science policy issues must be resolved, however, before assessors can use the MOIE in a consistent and reliable manner. The principal issues include:

- Should LADD, ADD, or another dose metric be used to characterize incremental exposure?
- Identification of the appropriate background exposure. Should it be a national background level, a site-specific level, or another possibility?

– Regarding the definition of MOIE, should the MOIE be defined as incremental exposure divided by background exposure, as in this paper, or total exposure (i.e., background + increment) divided by background exposure, or other?

While it seems quite reasonable that the 950% MOIE calculated for Facility #5 is a significant increase over preexisting exposures, and that such MOIEs would indicate the need to lower dioxin emissions at such facilities, it is not clear at what level the MOIE ceases to be negligible and becomes potentially significant. Development of a threshold value or range at which the MOIE ceases to be negligible is an important science policy decision for addressing non-cancer health effects of dioxin.

REFERENCES

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TABLE 1
PCDD/PCDF Emissions[1]

	#1	#2	#3	#4	#5
Type of facility	Commercial hazardous waste incinerator	Mobile incinerator at Superfund site	Sulfuric acid regeneration boiler unit	Mobile incinerator at Superfund site	Municipal solid waste-to-energy unit
Number of Test Runs at Facility[2]	26	3	6	0	5
Total PCDD/PCDF (7% O_2, ng/dscm)[3]	4.1	--	0.57	30	6800
Total TEQ[4] (7% O_2, ng/dscm)	0.08	0.8	0.04	0.73	140
Total PCDD/PCDF (ng/sec)	70	--	31	370	1,613,000
Total TEQ (ng/sec)	1.3	--	0.6	21.3	31,000

Notes:
(1) Emission information presented as shown in the risk assessment reports.
(2) Polychlorinated dibenzo-p-dioxin and dibenzofuran (PCDD/PCDF) emissions based on facility-specific measurements at Facilities #1, #2, #3 and #5. Emissions for Facility #4 based on maximum emission rate of 30 ng/dscm limit established in State permit.
(3) ng/dscm = nanograms per dry standard cubic meter.
(4) TEQ = Toxic Equivalent emissions of PCDD/PCDF, i.e., emissions of 17 congeners of concern expressed in terms of 2,3,7,8-tetrachlorodibenzo(p)dioxin toxic equivalents.

TABLE 2
Margin of Incremental Exposure (MOIE)

Scenario	MOIE (Using LADD)				MOIE (Using ADD)		
	Facility #1	Facility #2	Facility #4	Facility #5	Facility #2	Facility #3	Facility #5
Resident							
• Adult	--	0.0005%	0.007%	--	0.03%	0.02%	--
• Child	--	0.0007%	--	--	0.05%	--	--
• School Age Child	--	0.0002%	--	--	0.01%	--	--
• Infant	--	0.0003%	0.001%	--	0.02%	0.008%	--
Subsistence Farmer							
• Adult	0.7%	0.03%	0.02%	170%	2%	--	950%
• Child	--	0.1%	--	0.6%	10%	--	9%
• School Age Child	--	0.04%	--	--	3%	--	--
• Infant	--	0.02%	0.005%	--	1%	--	500%
Recreational Fisher							
• Adult	--	0.2%	0.003%	--	10%	0.005%	--
• Child	--	--	--	--	--	--	--
• Infant	--	0.08%	--	--	6%	0.002%	--

--: Not applicable