A Review of Three Documents

Exposure Analysis for Dioxins, Dibenzofurans, and CoPlanar Polychlorinated Biphenyls in Sewage Sludge Technical Background Document
(October 31, 2001 Draft)

Risk Characterization
(October 30, 2001 Draft)

Estimate of Population Exposed to Dioxins from Land Application of Sewage Sludge and Corresponding Number of Annual Cancer Cases from This Exposure
(October 30, 2001 Draft)

Work Assignment # 3-41

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General Comments

I found this review difficult to perform. The Document 1 was incomplete. Tables were blank and certain sections were labeled as under revision . An even greater problem is that Documents 1 and 2 are unclear as to the goals of the risk assessment and the role that the risk assessment would play in setting biosolid standards. Documents 1 and 2 should be revised to include a clear description of the regulatory process that will be used to set the standards for the compounds and the role that the risk assessment will play in the process.

The major questions that should be address in the revisions include the following:

1. **What is the purpose of the Monte Carlo analysis of the NSSS data? Was the analysis meant to be used a criteria for deciding the need for standards? The findings in Section 7.3 appear to provide a reasonable justification for no regulation of the compounds. (No risks exceeded 10^{-5} at either the 90th or the 95th percentiles). If this was not the purpose why was the analysis performed.**
2. **Does EPA intend to set standards for the compounds based on an aggregate exposure assessment (as implied by Figures 3.1 and 6.1 and the text in Section 7.1.2) or based on the highest single dose from one of the multiple routes of exposure (as implied by Table 7-12)?[1]**
   a. **If EPA is not going to perform an aggregate assessment why base the exposure on such a hypothetical conceptual site layout ? It would be more appropriate to assess exposures cattle ranches, poultry farms, and vegetable farms separately and develop separate and more representative fate/transport/exposure scenarios for each type of farm.**
   b. **If EPA was going to perform an aggregate assessment then additional documentation will need to be added to show how the total dose in a modeled individual will be characterized. Relevant guidance on performing aggregate exposures has been developed by EPA s Office of Pesticides Programs and can be found at: http://www.epa.gov/pesticides/cumulative/Cum_Risk_AssessmentDTM.htm#Aggregate**
      A key issue that will need to be considered is the correlation between the intake rates of foods (will high intake of beef suppress intake of

[1] While not asked, I strongly suggest that EPA should regulate based on aggregate exposure since this is the most protective of public health.

dairy and poultry?)

3. **How will EPA use this assessment to set standards? The current text and terms such as scaling factors, SBC, fixed concentration sample, and Risk Limiting Concentrations are unclear.**
    a. **The text in 7.2 suggests that EPA will assume that all biosolids will look like a known biosolids sample . This implies that all biosolids will be assumed to have the same proportions of compounds as the known biosolids sample . This is clearly untrue. As the NSSS demonstrates the concentrations of specific compounds vary from one sludge to another.**

       EPA states in Document 2 that beef consumption is responsible for most risk. If this is true, then the risks offered by a biosolids will be a function of the TEQ s for each of the compounds in combination with the relative potential of compound to reach receptors through the beef consumption pathway. See the addition discussion on this point below.
    b. **While Section 7 is being modified, it is disconcerting that the beef pathway risks predicted for the known biosolids sample (Table 7-7) are 20 time higher then the results from the NSSS Monte Carlo analysis (Table 7-18). EPA needs to provide an explanation for this difference.**

Other general comments

1. **The high-end population needs to be better defined. Specifically the population needs to be defined in terms of actual demographics and farming practices. Once this is done then EPA should relate the population to conceptual site layout . The layout and the derived exposure scenarios are not the high-end population as stated on Document 2 (Page 3-Paragraph 2), they are a simulation or model of the high-end population that needs justification.**
2. **The Monte Carlo model is clearly an essential portion of the regulation since it is the means of generating the 90th percentile dose, which appears to be the point of departure for the proposed regulations. Unfortunately, the use of the conceptual site layout is a problem for the Monte Carlo analysis. Because the layout is so contrived and unrepresentative it is difficult to talk about how it**

varies . It is valid to talk about data on regional variation in farm size, soil types, and meteorological data for cattle ranches, watersheds, dairy farms, and truck farms and whether the distributions in inter farm variations in these properties are accurate. However, a conceptual layout that that is a composite of all the land uses cannot be evaluated.

3. **What is the purpose of the Monte Carlo assessment? If the goal was to look at variation in the subpopulations (farmer adult, child, infant, and fisher) by pathway the model has the following problems:**
    a. **Did not consider variation of soil types or farm sizes within the 41 climatic regions.**
    b. **The 41 regions should be weighted according to the number of farms that will be used for biosolids disposal. For example, Billings would be given a very low weight since the farms are large and the populations (and thus sludge generation) will be small. LA would be given a high weight for the small farm size and large population size**
    c. **The use of residential mobility as a measure of duration only works if moving from on farm means a cessation of exposure. A farmer may move to another farm practicing biosolids disposal. This needs to be discussed.**
    d. **Children growing up on farm may become farmers. This needs to be discussed.**
4. **The discussion of the Monte Carlo model is incomplete and scattered.**
    a. **The model is apparently written from scratch but no description of the model language used, platform, or code is provided. The recent guidance for Monte Carlo (cited in document 1) provides guidance on the minimum information that should be included in a Monte Carlo analysis.**
    b. **The design of the model should be provided (a flowchart is essential).**
    c. **The relationship of the model to the soil, air dispersion, watershed and other fate and transport models should be described (were these models run inside of the Monte Carlo Model or were inputs and outputs of these models used to create a response surface that was used in the Monte Carlo Model).**
    d. **The description of the Monte Carlo should differentiate between the model that will be used to set the standards and the NSSS analysis.**
5. **EPA seems to have gone out of its way to fit empirical data to parametric distributions. The reason for this is unclear. Entering empirical data would have been easier and would not have introduced the uncertainty in parametric curve fitting.**

6. **Finally, the Monte Carlo model assumes that exposures to one individual will remain constant over time. That the dose to each simulated individual will be constant for the entire duration of his or her exposures. This means that each day the person will have the same beef intake and that all sludge applied to a farm will be constant in composition. These assumptions have the potential to bias upper the estimates of dose at the upper end of the distribution (Price et al. 1996).**

Response to Charge

In a number of cases I found the questions to be unclear, and as a result, difficult to answer.

Document 1

The pathways were appropriate for the analysis of a high-end population for exposure to chemicals in biosolids. It is not clear how the EPA Exposure Guidelines are relevant.
Soil modeling is outside of my area of expertise. I did not review the models. The equations were transparent. EPA/RTI should be congratulated on making the system of equations open for review. I did not exhaustively review all equations. See specific comments below for suggestions on certain equations. The paper and electronic copies of the equations were difficult to review since many of the symbols did not convert to the .pdf format correctly.

The pathways looked appropriate. The appropriateness of the specific models used is outside of my area of expertise.
In general, the values appeared to be reasonable. See specific comments on default values and distributions given below.
This question is not appropriate. I do not believe that external peer review should include performing a QA/QC of Agency s algebra. However, in my limited review I did not identify any math errors in the deterministic analysis. Finally, such a determination is not possible for the Monte Carlo analysis.

Document 2

It is difficult to agree with a document when its purpose is unclear. The document is a series of separate discussions on various aspects of risk characterization that no clear argument organization. I agreed with most of the points made.

See discussion under general comments.

Document 3

I agree with the finding of this assessment it to present a quick argument that the risks from the land disposal are very small. However, the current use of conceptual site layout presents a conceptual problem for estimates of population risks. It is difficult to talk about the number of individual who have exposures similar to those described in the conceptual site layout. In that sense, the number of individual exposed would be zero. The real question is what is the number of individual who consume home raised beef that has been pastured or fed silage from land treated with sludge. This could be better estimated.

The assessment has a number of problems with its inputs.

- **Where did the value of 6x 10^{-6} come from? This should be documented citing the page/table from Document 1. In addition, EPA should indicate if it is driven by beef/dairy exposures.**
- **The assessment is likely to be an overestimate of actual risks (see comments on beef consumption below).**
- **I find it implausible that 2% of the US live on farms, raise beef, and consume the beef they raise. Farmers that do not raise beef should not be included in the calculation since their risks are much less than cattle ranchers.**

I had the following suggestions for the calculations:

- **I would estimate the population size by taking the total number of farms estimated to take biosolids in a year and raise either beef or dairy cattle, and the demographics of farms (older adults, few children, etc) to estimate the size of the population affected.**
- **The annual risks should be estimated based on a division by the duration of exposure not 70 years (Price et al., 1992).**
- **The size of the population should be estimated by determining the number of farmers who will move to or reside at a farm over the 40-year application time. This can be estimated by taking the number of farms, multiplying it by 40 years and dividing by the average duration for adults.**

Specific Comments

Document 1

Chapter 2.0
EPA should have investigated whether risks from PCBs would be better regulated based on PCB specific cancer potencies rather than TCDD-related potencies.

Chapter 3.0

Section 3.1.3.1

Why is EPA assuming that a single farm will occur down wind of a watershed? EPA should investigate the impact of having air releases from multiple farms affect a single regional watershed.

Define what is meant by a third order stream since this is the first time the term is used.

Section 3.1.3.2

The proposed approach to modeling inter-farm variation in size, meteorological data, and soil type is to develop typical values for 41 meteorological regions. EPA should discuss why these 41 values are a reasonable model of inter-farm variation. This demonstration should address:

- **The soil and climate characteristics that may differ for pasture (lower quality soil or less rainfall) and crop land (better soils more rain).**
- **The number of farms in different portions of the US that use biosolids (this will be proportional to the amount of biosolids produced and the fraction that is land disposed, and farm size.**

EPA is to be commended for keeping the meteorological data, soil data, and farm size data linked on a regional basis. This will avoid errors from mixing data from different regions.

Section 3.1.7

Risks will <u>not</u> be linearly related to the TEQ of a biosolids. Consider the following example. Sludge A has 1 ppm of 2,3,7,8 TCDD. Sludge B has 10 ppm of 2,3,7,8-TCDF. Both have the same TEQ (1 ppm). However, the 2,3,7,8-TCDD has a beef bioaccumulation factor of 5.76 and 2,3,7,8 TCDF has a beef bioaccumulation factor of 1.25 (more than 4 fold lower). Assuming that the two compounds behave similarly in soil and the resulting soil concentrations are proportional to the levels in the sludges, then the exposure (on a TEQ basis) through the beef pathway will be four fold lower for B than A.

This example is hypothetical. It may be the case that, the biosolids are sufficiently similar that the variation in chemical concentrations and its effect on fate/transport/ bioaccumulation/exposure is sufficiently small that it can be ignored. However, EPA needs to investigate this issue and develop data that justifies the claim that TEQs are linearly related to risk.

Section 3.2.2

How were the values selected for soil type/farm size/and met data selected for the central tendency and the high-end analyses performed in the deterministic analyses? Were the values kept linked? EPA should describe the process.

Section 4.2.1

The Monte Carlo analysis implicitly assumes that the composition of the chemicals in the biosolids applied to a farm will remain constant over the 40-year period. At a minimum EPA should determine if this assumption is valid and if not what is the impact on the risk assessment. This also has implications for the enforcement of the final standards. If the levels in biosolids vary then the final standards may be best-evaluated using composite sample that reflect long-term averages in contaminate levels.

Section 4.3.2

As discussed above, the regions should not be weighted equally.

Section 4.3.2.3

Shouldn t the characteristics of the soils be modified to reflect the impact of prior sludge applications? It does not appear that this is taken into consideration. At a minimum, give an explanation why it is not important.

Tables 5-5, 5-8, 5-10, 5-12, 5-14, 5-16, and 5-18

The tables are empty.

Section 6.1.1

The time weighted exposure parameters estimated using Equation 6-1 will lead to incorrect predictions of doses in children and should not be used. The correct approach for deriving the average exposure over time periods where a child changes is as follows:

Average Dose =

$$\frac{Dose_{Breast\ milk} * D_0 + Dose_1 * D_1 + Dose_2 * D_2 + Dose_3 * D_3 + Dose_4 * D_4}{(D_0 + D_1 + D_2 + D_3 + D_4)}$$

Where each dose, $dose_i$, is calculated using the age-specific inputs for the ith age period.

Sections 6.2.1.2- 6.2.1.4

The distributions of beef consumption rates are not correct and are likely to be

significantly higher that actual intakes. The distributions are derived from the findings of the Nationwide Food Consumption Survey. This survey determined intakes for families and individuals over a 7-day period. In Table 13-36 of the EFH, EPA used the results to estimate the intake rate of beef. The approach used by the agency in developing the data for this table was only to use data from homes that had consumed beef during the week they were surveyed (Consumers Only).

There are two problems with the data. First, the method used by EPA has the potential to over estimate the intake at the upper portion of the distribution and underestimate the intake at the lower end. This potential for over estimation can be seen in the data in the following table. In this table, the reported intake is taken directly from the EFH table 13-36 and then converted to more understandable measures of intake.

Percentile	Reported	Body weight	Daily intake	Daily intake	Beef meals consumed per
			Adults (20-39)		
50	1.59	70	111.3	0.30	4.3
90	4.88	70	341.6	0.94	13.1
95	6.5	70	455	1.25	17.5
99	8.26	70	578.2	1.58	22.2
100	8.26	70	578.2	1.58	22.2
			Children 6-11		
50	2.11	30	63.3	0.17	2.4
90	11.4	30	342	0.94	13.1
95	12.5	30	375	1.03	14.4
99	13.3	30	399	1.09	15.3
100	13.3	30	399	1.09	15.3

As the table indicates, the top ten percent of the population of children and adults are predicted to eat little else then beef (more then 2 meals a day every day)[2]. This assumption, while conservative, is not out of the question for any one-week period of a person's life. (It would reflect an unhealthy but not impossible diet.)

[2] Some of this over estimation is due to lower than average body weights. But even assuming a body weight of 50 kg in adults the top 10 percent still eat two beef meals a day.

Second, the model developed by EPA assigns a single value of beef intake to each simulated individual for the entire duration of his or her exposures. This implies that a farm family must always eat beef at least once a week. It also implies that >10% of the population will have multiple beef meals each and every day for years.

The net result of these two problems is that the model over estimates beef intake at the higher percentiles. Since the beef pathway was found to be the driver for this risk assessment this is a critical flaw that must be addressed by EPA prior to using the analysis in a regulation.

The problem facing EPA is trying to estimate the distribution from chronic exposure using data on consumption patterns from short-term surveys (seven days or less). This problem is not unique to this assessment. There is very little data on chronic patterns of intake. Simulation models have been developed for estimating chronic exposures may be helpful (http://www.hrilifeline.org/).

Data on distribution has also been developed by the State of California (http://www.oehha.ca.gov/air/hot_spots/pdf/execsumm.pdf). USDA has also collected data on annual beef consumption rates (on a farm basis) as part of it collection of annual agricultural statistics. This data on annual consumption rates of home-raised beef is updated annually.

Finally, similar problems also happen with milk, poultry, and other food intake distributions.

Section 6.2.1.7

Average inhalation rates can be modeled as a function of age, body weight (Layton, 1993-see exposure factor handbook for the reference.) This method is preferable to the independent selection of inhalation rates. However, since inhalation does not appear to be an important pathway the change may not be worthwhile.

Section 6.2.2.1

The adoption of value of an exposure input for a child in one age group will be correlated with the values the child will have when her or she enters older age groups. For example an above average weight child at age 5 is likely to be above

average weight when they are 15. The model should consider this correlation when modeling a child over time. If the model randomly picks body weight for the different age periods, it may result in a child s body weight actually going down with age.

One way to deal with this issue is to link the relative percentiles taken for each age group. Thus, if a child is in the fifth percentile of body weight in one age group they will be in the fifth percentile of each of the subsequent age groups.

Section 6.2.1.5

The risk assessment for fish ingestion assumes that the fish will be taken from a small but fishable stream. The fish consumption rate used in the analysis is taken from Maine survey data as presented in the EFH. The distribution in EFH is based on the raw data from (Ebert et al, 1994). Ebert et al. includes multiple distributions for fish consumption. One distribution is specific to fish caught in streams and rivers. This distribution should be used rather than the general distribution given in the EFH, which includes fish taken from ponds, lakes, and reservoirs.

Table 7-18

Typo for the Child - 90th percentile.

Appendix H Table H 2-5

EPA and RTI should be congratulated on the model of start age for the Monte carol analysis of the population. By randomly selecting a start year for an individual year 1-40, then selecting the duration for the individual and then calculating the average concentration for the duration they are modeling the exposed population correctly.

Appendix H Tables H-2.3 and 2.4

The average soil concentration should be determined by averaging the soil concentration for each year between first and the last year of exposure.

Miscellaneous comments

EPA is to be congratulated for assessing the risk by modeling each compound separately and then summing the compound specific risks to give the total risk. The focus on maintaining the mass balance for each compound in the applied sludge is also commendable.

Finally, the incorporation of all of the fate and transport modeling into the Monte Carlo analysis is an impressive achievement.

References

Ebert et al (see Exposure Factors Handbook for the reference.)

Price, P., J. Sample, and R. Strieter. 1992. Determination of less-than-lifetime exposures to point source emissions. *Risk Anal*. 12(3):367-382.

Price, P.S., C.L. Curry, P.E. Goodrum, M.N. Gray, J.I. McCrodden, N.W. Harrington, H. Carlson-Lynch, and R. E. Keenan. 1996. Monte Carlo modeling of time-dependent exposures using a Microexposure event approach. *Risk Anal.* 16(3): 339-348.