amsa

Association of
Metropolitan
Sewerage Agencies

March 23, 2000

Part 503 Sewage Sludge Use or Disposal Rule
Docket Number W-99-18,
Comment Clerk, Water Docket MC-4101
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Re: Association of Metropolitan Sewerage Agencies' Comments to the December 23, 1999 Proposed Standards for the Use or Disposal of Sewage Sludge (i.e., Biosolids) Concerning Dioxin, Dibenzofurans and Dioxin-like Coplanar PCBs.

Dear Sir or Madam:

The Biosolids Management Committee of the Association of Metropolitan Sewerage Agencies (hereinafter "AMSA") and Cambridge Environmental Inc. (AMSA's dioxin consultant) have completed their review of the United States Environmental Protection Agency's (hereinafter "Agency") proposed "Standards for the Use or Disposal of Sewage Sludge" as published in the Federal Register on Thursday, December 23, 1999.

AMSA wishes to commend the Agency for proposing a rule that addresses the issue of dioxin, dibenzofurans and dioxin-like coplanar PCBs (hereinafter "dioxins") in biosolids and biosolids incinerator exhaust gases. As the Agency correctly indicates, only very small amounts of dioxins are released to the environment through the land application of biosolids and from biosolids incinerator exhaust gases.

Biosolids that are land applied account for, at most, 86 grams (dioxins) TEQ/year out of the 2,100 grams TEQ/year (4 %) that are applied to land in North America. (These quantities were obtained from the Agency's 1994 data.) While we can understand the Agency's position that a limit on dioxins is required for biosolids that are land applied, we have serious concerns as to how the very conservative limit of 300 ppt TEQ was developed.

We agree that a dioxins limit is not required for biosolids incinerators, since dioxins emissions from the 254 units located within the United States account for, at most, 6 grams TEQ/year out of the 2,745 grams TEQ/year (0.2%) released to the atmosphere in North America. (These quantities were obtained from the Agency's 1995 data)

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The following is a summary of our comments to the Agency's "Request for Public Comments" as contained in Section VII (page 72055) of the Federal Register Notice. More detailed discussion of the comments, recommendations, and additional information on theses and other issues are contained in the accompanying report, prepared for AMSA by Cambridge Environmental:

1. Establishing a cap of 300 ppt TEQ dioxins for biosolids that are land applied.

AMSA understands the Agency's position that a dioxins cap is necessary for biosolids that are land applied. However, it did not find adequate justification, in the proposed rule, for the proposed cap of 300 ppt TEQ.

AMSA believes that it would be more straightforward to calculate a risk-based, maximum permissible concentration for dioxin-like compounds. If the Agency establishes a cap for the dioxins in biosolids that are land applied, using a risk level of 1×10^{-4} (as done during Round 1 of the Part 503 Regulation for other regulated pollutants) the dioxins cap would be approximately 1,750 ppt TEQ. (This assumes that there are no errors in the Agency's original risk calculations.)

However, Cambridge Environmental indicates that there were errors in the original risk calculations and determined, based on corrected risk assessments for land application and a risk factor of 1×10^{-4}, the cap would be 833 ppt TEQ. (See the attached Cambridge Environmental report for details.)

AMSA does <u>not</u> believe that a 300 ppt TEQ cap would create an unnecessary or excessive burden for POTWs that land apply their biosolids. However, AMSA would rather see a 1×10^{-4} risk factor (i.e., good science) used to determine the cap. This action would more closely parallel previous Agency rulemakings, and would demonstrate that current dioxin levels in biosolids are far below maximum safe levels.

2. Using EPA analytical methods 1613B for dioxin and dibenzofurans, and methods 1668 or 1668A for coplanar PCBs.

AMSA is concerned since the proposed methods have not yet been approved for use in biosolids. In addition, it would be inappropriate for the Agency to require permittees to use test methods that have not completed the approval process. AMSA recommends that "approved" test methods be listed in the final rule, along with the usual regulatory language of "or approved EPA methods", in order to accommodate the aforementioned methods once they have been peer reviewed and approved.

A more detailed review of the proposed test methods by one of our members revealed that they are "performance based." The analyst is permitted to modify the method to overcome interferences or lower the cost of measurements, providing that all performance criteria are met.

There are not demonstrated holding times for the chlorinated dioxin congeners and coplanar PCB congeners in either aqueous or solid (soil, biosolids, tissue) samples. Properly refrigerated samples may be held up to a year. This is in contrast to USEPA Analytical Methods such as 624, 625, 1624 and 1625, which require analyses within 7 days of sample collection and 40 days after extractions.

The analysis times for dioxins may exceed the long-term mass stability of the spectrometer. Therefore, automatic mass-drift correction is necessary, and a low-mass m/z from perfluorokerosene (PFK) is required.

In summary, AMSA suggests that the Agency revise the test methods section of the proposed rule.

3. Requiring two consecutive year of monitoring results under 30 ppt TEQ before allowing a reduced monitoring schedule.

AMSA agrees that if testing of biosolids reveals that the dioxins concentrations are under a specified level for two consecutive years, the testing schedule should be reduced to once every five years.

However, we do have concerns that the public may view the 30 ppt TEQ level as the true "safe" concentration, instead of an arbitrary test level. Considering that this value is less than median value of dioxins in biosolids (when non-detects are set at one-half the detection limit), more than half of all generators will not be able to take advantage of the proposed reduced monitoring requirement even though their biosolids levels are well below safe concentration and may be stable or declining. This aspect of the rule is of concern and if retained in the final rule, the Agency should clearly identify the significance of the 30 ppt TEQ value.

AMSA would like to see the testing requirement dropped to once every five years, for POTWs that have dioxins concentrations of less than a specified amount. AMSA recommends that the specified amount be set closer to the 75th percentile and not at an arbitrary 30 ppt TEQ.

On the other hand, the Agency could utilize a tiered approach to dioxins testing. The following potential tiered approached is based on a cap of 833 ppt TEQ[1]:

$X < 100$ ppt TEQ	once every five years
100 ppt TEQ $\leq X <$ 400 ppt TEQ	once every three years

[1] Using corrected risk assessments, the 300 ppt TEQ cap has a risk factor of 3.6×10^{-5}, while if the Agency used the Part 503 Regulation's standard risk factor (i.e., 1×10^{-4}) the cap would be 833 ppt TEQ.

400 ppt TEQ $\leq$ X $<$ 833 ppt TEQ once every year

It should also be noted that there are only a limited number of laboratories in the United States that have the expertise/experience to properly conduct the dioxins testing of biosolids. (AMSA discovered this when it interviewed prospective testing laboratories before it conducted its 1994 dioxins study.) In addition, the testing will cost approximately $2,000 per sample.

AMSA also requests that the Agency specify, in the final rule, how congener concentrations that are below the detection limits should be addressed. AMSA recommends that concentrations below the detection limit be set, in accordance with standard Agency policy, at one-half the detection limit when determining TEQs.

4. Whether or not the assumption that the levels of dioxins in biosolids are relatively constant over time and may possibly be decreasing.

From the existing biosolids databases cited by the Agency in the proposed rule, AMSA cannot determine whether or not the levels of dioxins in biosolids are relatively constant or may be decreasing, since the available data only represents snap-shots in time.

However, data recently obtained from the city of Portland revealed that dioxins concentrations in their biosolids substantially dropped over an eight year period, as follows:

Year	Dioxin (ppt TEQ/dry kg)
1992	246
1993	122
1994	83
1995	53
1996	20
1997	15
1998	16
1999	19

AMSA was pleased to hear that during the year 2000 the Agency plans to analyze samples of biosolids (from 25 of the 33 POTWs that participated in the 1988 National Sewage Sludge Survey that contained PCBs) for dioxins.

In addition, on February 4, 2000, AMSA's Board of Directors approved a request from the AMSA

Biosolids Management Committee to conduct another study to determine dioxins levels in biosolids. As previously reported, AMSA conducted a survey in 1994, and shared its findings with the Agency's Dioxin Health Risk Assessment Workgroup. The data are cited in the proposed regulation.

AMSA hopes to conduct its dioxins study this year, and to present its findings to the Agency early next year.

5. **Whether the Agency has clarified existing monitoring requirements by separating § 503.16(a) into two paragraphs or if the proposed change unintentionally changes the substance of the frequency of monitoring provisions currently in §503.16(a)(1).**

A number of AMSA member agencies suggest that the Agency further clarify the differences in the frequency of monitoring requirements for dioxins and other regulated parameters.

6. **Requesting information on the dioxin content, annual application rates, number and size of sites, and applications per site for biosolids from treatment works with flow rates of one MGD or less whether to exempt small treatment works for both initial monitoring requirements and dioxin limits for land application.**

AMSA does not have any information on treatment works with flow rates of one MGD or less. However, given the concerns over dioxins in biosolids that are land applied, AMSA believes that all small treatment works that land apply their biosolids should be subject to dioxins testing once every five years.

7. **The proposed designation of small treatment works as one with a flow rate of one MGD or less, and the proposed designation of other small biosolids preparers that are not treatment works as those preparing biosolids for land application in an amount of 290 dry metric tons or less annually.**

AMSA agrees with the Agency's proposed designation of small treatment works and other small biosolids preparers. However, given the concerns over dioxins in biosolids that are land applied, AMSA believes that all small treatment works that land apply their biosolids should be subject to dioxins testing once every five years.

8. **Requesting information on exposure pathways not evaluated.**

AMSA does not have any information or opinions on the pathways that were not evaluated.

9. Proposing no action in regulating dioxins in biosolids that are placed in a surface disposal unit or incinerated in a biosolids incinerator.

AMSA agrees that no action be taken in regulating dioxins in biosolids that are land applied at surface disposal sites due to the unique nature of surface disposal, and the fact that the HEI individual cancer risk was determined to be 3.5×10^{-7}. There are only a limited number of biosolids surface disposal sites in operation, and they do not require any regulatory control for dioxins (AMSA is only aware of 3 surface disposal sites that are currently in service.)

AMSA also agrees that no action be taken for biosolids incinerators since:

a. Biosolids incinerators are an insignificant source of dioxins.

b. The fact that no estimated risk exceeded 2.1×10^{-6} including infants from the sub-population with the greatest exposure from the highest dioxins emitting biosolids incinerator.

c. The emissions of dioxins have been further reduced with the self-implementation of the Part 503 Regulation's Total Hydrocarbon Standard for biosolids incinerators. (THC is a surrogate for emissions of all organic compounds including dioxins.)

10. Whether EPA should establish numeric limits for dioxins in biosolids for all use and disposal methods.

AMSA believes, based on the risk assessment conducted by the Agency, and the minimal levels of dioxins contained in biosolids and biosolids incinerator exhaust gases, that there is no the need to establish numeric limits for dioxins in biosolids for all use and disposal methods. No significant risks have been demonstrated for any disposal pathway involving biosolids, using any reasonable assumption.

11. Proposing no action for dioxins in biosolids that are land applied.

Given the concerns over dioxins in the environment, and the fact that the land application of biosolids accounts for, at most, 4% of the dioxins applied to land in North America, AMSA understands the Agency's position that a dioxins limit is necessary for biosolids that are land applied.
However, AMSA suggests that the Agency use a 1×10^{-4} risk factor in determining a dioxins limit for biosolids that are land applied, consistent with what was utilized in Round 1 rulemaking.

12. Whether there are any privately owned treatment works with flows greater than one MGD that also have revenues less than $6 Million.

AMSA does not have any information concerning privately owned treatment works.

13. Data on the cost to switch from land application to alternative use or disposal practices (compared to the assumption of $189 per dry metric ton to switch to co-disposal with municipal solid waste.)

A number of AMSA members indicated that the Agency's assumption is realistic. However, one member noted that its costs would increase by almost $300 per dry metric ton. Therefore, the cost differential has to be determined on a case-by-case basis.

14. Potential impacts of the proposed rule on small entities and on issues related to such impacts.

AMSA does not have any information concerning this request. However, it does believe that all small entities that land apply their biosolids should be required to conduct dioxins testing once every five years.

15. The use of the proposed alternative definition of small entity-both for this proposed rule and for subsequent rulemakings.

AMSA does not have any comments concerning the proposed definition.

16. Consensus methods that are suitable for compliance monitoring for determining dioxins, dibenzofurans and co-planar PCBs in biosolids.

AMSA requests that the proposed test methods be peer reviewed and approved before they are included in the final rule. AMSA members are willing to work with the Agency, in a consensus mode, to determine acceptable test methods.

AMSA wishes to thank the United Sates Environmental Protection Agency for this opportunity to submit comments on the proposed rule, dated December 23, 1999, concerning dioxin, dibenzofurans and dioxin-like coplanar PCBs in biosolids (that are land applied, place in surface disposal sites, or in monofills,) and in biosolids incinerator exhaust gases.

AMSA also requests that the Agency thoroughly review the comments, suggestions and questions contained in this letter and the attached report.

If you have any questions or require additional information concerning AMSA's position on the aforementioned issues, or the items contained within the attached report prepared by Cambridge Environmental, please do not hesitate to contact Robert P. Dominak, Vice-Chair AMSA Biosolids Committee at 216/881-6600, or Mark Hoeke, AMSA Headquarters' Staff at 202/833-9106.

Sincerely,

Ken Kirk
Executive Director

Attachment

cc: C. Fox, EPA-HQ
G. Grubbs, EPA-HQ
R. Perciasepe, EPA-HQ
B. Dominak, AMSA
R. Kearney, AMSA
A. Rubin, EPA-HQ
M. Jordan, EPA-RTP
G. Crumpler, EPA-RTP
S. Armstrong, Cambridge Environmental
AMSA Biosolids Management Committee
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Comments on EPA's Proposed Standards for the Use or Disposal of Sewage Sludge, December 23, 1999

Docket Number W-99-18

Prepared for:
Association of Metropolitan Sewerage Agencies

by:
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March 22, 2000

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Contents

1 Introduction

These comments address "Standards for the Use or Disposal of Sewage Sludge," proposed by U.S. EPA in the Federal Register of December 23, 1999, and are sponsored by the Association of Metropolitan Sewerage Agencies (AMSA)[1]. AMSA sponsored comments by these same authors in 1995 for submission to U.S. EPA as EPA conducted its dioxin reassessment. Those comments, part of which presented and analyzed the dioxin[2] content of biosolids (treated sewage) samples from AMSA member POTWs and dioxin emissions from biosolids incinerators, are cited as Green *et al.*, 1995, in EPA's proposed standards now under consideration.

We have reproduced the risk assessment calculations for the major pathways of exposure as found in EPA's analyses, and generally agree that the other routes are likely to be minor. In the process, we have found errors, omissions, and inconsistencies. However, correcting such errors, omissions, and inconsistencies usually results in only small changes in the final results, confirming the EPA's decision that regulation of dioxin-like compounds in most uses or disposal methods of sewage sludge is not needed. The only serious omission that we have discovered was in the Proposed Rule discussion, which omitted any discussion of the exposure pathway — direct soil ingestion after land application — found in the supporting analysis to present the highest risks (possibly higher than acceptable). Examination of this exposure pathway, however, showed the analysis to be substantially flawed. Correcting the errors in the analysis still left this the pathway with highest risk estimates, but those risk estimates are in the acceptable range.

For incineration of sewage sludge, the analyses presented in the supporting documents are confusing, because there are two of them. The first, a screening analysis that estimates risk from the inhalation pathway only, is not mentioned in the Proposed Rule. It uses a simplified approach to dispersion modeling, incorporating an unjustified and arbitrary ten-fold multiplying factor applied to modeled results. While the inhalation pathway risks found in this screening analysis are themselves acceptable, the implied indirect risks might not be acceptable. However, the fuller analysis of sewage sludge incineration (provided in a separate document) indicates inhalation risks that are substantially smaller, and indirect risks that are in the acceptable range. We have confirmed that the inhalation pathway calculations are numerically correct and based on reasonable air dispersion estimates. While we expect there may be some errors in the indirect pathway modeling, the results are in a reasonable range for such indirect pathways. Complete

[1] "Standards for the Use or Disposal of Sewage Sludge," proposed by U.S. EPA in the Federal Register of December 23, 1999, hereafter, "the Proposed Rule."

[2] In general, "dioxin" in this document, and in the Proposed Rule, refers to chlorinated dibenzo-*p*-dioxins, chlorinated dibenzofurans, and PCBs with TCDD-like activity.

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analyses of these indirect pathways is impeded by the EPA's use of non-peer-reviewed models, and in our inability to obtain the Agency's spreadsheets until very recently.

These and other comments are detailed below. Our main concerns are: inconsistencies in the TEF systems applied to biosolids data sets and analyses; statistical errors in treating biosolids data sets; the arbitrary selection of a concentration cap which is associated with (hypothetical) incremental lifetime cancer risks below the traditional level of regulatory concern; and the lack of public access to documents and spreadsheets integral to a thorough review of the Proposed Rule.

We recommend that EPA establish a cap on dioxin-like compounds applied to land based on an excess lifetime cancer risk of 1×10^{-4}. Applying this risk limit to the soil ingestion pathway, corrected as we detail below, gives a concentration of approximately 800 ppt TEQ in biosolids.

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2 Response to Invited Comments

2.1 Definition of dioxins (IV.B.2)

EPA proposes a definition of dioxins — one that includes the standard 2,3,7,8-substituted congeners of polychlorinated dibenzo-*p*-dioxins and polychlorinated dibenzofurans as well as 12 specific PCBs with non-zero TEFs in the most recent scientific evaluation — that is reasonable in the context of regulations controlling use or disposal of biosolids. Other dioxins, furans, and PCBs lack TCDD-like activity, cannot be quantified in terms of TEQ, and should not be addressed in this rule. We suggest that the twelve PCBs of concern be identified in the final regulation by IUPAC number as well as by CAS registry number. A precise definition is particularly important since the backup documentation for this Proposed Rule is confusing with regard to the definitions of dioxin-like PCBs: the backup documentation for the risk analysis (Abt Associates, 1999) lists only four PCB congeners as having non-zero TEFs, the Proposed Rule implicitly uses twelve PCB congeners (the number with TEFs defined by Van den Berg *et al.*, 1998), the sewage sludge incineration backup document (EC/R Incorporated, 1999) uses a set of thirteen PCB congeners for which TEFs were defined by Ahlborg *et al.* (1994), and the analysis of the AMSA database used four PCBs with non-zero TEFs.

Recommendation:

Identify the 17 dioxin congeners and 12 PCB congeners by IUPAC number (and also by CAS registry number) in the final regulation.

2.2 Toxic Equivalency Factors (IV.B.2)

The final regulation, in citing Van den Berg *et al.* (1998) as the source of TEFs for the PCBs, should specify that the TEFs for humans/mammals, and not for other wildlife, be used. Indeed, for clarity, the regulation should list the TEFs to be used for each compound.

It is notable that EPA has turned to the scientific literature to obtain updated estimates for TEFs for the PCBs, yet has not updated the TEFs for some of the PCDD/PCDF congeners, based on more data and updated analyses. EPA does not discuss this contradiction. In view of the improved set of data on which the WHO TEFs are proposed (Van den Berg *et. al.*, 1998), and the scientific consensus achieved at an international expert meeting, EPA should adopt the updated TEFs for the PCDD/PCDF congeners as well. The updated TEFs are for 1,2,3,7,8-

pentachlorinated DD (from 0.5 to 1.0), octachlorinated DD (from 0.001 to 0.0001) and octachlorinated DF (from 0.001 to 0.0001).

This change might cause some administrative problems, but would improve, perhaps substantially, the correspondence between the proposed rule and its underlying rationale to reduce the potential environmental risks and maximize the beneficial use of sewage sludge. Thus, in addition to listing the current TEFs to be used in the rule, the rule should somehow contain a method by which those TEFs can be changed to take account of updated scientific information. Indeed, any regulation specifying limits on a TEQ basis should allow for improved estimates in TEFs; at the same time, the bases for such regulations should be revisited in light of modifications to TEF systems. Such changes are likely to have little effect on risk-based systems, provided the risk estimates do not depend heavily on the precise congener distributions evaluated. For the worst-case pathway evaluated (see Section 3.6.3), the variation in risk estimates due to different congener distributions is very small (indeed, the risk estimate cannot be more that 2-fold higher, or 3-fold less, for the most extreme congener distributions — namely, all one congener — with the same total TEQ).

Significantly the calculations underlying the Proposed Rule need to be performed with a consistent set of TEFs. Currently, there are mixed sets of TEFs used in different calculations in different analyses supporting the Proposed Rule:

Calculations on the AMSA database:	PCDD/PCDFs: I-TEF; PCBs: Ahlborg *et al.* (1994)
Calculations on the NSSS[1] database	PCDD/PCDFs: I-TEF (No PCBs)
Risk assessment	PCDD/PCDFs: I-TEF; PCBs: WHO-TEF (1998)
Incineration risk assessment	PCDD/PCDFs: I-TEF; PCBs: Ahlborg *et al.* (1994)

The EPA is thus mixing the TEF schemes substantially. The total TEFs estimated from the two biosolids databases are amalgamated, using different assumptions for non-incineration risk assessments (Abt Associates, 1999) and in the incineration risk assessment (EC/R Incorporated, 1999). In the first, the four PCB congeners with non-zero TEFs in the WHO-TEF scheme that were analyzed in the AMSA survey are carried through the process. In the second, a hypothetical distribution of the 13 PCB congeners with non-zero TEFs in the Ahlborg *et al.* (1994) scheme is constructed and analyzed.

The effect of using the recent WHO-TEF scheme for both CDD/CDF and PCBs, instead of the Ahlborg *et al.*, (1994) and I-TEF schemes, on the AMSA database is not substantial — two of the 74 samples exceed the proposed 300 ppt cutoff, rather than three, and the distributions of values are very similar. The effect of using current TEFs might be much larger on the NSSS database if the values are dominated by OCDD/OCDF. Unfortunately, we cannot assess the impact of updating the TEQ values for all the NSSS data before the end of the comment period. We have, however, evaluated the effect on the NSSS sample with highest total I-TEF TEQ, that

[1] EPA's 1988 National Sewage Sludge Survey.

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from Billerica, MA. Using the I-TEF scheme, this maximum value is 1760 ng TEQ/kg, while using the WHO-TEF scheme it is 892 ng TEQ/kg. We strongly believe that EPA should evaluate the effect of using the updated scheme, as this might change what EPA considers to be the 95% percentile of the distribution of PCDD/PCDF TEQ in biosolids. See also our comments in Section 3.2 on the evaluation of the 95th percentile.

Recommendations:

- Use the updated WHO-TEF values consistently, for dioxins as well as PCBs.
- Perform analyses using a consistent set of TEF values.
- State the current values of the TEFs that are used for all the congeners in the regulation.
- Write the regulation to allow updates for the TEFs to allow tracking the best available scientific information.

2.3 Mechanical incorporation into soil (V.B.2)

The EPA has provided no analysis of the necessity or otherwise of mechanical incorporation of biosolids into soil, or of the reasonableness of the 30-day exclusion period. Such analyses are possible, although we have not performed them. The rate of mixing of land-applied sewage sludge into the soil column will depend on the activity and density of soil organisms and on the effectiveness of other soil mixing mechanisms (*e.g.,* rainfall). The activity of soil organisms depends on the treatment and type of land — ploughed land has fewer earthworms, for example, than land left unploughed — and their activity will depend on temperature and other factors. Rainfall may act as an effective mixing agent in the surface layers of loose soils. In addition, there are mixing mechanisms that apply to the contaminants of concern (here, PCDD/PCDFs and PCBs) that do not apply to the sludge as a whole — for example, dissolution and water transport, and vapor transport. Some of these mixing mechanisms can be incorporated into standard models for movement of contaminants in soil layers — for example, water and vapor transport may be evaluated with diffusion models, and the effects of soil animals can also be incorporated into such models by using an effective dispersivity induced by their movement of soil.

A better approach might be to evaluate direct measurements of soil profiles immediately after land application, and during various periods thereafter. While such measurements may not be available for PCDD/PCDFs and PCBs, they almost certainly are for pesticides.

Recommendation:

Perform analyses and/or evaluate measurements and/or perform measurements of the transport of surface-deposited materials into the soil column.

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2.4 300 ppt TEQ cap (VII-1)

We do not believe that EPA adequately justifies its method of identifying a cap on the TEQ-based concentrations of dioxin-like compounds in biosolids. What is the public health rationale for picking a percentile of the distribution of these concentrations, whether at the 95th, 99th, or 50th percentiles? Public health is protected by back-calculating what maximum concentration of dioxin-like compounds does not pose risks of concern by various biosolids use and disposal pathways, or by ascertaining whether the worst-case concentration poses a risk of concern — and 1.7×10^{-5} is not a traditional level of concern at EPA. To pick a point on the distribution simply makes it certain that some biosolids will fail the regulatory test from time to time.

Indeed, EPA has already, in the Part 503 regulations, chosen a risk level of concern at 1×10^{-4}. Using this value as the level of concern would imply a cap of approximately 1765 ppt TEQ, if the risk estimates of 1.7×10^{-5} discussed in the Proposed Rule were indeed worst-case and correct. However, neither of the two risk estimates (for different exposure pathways) leading to the value 1.7×10^{-5} is correct (they are both overestimates, as discussed in Sections 3.6.4 and 3.6.5), and neither is the worst-case (see Section 3.6.3). The worst-case pathway is actually child soil ingestion (pathway 3) at a public contact site, a pathway that is not discussed in the Proposed Rule, and for which a corrected risk estimate is 3.6×10^{-5} using the parameters of the Proposed Rule and the technical documentation. This worst-case exposure estimate leads to a cap of approximately 833 ppt TEQ, corresponding to estimate of increased lifetime cancer risk of 1×10^{-4}.

It would also be useful for EPA to conduct a cost-benefit analysis of its proposed rule: it has or can develop information on the cost of chemical analyses, the number of POTWs, likely test frequencies, amount of biosolids that are land applied, and the risks avoided by preventing land application of biosolids containing more than 300 ppt TEQ (or any other cap) of dioxin-like compounds.

Recommendations:

- Select a cap value based on a defined risk of 1×10^{-4}. Our best estimate for this cap is currently 833 ppt.
- Perform a cost-benefit analysis for the proposed rule.

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2.5 *Trend in dioxin concentration over time (VII-4)*

EPA refers to two databases containing concentrations of dioxins and furans in biosolids, its National Sewage Sludge Survey (NSSS), and the AMSA survey cited as Green *et al.* (1995).[2] The AMSA data, collected in 1994, and the 1988 NSSS data derived mean concentrations of dioxins and furans in biosolids of 48 and 50 ng TEQ/kg dry weight (48 and 50 ppt, TEQ), respectively, when non-detects are set equal to zero. The respective medians are 30 ppt and 11 ppt TEQ. When non-detects are set equal to the detection limit, the mean concentrations are 65 and 86 ppt TEQ, for the AMSA and NSSS data sets, and the medians are 50 ppt TEQ in each survey. These values are presented in the table below.

Whether one sees a trend in the data depends on one's opinion about the best way to numerically evaluate non-detected compounds at two points in time. It is likely that detection limits in the 1988 NSSS were higher than in 1994, which would lead to an overestimation of non-detected compounds if detection limits were used instead of zero values or one-half of the detection limit. The effect would be large in the case of 2,3,7,8-tetrachloro-p-dioxin, which was detected in only 16% of samples from the 1988 NSSS, and which has, of course, the largest TEF. In our judgment, no clear conclusion about changes in the TEQ-based dioxin and furan concentrations in biosolids over time can be made from these data sets. EPA, in fact, described the results of the two surveys as "very similar" (U.S. EPA, 1998). Indeed, the way in which the PCDD/PCDF results from the NSSS were combined with the PCB results from the AMSA survey by EPA's contractor SAIC would require that there be no change, at least between 1988 and 1994, in the distributions of concentrations of either the PCDD/PCDFs or the PCBs (see Section 3.2).

[2] The 1990 Federal Register document cited by EPA in the proposed rule as the source of the 1988 NSSS data does not, as best we can determine, give any quantitative information regarding concentrations of chlorinated dioxins and furans. Our information on the 1988 NSSS data comes from EPA's 1994 *Estimating Exposure to Dioxin-Like Compounds*, Review draft (EPA/600/6-88/005Cb) and from EPA's 1998 *Inventory of Sources of Dioxin in the United States*, External review draft (EPA/600/P-98/002Aa).

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Concentrations of chlorinated dioxins and furans in biosolids in two surveys (ppt TEQ, dry weight)				
	Non-detects = zero		Non-detects = detection limit	
	Mean	Median	Mean	Median
1988 NSSS	50	11	86	50
1994 AMSA	48	30	65	49

While we are aware of no published information on time-trends of PCDD/PCDF/PCB concentrations in individual facilities, we believe that individual AMSA members intend to submit such data. Perhaps the Agency will thus obtain data describing concentrations over time at particular facilities that would allow its hypothesis to be tested, at least on a local scale.

In addition, further data will be obtained in the forthcoming AMSA study of PCDD/PCDF/PCB concentrations in biosolids, intended to update the previous (1994) AMSA study. Cambridge Environmental Inc. will be analyzing the data from the forthcoming study, and intends to perform comparisons with the 1994 study. These analyses will be provided to EPA as soon as possible. Furthermore, we understand that EPA will undertake its own survey, and AMSA hopes to collaborate with the Agency. Collectively, these data should help the Agency determine whether dioxins concentrations are decreasing over time.

Recommendation:

- Explain more fully the reasons for an expectation of a decrease in concentrations.
- Seek out and evaluate any time trend data from individual facilities.

2.6 Flow rate exclusions (VII.(7) and IV.B.1)

The flow rate is specified as one million gallons per day (mgd), presumably of total liquid + solids, although the precise meaning of flow rate is not specified. A flow rate based on total solids would be more appropriate, to take account of variations in solid content. Such variations may occur over long time spans (multiple years) in individual sewage systems, and between different sewage systems. The current approach might more strongly affect sewage treatment works in areas with combined sewer overflows.

The flow rate should be specified as an "average" flow rate, otherwise the rule might be interpreted as applying to any treatment works with a peak flow rate of 1 mgd. We suggest using an annual average, to take some account of seasonal variations in flow rates.

If EPA retains a flow rate exclusion in the final rule, it should confirm that small POTWs do not produce biosolids with higher concentrations of dioxin-like compounds than are produced by

larger facilities. EPA could assess dioxin concentration as a function of flow rate, for instance. AMSA failed to find any such correlation in its database, but we do not know if EPA has made a similar analysis of the NSSS.

Recommendation:

- State any flow rate exclusion in terms of solids content of the flow.
- Specify that the flow rate involved is an annual average.
- If EPA retains a flow rate exclusion in the final rule, it should check the range of dioxin concentrations in biosolids from small POTWs.

2.7 Reasonableness of the proposed monitoring schedule (IV-B-4)

EPA is proposing that POTWs sample biosolids annually if the concentration of dioxin-like compounds is 30–300 ppt TEQ, or every five years if the concentration is less than 30 ppt TEQ two years in a row. EPA has not specified any schedule for biosolids found initially to contain >300 ppt TEQ, if that POTW wishes to subsequently prepare sewage for land application or land-apply the sludge — for example, would that POTW monitor annually and be free to apply the biosolids to land as soon as even one test result was in the 30–300 ppt TEQ range? Or could it test monthly and apply to land once the results was <300 ppt TEQ?

In addition, we do not see that the proposed monitoring schedule is justified by the database describing biosolids concentrations of dioxin-like compounds. While we know of no published data showing concentrations of dioxin-like compounds over time from a single POTW, we expect other comments submitted to this docket from AMSA members to include monitoring data that contain relatively frequent monitoring for PCDD/PCDFs. Without such data, the day-to-day (or month-to-month) variability in concentrations in unknown. If the variability is small, then annual (or less-frequent) tests may adequately characterize the material over time. However, EPA has not yet shown this to be the case. EPA should evaluate the variability in any submitted data to support their proposed sampling schedule.

We agree with EPA that even with current knowledge it is highly unlikely that unmeasured exceedances of 30 ppt for five years would cause significant increments in risk. The risk assessment evaluated exposures that were as short as 2 years in the land application scenarios, and in fact the highest risk estimate comes from an exposure duration of five years (see Section 3.6.3). However, such high-end risk estimates are predicated on a preceding period of land application of biosolids of close to a century, and the effective averaging time is much longer than five years. Even so, this conclusion should be bolstered, if possible, by an evaluation of any available time-series data for PCDD/PCDF/PCB concentrations.

Recommendation:

- Seek out time series data for PCDD/PCDF/PCB measurements in biosolids and evaluate the implications of any observed variability.

2.8 Request for information on exposure pathways that were not evaluated (VII-8)

To our reading, the request for comments on "direct risks to livestock, soil organisms, wildlife, and plants," refers to other receptors rather than pathways.

We have no opinion about whether these other receptors should be assessed, although clearly, if they were, the Agency would have to attend to other end-points than cancer. Regardless, the following information may be of use to the Agency.

Of possible ecological receptors, mink are particularly sensitive to PCBs (to reproductive toxicity, not cancer). Assuming that large releases of biosolids to water bodies are unlikely, however, risk to mink seem low. Recent papers addressing toxicity of dioxin-like compounds to mink are:

Restum, J., *et al.* (1998) *J. Toxicol. Environ. Health Part A 54*:343.

Shipp, E. *et al.* (1998a) *J. Toxicol. Environ. Health Part A* 54:377.

Shipp, E. *et al.* (1998b) *J. Toxicol. Environ. Health Part A 54*:403.

The following references describe toxicity (or, more usually, lack thereof) of Aroclor mixtures to cows and crops. In conjunction with information about the concentration of dioxin-like PCBs, these papers may be useful to EPA if it wishes to assess these ecological receptors:

Bacci, E. and Gaggi, C. (1985). *Bull. Environ. Contam. Toxicol. 35*:673.

Perry, T. W. *et al.* (1984). *J. Dairy Sci. 67*:224.

Strek, H. *et al.* (1981). *J. Agric. Food Chem. 29*:288.

Weber, J.B. and Mrozek, E. (1979). *Bull. Environ. Contam. Toxicol. 23*:412.

Willett, L.B. and Hess, J.F. (1975). *Residue Rev. 55*:135.

Willett, L. B. *et al.* (1987). *Fundam. Appl. Toxicol. 9*:60.

With respect to other pathways of exposure, we believe that the Agency has evaluated all the most significant ones. Similar multi-pathway exposure and risk evaluations have now been performed for many circumstances, and there is no evidence to indicate that major pathways of exposure have been omitted.

Recommendation:

No further pathways need to be evaluated.

2.9 No-action proposal for incineration and surface disposal (VII-9)

Given the very small risk estimates for the surface disposal and incineration pathways, and the small populations involved, we endorse the no-action proposal for these pathways. We have not duplicated the risk assessment results for the surface disposal pathway, but the results obtained are well in line with expectations, given the low volatility of the compounds under consideration.

For the incineration pathway, we have verified that the air dispersion results appear reasonable, and have verified the calculations for the air inhalation pathways. For the more complex pathways, we congratulate the EPA on using what appear to be appropriate estimates for many of the parameters involved, rather than selecting extreme upper estimates and so compounding the conservatism of the risk estimates. We have not verified the calculations or the modeling for these more complex pathways, given the available time and resources, but the results obtained appear to be reasonable.

We should like to remind the EPA that the complex modeling used in the incineration risk assessments has largely not been adequately peer-reviewed, has largely not been verified, and has not been subjected to rigorous quality control measures. Most of the references for the modeling performed within the documentation are to draft documents that have not themselves been peer-reviewed. Previous modeling efforts along these lines have not been entirely successful, and have themselves suffered badly as a result of the lack of adequate quality control and review. In particular, an SAB review of the similar HWIR modeling (SAB, 1996) pointed out some of the problems, and more recently an NAS report (NRC, 1999) has re-emphasized the need for careful quality control, adequate review, and verification. Adequate evaluation of such complex modeling really requires a longer period that even the 90 days allotted for review of this proposal, and demands resources that are beyond what most commenters can allocate.

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2.10 Numeric limits for all disposal methods (VII-10)

See comment 2.4 above.

2.11 No action for land application (VII-11)

It is unlikely that a no-action policy would cause many (or perhaps any) people actually to incur excess cancer risks of approximately 1 x 10^{-4}, as EPA states would occur at the highest observed CDD/CDF concentration of 1700 ppt TEQ. Indeed, it is likely that the highest PCDD/PCDF concentrations measured in the NSSS correspond to substantially lower total TEQs when account is taken of the latest scientific information on TEFs (see Comment 2.2).

The EPA's rationale for setting a lower cap based on background exposures is incompletely justified, however, and it is odd to find a risk-related explanation of a 300 ppt TEQ cap this late in the Proposed Rule. Does EPA believe the risk due to background exposures is unacceptable? And is a background risk of 10^{-4} the 50th, 95th, or other percentile of the risk distribution? Is EPA establishing a new policy by which acceptable cancer risk increases depend on background exposures? How likely is it that a person's risk of cancer from dioxin-like compounds would actually be doubled if land application of biosolids were not regulated as to concentration? As we stated earlier, it would be more straightforward to calculate a risk-based, maximum permissible concentration of dioxin-like compounds and make that an action limit for land-applied biosolids. Or, such an analysis could take account of other sources of exposure, as is done via relative source contributions for non-carcinogens in the drinking water standards program.

Recommendation:

EPA should retain a cap value for land application, but with a TEQ concentration specified for 1 × 10^{-4} increment in lifetime risk estimate.

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3 Comments on EPA's risk assessments

3.1 Introduction

In this chapter, references to "RA" are to the EPA's risk assessment document *Risk Analysis for the Round Two Biosolids Pollutants*, prepared by Abt Associates Inc. for the U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division, December, 1999. "RAI" refers to *Sewage Sludge Incinerators' Dioxin-Like Compound Risk Analysis Technical Documentation* (EC/R, 1999).

3.2 Evaluation of percentiles of concentrations

The procedure used by SAIC (1999) to estimate the relative contribution of PCBs to total TEQ is incorrect for three reasons. First, the mathematical procedure is incorrect, since it aligns the most extreme values from two data sets that have differing numbers of samples. This error can be made starkly obvious by considering applying the same procedure as used by SAIC on the PCDD/PCDF TEQ values obtained in the NSSS data and the PCDD/PCDF TEQ values (rather than the PCB values) obtained in the AMSA survey. If the SAIC procedure were correct, this should separately generate two estimates for the same percentiles of the distribution of PCDD/PCDF TEQ values; but clearly the percentile estimates obtained for the two cases are drastically different at the upper end, since the maximum values observed in the two cases are so different. Similarly, attempting to "overlay" the PCB values from the AMSA survey with the PCDD/PCDF values from the NSSS gives incorrect results.

Second, the samples were taken at different times. It is the EPA's own contention that the concentrations of PCDD/PCDF/PCBs have been decreasing with time. In that case one cannot expect the distributions obtained at different times to be equal, as assumed by the SAIC procedure.

Third, the procedure used by SAIC implicitly assumes complete correlation between PCDD/PCDF TEQs and PCB TEQs. For the AMSA dataset, this assumption is false. While the combined distribution for total TEQs obtained by making this assumption is not too different from the observed distribution of total TEQs over most of its range, there are substantial differences at the upper end of the distribution that affect estimates of the 95th percentile if this estimate is obtained as SAIC attempts it (although in this case, the 95th percentile estimated this way comes out too low by about 10%).

To correct the first error, a better approach for estimating the relative contributions of the PCB TEQs to the total is to evaluate that relative contribution in the AMSA survey. The AMSA database shows that PCBs actually amount to about 24% of the total using the mixed TEF system (I-TEF 89 for PCDD/PCDF, WHO-TEF for PCBs), or about 28% using the WHO-TEF system consistently. These values appear to be almost independent of the total amount in the sample, or perhaps increasing a bit as the sample total increases — the scatter certainly appears to increase as the sample total increases.[3] SAIC's procedure has introduced a substantial artefact in this aspect of the joint distribution of concentrations of PCDD/PCDFs and PCBs. The effect of correcting this artefact is not obvious. It will probably make the 95th percentile total higher, but with a higher PCB fraction — and we have not calculated what effect, if any, that has on the risk assessments.

To correct the second and third errors and correctly take account of the time variation in concentrations and the PCDD/PCDF vs. PCB correlations, the best approach is to use the latest set of the most complete data — the AMSA survey — to obtain the best estimate of more recent concentrations including PCBs. The AMSA survey suggests that the 95th percentile is now closer to about 250 ng/kg, with PCBs contributing about 25%.

Finally, SAIC used linear interpolation of the TEQ values themselves on a scale of percentiles. Such an approach can be expected to introduce substantial errors for any non-linear distributions, particularly at the extremes (for example, the highest measured value from a sample is certainly not expected to be the 100th percentile of the population distribution). Plotting the TEQs from the AMSA data as logarithm of TEQ versus expected normal order statistic shows a much more linear plot, so that linear (or higher order) interpolation on such scales can be expected to give better estimates for intermediate percentiles. We expect the same to be true for the NSSS data. Such an approach also takes account of the problem of differing sample sizes discussed above, if it is necessary to combine distributions from two sample sets that are otherwise compatible (in this case, measured at the same time).

3.3 Dose-response analysis (RA, Section 2.1)

The risk assessment is said to use a value of 1.5×10^5 kg-d/mg as the carcinogenic potency slope for 2,3,7,8-TCDD (although the spreadsheet contains the value 1.56×10^5). This value is given

[3] It seems likely to us that the distribution of CDD/CDF alone in biosolids samples is less skewed than the distribution of PCBs alone; that is, the upper end of the PCBs distribution is probably influenced by specific sources (hot spots, or discrete discharges) of PCBs. Thus, PCBs are likely to contribute a greater fraction of the total dioxin-like activity at the upper end of the distribution.

as obtained from HEAST (the *Health Effects Assessment Summary Tables*) from 1995, and is explicitly supposed to be an upper-bound estimate for the carcinogenic potency in humans. Unfortunately, it appears that HEAST is now defunct (since queries to EPA indicate that they cannot locate anyone who maintains it). EPA's recent dose-response assessments appear to give an upper-bound estimate of order 1×10^5 kg-d/mg for the carcinogenic potency slope (U.S. EPA, 1994). The Agency might wish to present a brief sensitivity analysis, using the range of potencies under consideration.

EPA should discuss its decision to assess risk of cancer only, as opposed to non-cancer health effects which the Agency believes can be caused by exposure to dioxin-like compounds (U.S. EPA, 1994).

3.4 TEF selection (RA, Section 2.2)

The risk assessment lists TEFs for PCBs in Exhibit 2-2. However, Exhibit 2-2 contains only four PCB congeners, not the twelve that are given non-zero TEFs in the cited reference (Van den Berg *et al.* 1998), presumably because of the seven PCB congeners available in the AMSA database, only these four have non-zero TEFs in the Van den Berg *et al.* (1998) scheme. This probably has no effect on the risk assessment, but could be misleading to those who used the risk assessment as a guide to performing the analyses of their waste stream, particularly since this is the only explicit documentation of the values of the TEFs to be used in the Proposed Rule. The table could list all congeners of interest, and note "not measured" if that was the case.

3.5 Number of upper end parameters (RA, Section 3)

It is stated in the RA, Section 3 (before Section 3.1) that "the HEI is generally defined by using high-end (usually 95th percentile) values for *at least* two parameters." (italics added). This appears to contradict the Proposed Rule's statement that EPA ". . . chose the 95th percentile concentration (USEPA, 1999e) of dioxins in sewage sludge and the highest dioxin emitting incinerators; and used one other high end exposure factor . . . ", meaning *exactly* two high-end parameters. In practice, more than two high end parameters were certainly used. For example, for the pathway giving the highest risk estimates — pathway 3 at the public contact site (see Section 3.6.3) — at least four, and possibly six or more, of the parameters are set at high-end values.

3.6 Land application

3.6.1 Parameter values

Erosion rate

The soil erosion rate is estimated at 6×10^{-4} m/yr (RA Exhibit 3-5) based on a reference to a 1987 Soil Conservation Service document, and this value is used for all land uses (agricultural, public contact, forested, and reclamation). More recent estimates[4] give an average Continental U.S. estimate (1982 through 1997) for the water (sheet and rill) erosion from cultivated cropland of 5.7×10^{-4} m/yr, but a total (wind together with water erosion) of 1.0×10^{-3} m/yr. (These estimates convert from the NRI's values in tons/acre-year using the assumed soil bulk density of 1600 kg/m^3.) The latter value should be used in estimating average soil concentrations (leading to lower soil concentration estimates), and the former value in estimating erosion into local water bodies, since the former includes a physical process not included in the latter — that is, the two parameters are distinct, and should be so treated in the modeling.

For non-cultivated croplands, however, erosion rates are substantially lower. For the public contact, forested, and reclamation land uses, average erosion rates are likely to be better estimated by the NRI's estimates for non-cultivated cropland or pastureland (totals 1.5×10^{-4} m/yr and 1.7×10^{-4} m/yr respectively, water erosion alone 1.0×10^{-4} m/yr and 1.5×10^{-4} m/yr respectively).

The NRI estimates indicate a declining trend in erosion rates over the 15-year period evaluated. However, in view of the long periods for weather cycles affecting erosion rates, it would be unwise to extrapolate the time trend observed in such a short record.

K_{ow} and Henry's law constant

These pollutant-specific parameters given in RA Exhibit 3-6 are referenced to "U.S. EPA .1999. Excerpt from Draft Update of: Estimating Exposure to Dioxin-Like Compounds. Office of Health and Environmental Assessment, Office of Research and Development. [Provided to Abt Associates by Matthew Lorber, Office of Research and Development.]" This document is not generally available, does not appear to be referenced anywhere on the EPA internet site, and does not appear in the Docket for examination. It is therefore difficult for the public to comment on the values used.

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[4] 1997 National Resources Inventory Summary Report available at http://www.nhq.nrcs.usda.gov/NRI/1997/summary_report/contents.html .

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K_d and the soil organic carbon content

The values of K_d given in RA Exhibit 3-6 have been obtained using RA Equation 3-67 and 3-68, which in turn use an estimate of the organic carbon content of the soil (f_{oc}). In the context of RA Equations 3-67 and 3-68, the required organic carbon content is that of suspended sediments, but it is there stated that "A value of 0.01 is used for the f_{oc} of suspended solids, to correspond to the f_{oc} of the mixing zone from which the suspended solids are assumed to have eroded (U.S. EPA, 1993)." An organic carbon fraction as low as 1% would be unlikely in fertile agricultural soil, and for the public contact site where the mixing depth is only 1 cm the sewage sludge alone would contribute at least 2% organic carbon to the mixture, assuming 30% organic carbon in the sewage sludge (EPA, 1992). Since measured soil organic carbon content is apparently available in soil databases (*e.g.* STATSGO), EPA should obtain averages of actual measurements for the types of soils involved, rather than relying on generic estimates.

Exposure duration

The exposure duration for the agricultural application analysis is said in the Proposed Rule to be 58 years. As discussed below in paragraph 3.6.4, the exposure duration used in the RA was 75 years. However, both these are far too long to correspond to average estimates, as required by the statement in the Proposed Rule (V.A) that the risk assessment " . . . used one other high end exposure factor". Indeed, according to the Proposed Rule (V.D.2), the incineration pathway analysis used an exposure duration for farmers of 17.3 years. This last is closer to the estimated average residence time for farm households (Israeli & Nelson, 1992).

3.6.2 Concentrations in biosolid/soil mixture (many pathways)

The equations given at RA Equations 3-35 and 3-37 are incorrect. RA Equation 3-35 would be closer to what was apparently intended if the subscript n on the left is altered to b (n is a summation index on the right, and so cannot appear on the left). RA Equation 3-37 would be approximately what was apparently intended if the divisor on the right was replaced by the *number of applications* summed over (37) rather than the *number of years* (75). However, even with such a correction, RA Equation 3-37 does not correspond to the apparent intent of approximating the annual average concentration by the concentration at the end of each year (RA, para following Step 2 just above Equation 3-34) — instead RA Equation 3-37 appears to be approximating the average concentration between applications (a 2- or 3-year period) by the concentration just before the next application. Such approximations can accumulate substantial errors if the decay rate in soil is fairly large, as occurs for some of the congeners in some scenarios.

There is no need any need for approximations with the assumptions used in the risk assessment: it is straightforward to obtain the following exact expressions.

Assume (as in the RA) that an increment of concentration C_0 is added to soil at time zero and thereafter at intervals of Δ, until there have been N applications, so the last application occurs at

time $(N-1)\Delta$. Assume also that the concentration in soil decreases exponentially (first-order decay) with a decay constant κ. Then define the function

$$F(t,\kappa,\Delta,N)=\frac{1}{\kappa}\left(p-e^{-\kappa\Delta}\frac{1-e^{-p\kappa\Delta}}{1-e^{-\kappa\Delta}}+\left(1-e^{-(p+1)\kappa\Delta}\right)\frac{1-e^{-\kappa(t-p\Delta)}}{1-e^{-\kappa\Delta}}\right)$$

$$\text{where}\quad p=\min\left(N-1,\left\lfloor t/\Delta\right\rfloor\right)$$

(the notation $\lfloor ... \rfloor$ indicates the "next integer below" function, so that p is the smaller of $N-1$ and the next integer equal to or below the ratio t/Δ). Then the average soil concentration over the time interval T_1 to T_2 is exactly given by:

$$\overline{C}=C_0\frac{F(T_2,\kappa,\Delta,N)-F(T_1,\kappa,\Delta,N)}{T_2-T_1}$$

for any values of T_1 and T_2, provided only that $T_2 \geq T_1 \geq 0$ (this applies even if either or both of these times are beyond the end of the period of soil additions, and even for $N=1$, a single application). The function F is just the time integral of the soil concentration from time zero to time t for N equally spaced unit concentration additions.

However, it appears that Abt Associates Inc. did not actually use RA Equation 3-37 to calculate the average concentrations, since the results given in RA Exhibit 3-7 do not agree with the RA equations. Compared with the exact expressions just given, the soil concentrations for the agricultural scenario given in RA Exhibit 3-7 appear to be approximately correct (within about 4% of the exactly calculated averages, this difference possibly being due almost entirely to the roundoff in Exhibit 3-7), except for 1,2,3,7,8-pentachlorodibenzofuran where the given value is too small by a factor of approximately 100.

The concentrations for the reclamation scenario given in RA Exhibit 3-7 also appear to be approximately correct (within about 9% of the exact averages), except for 2,3,7,8-tetrachlorodibenzofuran where the given value is about 60-fold too low, and for 1,2,3,7,8-pentachlorodibenzofuran where the given value is too small by a factor of approximately 100.

For the public contact scenario, the average concentrations given in RA Exhibit 3-7 are between 3% and 20% too low compared with exact averages, again except for 2,3,7,8-tetrachlorodibenzo-furan where the given value is about 60-fold too low, and for 1,2,3,7,8-pentachlorodibenzofuran where the given value is too small by a factor of approximately 100.

Finally, for the forest scenario, the average concentrations given in RA Exhibit 3-7 are between 1% and 20% too low compared with exact averages, again except for 2,3,7,8-tetrachlorodibenzo-

furan where the given value is about 110-fold too low, and for 1,2,3,7,8-pentachlorodibenzofuran where the given value is too small by a factor of approximately 100.

The highly discrepant values for 2,3,7,8-tetrachlorodibenzofuran and 1,2,3,7,8-pentachloro-dibenzofuran in RA Exhibit 3-7 are very obvious by inspection of relative values between the congeners, and by comparison with the concentrations in the input biosolids (RA Exhibits 3-1 and 3-2). However, the discrepancies just noted do not have a substantial effect on any of the risk assessments, changing them by at most a few percent.

3.6.3 Direct soil ingestion — Pathway 3

The Proposed Rule does not comment on the results obtained for Pathway 3, direct soil ingestion. In the RA, Exhibit 4-1, Pathway 3 is shown as having the largest risk estimates of all land application pathways, namely 8.3×10^{-5} for Agricultural and Public Contact, and 3.5×10^{-5} for Forest and Reclamation. However, the values given in Exhibit 4-1 are incorrect.

The equation given at RA Equation 3-51, and said to be used by Abt Associates Inc. for this pathway, is incorrect. It refers to the concentration in biosolids, where what is explicitly required (RA Section 3.3.3) is the concentration in the biosolids/soil mixture, since it is that mixture that children would ingest (Proposed Rule V.B.1). The values in Exhibit 4-1 can only be reproduced by using the assumption that the concentrations in the soil ingested are equal to the concentrations in the original biosolids (as applied), and also by assuming that the exposure duration is 6 years for children aged 1–6 in the Agricultural and Public Contact scenarios, and 3 years for children aged 4-6 in the Forest and Reclamation scenarios, in direct contradiction to the 5 and 2 years used elsewhere in the RA, implied by the age ranges, and explicitly described in RA Exhibit 3-3 and in the Proposed Rule (V.B.2).

A corrected risk estimate may be obtained by evaluating the concentrations of PCDD/PCDFs and PCBs in the biosolid/soil mixture, and inserting the correct parameters from the RA and Proposed Rule. To obtain the maximum estimates, it is necessary to evaluate the highest average concentrations in the biosolid/soil mix over 5- or 2-year periods. In the spirit of the RA descriptions,[5] these occur approximately over years 95 to 100 for Agricultural, 96 to 98 for Forest, 0 to 2 for Reclamation, and 95 to 100 for Public Contact. The averages may be computed using the methodology described above (paragraph 3.6.2). The results give:

Agricultural	9.9×10^{-6}
Forest	1.2×10^{-5}

[5] The actual periods giving maxima for the average concentrations are slightly different (by about 0.5 year) from these ranges, but the RA only considers integer start and stop points; the differences are negligible.

Reclamation	1.2×10^{-5}
Public Contact	3.6×10^{-5}

The last is three times the highest by any other pathway, and thus must be considered the limiting exposure in the risk assessment. Examining the sensitivity of this estimate to variations in the risk assessment parameters, we find that the estimate is:

Almost independent of:	Depth of soil mixing.
	Number of applications (adjusting the period of averaging to always obtain the maximum).
Inversely proportional to:	The interval between applications.
Almost inversely proportional to:	The assumed erosion rate.
Directly proportional to:	The application rate.
	The assumed soil ingestion rate.
	The assumed length of exposure.
	The carcinogenic potency assumed.

The other parameters are either unlikely to vary substantially (*e.g.*, bodyweight, soil density), or the risk estimate is relatively insensitive to them (*e.g.*, soil porosity parameters). It should be noted that to obtain the highest value shown here, 3.6×10^{-5}, several more than two of the parameters have been set at high estimates. This estimate assumes that a child comes every day into contact with soil during childhood (every day, all year, for the five-year age range 1 through 6), and ingests an average of 0.4 g/day. This corresponds to the maximum possible exposure duration, the maximum possible frequency of contact, and a high end estimate of soil ingestion, in addition to a high end estimate for the concentration of TEQs in the applied biosolids. Moreover, it is assumed further that biosolids with this high-end estimate of concentration have been applied every two years for approximately 95 years before the start of exposure. The documentation is silent as to whether this application frequency and duration, or the application rate of 10 Mg/ha per application, is considered average or upper-end. Thus this estimate corresponds to at least four parameters set at their highest possible value, and possibly more.

3.6.4 Biosolids —> Animals —> Humans — Pathway 5

The risk estimate given at RA Exhibit 4-1 and discussed in the Proposed Rule for Agricultural Pathway 5 is 1.7×10^{-5}. However, this value (we get 1.74×10^{-5} when we reproduce the calculations) can only be obtained by assuming that the farmer is exposed for an entire lifetime of 75 years; and that assumption is implicit in the discussion in the RA (at RA Section 3.3.5) since no Exposure Duration is there discussed or incorporated in the equations. However, the Proposed Rule (at V.B.2) explicitly states "we assumed that the highly exposed individual lives on the same site for 58 consecutive years," and so the exposure duration should be set to 58 years not 75 years. With this alteration, the risk estimate for Pathway 5 becomes 1.34×10^{-5}.

3.6.5 Inhalation of dust during tilling — Pathway 11

The risk estimate given for Pathway 11 in RA Exhibit 4-1, and discussed in RA Section 3.3.6, is 1.7×10^{-5}. Our reproduction of the arguments given in RA Section 3.3.6 leads to a risk estimate of 1.98×10^{-5}. We suspect that the difference may be due to the erroneous treatment in the RA of the concentration averaging (see paragraph 3.6.2 above, where we point out that Abt Associates did not use the equations given in the RA). However, the RA discussion is deficient in the following respects:

- Exposure duration. The exposure duration is not discussed in the RA, and is implicitly set to 75 years. This contradicts the Proposed Rule (at V.B.2) which explicitly states "we assumed that the highly exposed individual lives on the same site for 58 consecutive years" for the land application scenario.
- The RA makes no allowance for weekends, vacations, etc. It assumes that a tractor operator works 8 hrs/day, 7 days per week, for a lifetime. A more plausible upper-end, exposure assumption would be 8 hrs/day, 5 days/week, during the parts of the year in which there is such exposure. In addition, using an upper-end estimate here is a contradiction of the Proposed Rule's statement that only one upper-end exposure parameter was used (see paragraph 3.5).
- The RA incorrectly associates a short-term upper-bound estimate of breathing rate of 3.3 m^3/hour with an upper-end long-term average. The value of 3.3 m^3/hour is explicitly included in the *Exposure Factors Handbook* as an upper-bound for short-term estimates (falling within the range corresponding to heavy exercise). As stated in the *Exposure Factors Handbook*:

  > "The daily average inhalation rates for long term exposure for adults are: 11.3 m^3 /day for women and 15.2 m^3 /day for men. These values are averages of the inhalation rates provided for males and females in each of the three approaches of Layton (1993) (Tables 5-11 through 5-14). *An upper percentile is not recommended.*" (emphasis added)

  A plausible long-term upper-end estimate for the 8 working hours during which exposure might occur is 10 m^3/day, a value that has been used in other assessments. We use this below to be extremely conservative, but re-iterate that an upper-bound estimate should not be used here.
- The RA makes no allowance for winter, for the growing season, and for other periods (including periods of heavy rain) when the tractor operator would not be out ploughing, harvesting, or otherwise stirring up dust from the biosolids-treated fields. A rapid and incomplete literature survey turned up no obvious source of information on the fraction of time spent in activities that would raise dust from the biosolids-treated fields, but six months per year would be a plausible upper bound.

- The RA assumes, without justification, that the dust exposure would be 10 mg/m^3. A rapid and incomplete literature survey indicates that there is a fairly extensive literature on the quantity and types of dust associated with farm and field crop work (*e.g.*, Molocznik *et al.*, 1998; Nieuwenhuijsen *et al.*, 1997, 1998a, 1998b, 1999; Nieuwenhuijsen *et al.*, 1999; Green *et al.*, 1990; Molocznik and Zagorski, 1998; Louhelainen *et al.*, 1987). Nieuwenhuijsen *et al.*, (1999) provide a table of personal dust measurements in California agriculture that suggest that in almost all operations the inhalable soil dust concentration would be substantially lower than 10 mg/m^3 (some of the high measurements are of organic dusts, not dusts from soils); Nieuwenhuijsen *et al.*, (1998a) indicates that higher exposures could occur in certain ground preparation operations if the tractor operator does not have a cab. However, based on such measurements, an average of 10 mg/m^3 should be considered an extreme upper bound if this is to be applied to an extended period (such as six months per year) and to the same person.

Accepting that 10 mg/m^3 might indicate an extreme upper-bound average exposure, incorporating the other factors just discussed into the risk assessment makes the following changes, still for an exceedingly conservative estimate:

Exposure duration	A factor of 58/75
Weekends	A factor of 5/7
Breathing rate	A factor of about 10/24.4
Seasons	A factor of 1/2 or less

Overall, the RA estimate is too high by a factor of at least 9.6, and probably much more, even for an extreme upper-end estimate. Thus the risk estimate for Pathway 11 should be at most 2.1×10^{-6}.

3.7 Surface disposal

Given the small risk estimates, we agree with EPA's conclusions that risk of cancer posed by surface disposal of biosolids is too small to merit regulation. However, given the small emission rates for the compounds of concern by evaporation, we believe that EPA should check that the emission rates of dust are similarly small. While dust emissions might not be expected from surface impoundments or monofills, they could occur from dried deposits round their edges or from dried accidental spills if suitable management practices are not in place to prevent such emissions. A simple modeling estimate would be all that is required to verify that dust emissions are smaller than vapor emissions, taking account of plausible dried edge or spill areas. We do not know if such a possibility was taken into account in the Comprehensive Hazard Identification referred to in the RA.

3.8 Incineration

The combination of the Proposed Rule and the RA is extremely confusing. Section 3.5 of the RA is entitled "Incineration Pathway Analysis," and this section appears to go through an analysis of the direct inhalation pathway from incineration. Moreover, the estimates from this section are included in the summary information in the RA. However, the description of the incineration pathway in the Proposed Rule is completely distinct from what was done in the RA, and indeed does not appear to use the results presented in the RA at all. It is possible that what is described in the RA is the initial modeling described in the document *Sewage Sludge Incinerators' Dioxin-Like Compound Risk Analysis Technical Documentation* (EC/R, 1999 — hereinafter the RAI) as being performed using the "Human Exposure Model", since there appears to be some sort of correspondence, but that model is not mentioned in the RA.

The following comments will concentrate on the RAI, rather than the RA, since the former appears to be the relevant document and the latter is at best a screening analysis. However, we note that at RA Exhibit A-2, the values given for "HEI exposure" for facility IDs 3 and 31 do not correspond with the "MAXCONC" values given in RA Exhibit A-1. They are 10,000-fold smaller than would be expected from the MAXCONC values.

RAI Page 5
The cited reference for toxic equivalency factors is an internet site, http://www.epa.gov/ncea/dchem.htm , that contains outdated information on TEFs. The TEFs given for PCB congeners are from Ahlborg *et al.* (1994), and these were indeed used in the RAI analysis, contrary to the statement in the Proposed Rule that the TEFs defined by Van den Berg *et al.* (1998) were used.

RAI Page 6, Table 2.1 and Table A.2
The text at RAI page 6, and Table 2.1 indicates that the congener-specific TEQ emission factor should be identical for all facilities. For OCDD this fraction should be 0.115 µg/kg (Table 2.1), but in Table A.2 the values for this fraction all but facilities A and B is set at 0.114.

RAI, pages 5 to 6
We do not understand the methodology described to obtain the congener-specific emission rate estimates. The statements made are:

> The first step was to determine the average 2,3,7,8-TCDD-TEQ emissions, in µg/kg of dry sludge burned for a typical sewage sludge incinerator. The 2,3,7,8-TCDD-TEQ emissions in g/yr and the throughput in Mg/yr were available for four multiple hearth incinerators without afterburners. The average 2,3,7,8-TCDD-TEQ emission rate was calculated to be 1.19×10^{-2} µg/kg dry sludge burned.

Secondly, the congener-specific dioxin/furan/co-planar PCB mass fractions in terms of 2,3,7,8-TCDD-TEQ for a typical SSI were estimated. The percent by mass for each congener was calculated from the total mass emitted and the congener-specific mass emission rates (U.S. EPA, 1998a). The percent by mass for each congener was multiplied by the appropriate 2,3,7,8- TCDD-TEF and the values summed to arrive at the total 2,3,7,8-TCDD-TEQ weighted mass fraction for a typical SSI. The value estimated was 4.53×10^{-1} µg/kg dry sludge burned.

The third step in the process was to determine the total dioxin/furan/co-planar PCB emissions in µg/kg dry sludge burned for a typical SSI. This was estimated by dividing the average 2,3,7,8-TCDD-TEQ emissions, in µg/kg of dry sludge burned, for a typical sewage sludge incinerator (Step 1) by the total 2,3,7,8-TCDD-TEQ emissions for a typical SSI (Step 2).

The final step was to calculate the individual congener-specific emission factors for use with all facilities. These values were estimated by multiplying the total dioxin/furan/co-planar PCB emissions in µg/kg dry sludge burned for a typical SSI (Step 3) by the congener-specific percent mass values (Step 2) to obtain the congener-specific emissions factors in terms of µg congener/kg dry sludge burned. The emissions factors are presented in Table 2.1 for the dioxin and furan congeners and Table 2.2 for the co-planar PCBs.

Step 1 obtains an average TEQ emission factor for "multiple hearth incinerators without afterburners." How this is subsequently related to "average" SSIs is not described, nor is the significance of selection of four "multiple hearth incinerators without afterburners" for analysis, as opposed to "average" SSIs. In addition, the "throughput" is presumably of dry biosolids, although the sentence implies TCDD. The first sentence should read emissions factor, not emissions, since the latter are already known.

Step 2 as described produces a mass-emission-weighted TEF multiplied by 100 (since percentages are said to have been used), not an emission factor.

Since the abbreviation "SSI" is defined on page 1 to mean "sewage sludge incinerator", Step 3 of this procedure produces unity by definition if the third use of the term "emissions" means the same as the first two in the paragraph (that is, µg/kg of dry sludge), since it is apparently the ratio of two identical values — except what do "total" and "average" mean here? If "emissions" is supposed to mean something different the third time it is used within the same paragraph, that should be explained.

What appears to have been the aim was to derive the emission rates of individual congeners, not TEQ-weighted, since that is the only sane way to interpret Tables 2.1 and 2.2. An adequate explanation needs to distinguish clearly between unweighted and TEQ-weighted estimates, and estimates for averages that include and exclude PCBs in the total. It is clear that the TEQ-

weighted sum of the emission rates in Table 2.1 (PCDD/PCDFs only) is 0.0119 μg/kg, agreeing with the value given in Step 1. However, what is that value of 0.453 μg/kg in step 2 supposed to be — none of the TEQ-weighted or unweighted sums of Table 2.1 or Table 2.2 or both combined give that value?

In addition, if we are right in interpreting this analysis as a derivation of the emission rates of individual congeners, not TEQ-weighted, we point out that the measured concentrations of CDD/CDF in stack gas from incinerators, which data were used in EPA's *Inventory of Sources of Dioxin in the United States*, were provided in Green *et al.* (1995), which documents are part of the Docket for this proposed regulation. Clearly, it would be far simpler and more accurate to return to the original data.

RAI, page 55

"The unit risk estimate for 2,3,7,8-TCDD is 3.3×10^{-8} μg/m^3 (U.S. EPA,1997f)."
The value given is one-billion-fold in error, and the units given are incorrect. The correct value in the cited document is 33 m^3/μg, obtained from the stated potency estimate of 156,000 kg-d/mg using an assumption of 20 m^3/day breathing rate, absorption of 75%, and a body weight of 70 kg. Since we can reproduce the risk estimates using the correct unit risk, it appears that this is a transcription error affecting this document only (and the spreadsheets contain the correct value)..

Probabilistic assessments

EPA is to be congratulated on its efforts to perform probabilistic assessments for parts of this analysis. However, it is not clear why the assessments were limited to the populations examined; and the results of the probabilistic assessments cannot be interpreted as showing population distributions because of those limitations.

The probabilistic assessments were limited to home gardeners 20+ years of age residing in Sector 1 of Facility D for the inhalation pathway, and to the farmers 20+ years of age residing in Sector 6 of Facility C for the beef and dairy ingestion pathway.[6] The former contained an estimated population of about 2,184 such home gardeners, the latter just 5 such farmers. These sectors had been identified in the deterministic analysis as giving the highest estimates of risk.

The approach taken to using the area-weighted distribution of dispersion estimates is correct, and the other distributions used appear to be reasonable, although we have not subjected them to a detailed analysis. The analysis mixed some variability distributions with some uncertainty distributions, as noted in the discussion.

There is only one way to use the resulting output distributions, although that is not apparently discussed in either the RAI, or in the risk characterization document. These distributions are

[6] The discussion is confusing on page 67 of the RAI document by the statement (second line) that Sector 1 of Facility B was selected for the farmers. There is estimated to be only 1 such farmer in Sector 1 of Facility B.

pure uncertainty distributions for a randomly selected home gardener in Sector 1 of Facility D, and for a randomly selected farmer in Sector 6 of Facility C. Since these sectors were pre-selected as presenting the highest risks, the distributions obtained in the probabilistic modeling cannot be interpreted in any way as representing any but the uncertainties associated with the risk estimates for that highest-exposed very small fraction of the population.

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4 Other comments

4.1 Treatment of non-detects

The Proposed Rule does not specify the approach that should be taken to account for non-detects in measurements of PCDD/PCDF/PCBs, for comparison with the caps of 30 ppt or 300 ppt. TEQ. All the risk assessment analyses have been performed by substituting ½ the detection limit wherever a measurement resulted in a non-detect, and this methodology is suitable for comparison with the caps of 30 or 300 ppt. We suggest that this approach, which is typical in other EPA programs, be explicitly incorporated into the final rule.

4.2 Incineration of dioxins (IV.A)

EPA states that "The few sewage treatment works that incinerate sewage sludge may generate small amounts of dioxins and coplanar PCBs during the process of combustion." While correct for dioxins (including furans), this is (as far as we know) incorrect for PCBs, and for both the statement leaves an incorrect impression because it neglects to point out that the incineration process also destroys much of the dioxin and PCBs in the input stream; the net effect appears to be that a sewage treatment plant with an incinerator is a net destroyer of dioxins and PCBs. The independence of the emission of dioxins from incinerators from the concentrations in the input sewage sludge is acknowledged in V.D.3, although we are not sure whether this is also true (or even whether this is known) for PCBs.

4.3 Dioxin source inventory (V.D.3)

Section V.D.3 states that EPA's recent draft dioxin source inventory gives an estimate of 14.6 g TEQ (dioxins and furans only) as annual emissions from sewage sludge incinerators nationwide. This is incorrect. Page 3-40 of the 1998 draft *Inventory of Sources of Dioxin in the United States* (which clearly states upon its front cover "DO NOT QUOTE OR CITE") gives a central tendency estimate of 6.0 g TEQ per year, with a range of 2.7 to 13.4 g TEQ. The central tendency estimate of 6.0 g TEQ/yr is very comparable to the emission rate we calculated and submitted to EPA in Green *et al.* (1995).

4.4 Document access

It seems that only paper copies of the proposed test methods 1668 and 1668A exist (IV.B.3). These documents are not referenced anywhere on the EPA web site, yet surely they must be present somewhere in EPA in electronic format. In addition, spreadsheets in which calculations for the Proposed Rule were performed were not available in the docket. In this electronic age, EPA should make all reasonable efforts to provide internet access to supporting documents and spreadsheets, if the public is to have a meaningful and timely opportunity to comment on proposed actions.

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