September 10, 2002

Transmitted electronically to: OW-Docket@epamail.epa.gov

W-99-18 NODA Comment Clerk
Water Docket (MC-4101)
USEPA
Room EB57
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Sir or Madam:

Please accept these comments by Synagro Technologies, Inc. with regard to the Federal Register request by EPA for public comments concerning the Notice of Data Availability concerning Standards for the Use or Disposal of Sewage Sludge. Please refer any questions regarding this submission to Mr. Robert O'Dette, Vice President for Government Affairs for Synagro Technologies, Inc., 1800 Bering Drive, Houston, Texas 77057. Or I can be reached at 713-369-1731.

Thank you for your consideration.

Sincerely yours,
Robert O'Dette, PE
Vice President

Comments Submitted to the U.S. Environmental Protection Agency by Synagro Technologies, Inc., Concerning -

"STANDARDS FOR THE USE OR DISPOSAL OF SEWAGE SLUDGE" (Federal Register Vol. 67, No. 113, Wednesday, June 12, 2002, at pp. 40554-40576)

Comments submitted September 10, 2002
By: Robert O'Dette, PE
Vice President

Introduction

Synagro Technologies, Inc. is a leading provider of residuals management services in the United States, serving over 1,000 customers located in 38 states. It provides a full array of services and specialized products to the public and private water and residuals management market. The experience we have as a successful operating company provides insight that is germane to certain aspects of the proposed rule. Synagro would like to share these insights in this response to the NODA with the following comments.

Synagro Technologies, Inc. acquired Wheelabrator Water Technologies – Bio Gro Division (Bio Gro) in 2000. Synagro adopts Bio Gro's March 22, 2000 comments on the 1999 proposed Part 503 rule; the following comments should be considered a continuation of the previous comments.

Summary of Recommendations

- **EPA's new survey sample data document that the levels of dioxin and dioxin-like compounds have declined from 1988 to 2001.**
- **EPA's new probabilistic risk assessment has a number of major flaws that should be addressed by the Agency.**
- **In spite of the overly-conservative and exaggerated risk estimates for excess lifetime cancer for the highly exposed farm adult and child, the estimates of risk are well within what the Agency normally interprets as acceptable. Therefore, there is no human health risk basis to impose numerical limits for dioxin and dioxin-like compounds in biosolids that are land applied in accordance with EPA rules and agronomic application rates.**
- **While the current decreases in dioxin levels in biosolids are related to dioxin emissions reductions from combustion sources there is a need to continue to monitor levels in biosolids over time, and EPA should consider use of an inexpensive bioassay screening approach (an EPA reference test method validated on sewage sludge), coupled with a commitment to use a confirmatory test using GC/MS when a spike is detected via the bioassay test, (see Recommendations below).**

Important New Information Contained in the NODA

1. The Notice of Data Availability (NODA) published in the Federal Register, and notably the new survey sample data, are a vast improvement over the limited data base in the 1999 proposed Part 503 Round II rulemaking. The data provide better quality data, using new EPA reference test methods. The new data also provide, for the first time, a more reliable characterization of the PCB content of the TEQ. Also, the EPA utilized the new World Health Organization toxic equivalency factors for the 29 congeners of interest. All of these actions serve to greatly improve the overall quality of the method employed by the Agency in this rulemaking.

2. The NODA also presents a new probabilistic risk assessment intended to help the Agency better characterize the risks to the general population and to especially sensitive populations. In brief, the risk assessment suffers from a number of important shortcomings that cause the assessment to substantially overstate the risk (see the attached detailed comments on the risk assessment and technical background document); nonetheless, even with an exaggerated excess cancer risk quantification for an unlikely sensitive farm adult and child the Agency states the risks at the 50^{th} percentile are 1 x 10-6, and at the 99^{th} percentile are 4 x 10-5, (based on Q* = 1.56 x 10-4/pg TEQ/kg-d).

3. The EPA states (in FR 67:113 at 40573) "…,the Agency considers risks in the range of 1 x 10-6 to 1 x 10-4 ('one in one million' to 'one in ten thousand') to be acceptable levels of risk"

4. The EPA states (in FR 67:113 at 40567) "No quantifiable decrease in risk is calculated if sewage sludge with greater than 300 ppt TEQ dioxins or greater than 100 ppt TEQ dioxins were restricted from being land applied.

5. The EPA also states (in FR 67:113 at 40573) "The revised risk assessment also shows no measurable change in risk from requiring all sewage sludge to meet a 300 ppt TEQ limit."

6. The EPA applied the dioxin potency slope factor from the 2000 Draft Dioxin Reassessment (Q* = 1 x 10-3/pg TEQ/kg-d). The Agency states (in FR 67:113 at 40569) that using the more potent slope factor results in an excess cancer risk quantification for the sensitive farm adult and child at the 50^{th} percentile are 6 x 10-6, and at the 99^{th} percentile are 2 x 10-4 , i.e., still within the range of acceptable risks.

7. EPA recognizes (in FR 67:113 at 40565) that **"…a decision that is protective of this highly exposed modeled population is thus protective of the general population from the same pathways of dioxin exposure with a greater margin of safety since the diet of the general population contains only a small fraction of meat and dairy products grown on farms with land-applied sewage sludge."**

8. The increment to body burden for the highly exposed farm population is small (Table), and EPA states (in FR 67:113 at 40569) **"…high-end incremental risk estimates for highly exposed farm families from land application of sewage sludge are approximately an order of magnitude (i.e., ten times) lower than background risks for the general population.",** when compared to estimates from the draft dioxin reassessment.

EPA Estimates of Increment to Body Burden for the Highly Exposed Farm Population Exposed to Land Application of Sewage Sludge

Percentile	Incremental Body Burden (ng TEQ/kg bw)	Increment in Body Burden (%)
50th	0.019	0.6
75th	0.072	2
90th	0.19	6
95th	0.39	13
99th	0.84	28

Some Conclusions Based on the NODA Information

The most important conclusion to be drawn from this new information is that levels of dioxin have declined; and that risks to human health based on the new data, review of 6 key exposure pathways, the use of overly conservative risk assessment assumptions and 3,000 iterations of risk outcomes involving the highly exposed farm population are both low and remote, and certainly within acceptable levels of excess lifetime cancer risk.

Based on such a conclusion the risk assessment and characterization do not support setting a limit of 300 ppt as a concentration limit in land applied sewage sludge. Indeed, the EPA recognizes that a 300 ppt limit would have **"…no measurable change in risk". M**ore importantly, EPA applied the Monte Carlo technique to the risk estimates setting the dioxin concentration limit to the highest concentration of TEQ found in the EPA sample survey, around 800 ppt TEQ, and found no change in risk outcome**.**

Based on new estimates (in FR 67:113 at 405070) describing increments to body burden, one way to view the potential for non-cancer endpoints, such increments are low for the 50th percentile farm adult and child at less than 1 percent. The most unlikely 99th percentile suggests a 28 percent increment in body burden, but the 99th percentile high exposure scenario is not likely to reflect real conditions. The inherent orders of magnitude of conservatism involved with the estimates of the 99th percentile highly exposed model group should not be relied on as a realistic characterization of risk since it is both low and remote.

The proposed monitoring trigger level of 30 ppt TEQ, or the suggested 50 ppt presented in the NODA, has very little meaning either as an indication of potential spikes or for assuming that human body burden would be significantly impacted; additionally, the 20 ppt difference between the two levels would be imperceptible if as described in the

NODA, reducing dioxin concentrations from 300 ppt to 100 ppt results in no quantifiable decrease in risk.

The NODA lacked a convincing discussion on how chlorinated compounds that bind to organic matter migrate after controlled land application. The organic content of receiving soils, and the 50 percent or greater organic content of biosolids provide enough carbonaceous matter to bind a good portion of the dioxin and dioxin-like compounds in the receiving soil. Yet the source receptor model, mediated through the food chain, relies heavily on volatilization of dioxins from soil to plant leaf. In the case of pasture lands, EPA asserts that none of the dioxin leaves the top 2 centimeters of soil, but it also volatilizes. Conclusions based on these inconsistent assertions can not be supported.

Recommendations

On Concentration Limits

The EPA should not set a 300 ppt TEQ concentration limit of dioxin and dioxin-like substances in sewage sludge that is land-applied. Such a concentration limit is inconsistent with the established policy and practice to regulate activities that present unacceptable risks under authority of the Clean Water Act. In this particular case, EPA found that the exaggerated highly exposed farm adult and child exposed to land-applied sewage sludge has a high-end risk that is an order of magnitude less than the general population. The Agency has previously come to essentially the same conclusion with regard to surface disposal and incineration of sewage sludge. There is no apparent justification based on human health risk to take another course of action for land application of sewage sludge.

The Clean Water Act requires EPA regulation of pollutants in biosolids to be based on evidence of risk to "public health and the environment from any reasonably anticipated adverse effects" from that pollutant. 33 U.S.C. § 1345(d)(2)(D); Leather Industries of America, Inc. v. EPA, 40 F.3d 392, 400 (D.C. Cir. 1994) (invalidating chromium and selenium biosolids limits based on 99th percentile of concentrations detected in biosolids where those concentrations had not been shown to pose risks; "the statute clearly mandates regulations . . . bearing some relation to risk."). As the currently available data on dioxin levels in biosolids and EPA's risk assessment based on those data make clear, neither the 300 ppt TEQ limit initially proposed by EPA in this rulemaking – nor any other numerical limit – would satisfy the Act's requirement for risk-based regulation.

Nor does the existence of occasional outlier data justify setting numerical limits that can not be justified on the basis of the more representative data. EPA routinely excludes outlier or unrepresentative data in promulgating Clean Water Act regulations. In prior biosolids regulations, for example, EPA withdrew molybdenum limits pending reconsideration after determining that including data from certain highly contaminated samples "could overpredict crop uptake and background molybdenum levels. . . .lead[ing] the Agency to conclude that the limits adopted. . .may be more restrictive than

required to protect public health and the environment. . . ." 59 Fed. Reg 9095, 9096 (Feb. 25, 1994). See also 66 Fed. Reg. 424, 449-50, (Jan. 3, 2001)(EPA Proposed Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Metal Products and Machinery Point Source Category) (excluding unrepresentative data in establishing proposed effluent limitations for the metal products and machinery sector), and courts have upheld EPA's doing so. See, e.g., Marathon Oil Co. v. EPA, 564 F.2d 1253, 1271 (9th Cir. 1977)("EPA's exclusion of small samples and outliers was statistically valid.")

Indeed, given the requirement that EPA's biosolids regulations be risk-based, EPA can not properly base its regulation on high dioxin levels in occasional, isolated samples. The relatively few "spikes" in the data are unlikely to change the results of the risk assessment, based on numerous samples that concluded that existing risk levels are within the range that EPA has long recognized as acceptable.

In short, neither the typical dioxin concentrations found in biosolids, nor occasional outliers with significantly higher than normal concentrations, support the imposition of a numerical limit on dioxin concentrations in land-applied biosolids

On Sewage Sludge Monitoring

While human health risks are both low and remote, there is still a need to collect dioxin concentration data in the future to monitor levels should they change. The experience over the last decade is to anticipate declines in anthropogenic sources. Controlling air emissions from combustion sources has a demonstrated salutary effect on dioxin levels in sewage sludge, (note the decrease in total dioxin releases in the 1995 versus the 1987 dioxin emissions inventory). However, the addition of natural sources and issues involving reservoir sources and re-entrainment should not be ignored. Therefore, Synagro recommends that the Agency consider either a voluntary or mandatory monitoring event once every five years, using an inexpensive immunoassay test (but only a test that the EPA has adopted as a reference test method, and is validated for application to sludge matrices) as a screening monitor. Additionally, when spikes are encountered based on an immunoassay test, then there should be some commitment on the part of the generator to confirm dioxin levels using the appropriate EPA reference test method, and if confirmed to be a spike in levels, the generator should take steps to identify and reduce the source of dioxins entering the sewage sludge.

A major qualification to this monitoring recommendation is the determination of what constitutes a spike in dioxin concentrations in sewage sludge. The Agency proposed 30 ppt TEQ in 1999, and has asked for comments in the NODA concerning using 50 ppt TEQ in the NODA. Neither of these levels makes sense**,** they would only add to the paperwork, time resources, and cost to the generators and handlers of sewage sludge that is land applied with no corresponding health or environmental benefit. For example, if EPA determined that a concentration in sewage sludge less than 300 ppt TEQ that is land applied has **"…no quantifiable decrease in risk"** then using a trigger below that level

will not affect risk. What EPA should consider is that spike concentrations in sewage sludge do not equate linearly with risk to human exposure. For one thing, sewage sludge with high a concentration of dioxin TEQ are attenuated along the 6 or more key exposure pathways. The concentration going into the soil is diluted through the land application process.

Second, as pointed out in the NODA probabilistic risk assessment discussion, a variable that is most important through the food chain model employed is exposure duration. EPA states (in FR 67:113 at 40566) a sensitivity analysis identified dietary intake of beef and dairy products over the lifetime adult daily dose (LADD) accounts for over 80 percent of the variation in the risk. The Agency cites in numerous places in the NODA that the concentrations of dioxin TEQ in sewage sludge are fairly well characterized; those levels are consistent over a seasonal basis; and that spikes are rare and short-term events. Increments to body burden really depend on sustained and long-term increments in exposures, not short-term spikes that are likely to be transient, further reducing their relevance to a risk assessment based on a highly exposed individual over a lifetime.

On Risk Characterization

Synagro recommends that the EPA recognize and footnote findings of the recent National Academy of Science (NAS) report on land application of biosolids. The NAS report clearly states that there is no documented evidence of human health impact or death due to this practice if done according to the Part 503 regulations. The risk characterization presented in the NODA deals with theoretical risk but makes no mention of the fact that an exhaustive literature search conducted by the NAS scientific panel revealed nothing other than anecdotal allegations of adverse effects from land applied biosolids.

Synagro recommends that EPA place greater weight on risk assessments estimates related to the 50^{th} percentile because they are less exaggerated than the estimates related to the 95^{th} and 99^{th} percentile risk estimates. We recognize, and agree with EPA's reliance on conservative assumptions to ensure that its regulations are adequately protective. However, the risk assessment already builds in a number of highly conservative, (by orders of magnitude) assumptions. Those assumptions, coupled with the fact that the sewage sludge TEQ is comprised primarily of congeners other than 2,3,7,8-TCDD, the exaggerated effects of modeling dioxin in the top 2 cm of soil that never dissipates from pasture soil, but is suggested to volatilize to plant leafs and be the single most important exposure pathway in the food chain and the unlikely highly-exposed farm family scenario make it unnecessary – indeed, unreasonable – to introduce further conservatism through reliance on the 95th and 99th percentile estimates. In fact, the above factors suggest that even the 50^{th} percentile risk assessment quantification is unnecessarily high for evaluating real world impacts.

Synagro would also like to recommend that the final rule pay more attention to the social and economic benefits of sewage sludge land application. Recycling biosolids (treated

sewage sludge) has become one of the most successful forms of recycling that is not overly dependent on federal subsidies to achieve.

Detailed Comments on EPA's Risk Assessment and The Background Document (TBD)

As noted in our more general comments, we agree with EPA's ultimate conclusion that any existing risks are within acceptable ranges. As noted in our comments, this conclusion means that there is no justification for imposing a numerical limit on dioxin concentrations in land-applied sewage sludge and that EPA's focus should instead be on appropriate monitoring to ensure that dioxin levels do not increase over time. That such a course is the correct approach is particularly clear when it is recognized that the risk estimates derived from EPA's risk assessment are significantly overstated as a result of certain flaws in the assessment, as described below. Correction of these defects would demonstrate even more strongly that the regulatory requirements for land-applied sewage sludge should mirror those for surface disposal and incineration.

Overall Report Organization and Content

1. The assessment does not meet EPA's risk characterization criteria for clarity, transparency, reasonableness, and consistency.

EPA has developed detailed guidelines for conducting risk characterization[1]. The Agency's guiding principles for risk characterization are that all characterizations be (1) clear (2) transparent, (3) reasonable, and (4) consistent with other risk characterizations of similar scope prepared across EPA programs. EPA has developed a series of criteria that, if satisfied, indicate an adequate risk characterization. The draft risk assessment fails to meet these criteria in several respects.

- **Clarity.** The current discussion of the methods, assumptions, and equations used in its assessment, the current presentation of this information is not adequate to support an explicit understanding of the risk assessment procedures and findings, or how particular values were developed and used.

  This seems to stem largely from the presentation of related modeling information in multiple locations throughout the report and appendices without an effective cross-referencing system for accessing this information. For example[2]:

  - Soil bulk density's use in modeling is discussed in multiple locations throughout chapter 5 of the TBD, and in Appendices E, F, and H, though the only way one can find all the information relevant to this is by either reading hundreds of pages or searching for these terms in the electronic versions of the documents.

  - In some cases, the cross references that are provided are incorrect. For example, Table H2.21refers the reader to Appendix E for a discussion of soil bulk density, though no presentation of this

[1] EPA. 2000. Science Policy Handbook. Risk Characterization. Office of Science Policy, Office of Research and Development. Washington, DC. EPA 100-B-00-002

[2] These examples are intended to be illustrative rather than exhaustive. EPA should perform a detailed quality assurance review to identify and correct similar problems throughout the document.

material occurs there. Section 5 of the TBD (page 5-21) refers the reader to Table H-2.20 for the calculation of the parameter LS USLE, but the information is absent from that table.

- In other cases, it is extremely difficult to follow how important parameters are incorporated into the modeling. For example, though the Agency mentions early in the report (Section 4) that the fraction organic carbon (foc) of biosolids is used in the modeling, it is not possible to track where in the process that particular value is used. Nowhere else in the 200 page TBD is biosolids' foc mentioned. There is a parenthetical reference in Appendix F to and foc_w, which presumably is where biosolids' foc is considered, but the reference is so obscure that the precise approach used by EPA is not apparent.

The Agency also presents contradictory information about some parameter values, further clouding their approach. For example, EPA states that soil:water partitioning coefficients (kd) are calculated using the organic carbon partitioning coefficient (koc) and the foc in the tilled zone. However, the tables in Appendix D present single values for soil:water partitioning coefficients, referencing the Dioxin Reassessment.

Further, the Agency includes irrelevant information on metals when describing some of its fate and transport models (e.g., Appendix F soil column modeling discussions). Any discussion of metals in the modeling sections is confusing because it implies that the Agency is somehow considering metals in its modeling approach. In addition, generic statements about model conditions that, in fact, do not apply to biosolids assessment (e.g. modeling limitations in the presence of NAPLs) add to the confusion.

EPA should revise the risk assessment to include a comprehensive cross-referencing system for models and model parameters. This could be in the form of more detailed flow charts that show how all the different source, fate and transport models are linked and where they are discussed in the report. A comprehensive index of all model parameters, the value(s) used, and the report and appendices' pages can accompany these flow charts where these parameters are discussed. Finally, the Agency should correct inconsistencies in the discussion of parameters and values and delete discussion of irrelevant information.

- **Transparency.** The lack of clarity in the presentation makes renders this risk assessment non-transparent. In addition, insufficient data are presented to reproduce calculations in the deterministic ecological risk assessment. EPA should present the exposure concentrations in biosolids and soils that were used to calculate Phase 1 and Phase 2 ecological risks.

- **Consistency.** The risk assessment is not consistent with the other EPA assessments.

    - Characterization of risks at percentiles greater than 95th percentile is inconsistent with EPA policies and procedures used in other rulemakings, and internally inconsistent within the report. EPA risk characterization typically relies upon assessment of the 90th or 95th percentile risks when assessing chronic exposures. EPA's Lead Rule, for example, uses a 95% level of protection. EPA's water quality criteria are derived to protect the majority of the human population, defined by the 90th percentile of risks. Consideration of human health risks at substantially higher percentiles (e.g., 99th percentile) in the biosolids assessment also is inconsistent with the level of protection specified in the biosolids ecological risk assessment, in which the 50th and 90th percentiles were used.

    - The congener -specific chemical inputs assumed by EPA in the TBD differ from those used in other programs. We compared the chemical-specific inputs for specific congeners detailed in Appendix D of the TBD differ to those recommended by EPA in its combustion facility risk assessment guidance[3] and found differences in the assumed Henry's Law constant, diffusivity in air, organic carbon partition coefficient, octanol-water partition coefficient, air-to-plant biotransfer factor, biota-to-sediment accumulation factors, and bioconcentration factors in poultry and eggs. The impact of these parameter differences is sufficient to cause a risk assessment conducted according to the combustion guidance to arrive at a totally different conclusion for the same chemical compared to the risk assessment presented in the TBD.

    EPA must revise this risk assessment to be consistent with its other programs.

- **Reasonableness.** EPA guidance requires that upper-bound risks not be greater than that potentially experienced by members of the population. The exposure scenarios assumed in the NODA and TBD are not plausible (see below), and therefore do not accurately represent possible upper-bound risks in highly exposed individuals. .

[3] EPA. 1998. Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities, Peer Review Draft. July 1998. EPA 530-D-98-001A. (including August, 1999 Errata).

2. The risk characterization presented in the TBD is incomplete.

EPA risk characterization guidelines state that risk characterization should integrate the results with key uncertainties, place the risks into context with similar risks, identify the major conclusion considered and address research needs. The risk characterization sections in the TBD do not contain these elements. A more comprehensive risk characterization is needed for both the human health and ecological risk assessment and for the integrated assessment as a whole. Without it, the risk characterization outlined in the TBD is insufficient to support any numerical limit on dioxin concentrations in sewage sludge.

3. EPA's analysis does not appropriately consider the risks of alternatives to biosolids application.

To place the results of the biosolids risk assessment into perspective and to support the most informed risk management decisions, EPA should include an analysis of the health risks associated with fertilizer use, which would be required if biosolids were not used as a nutrient source in agricultural lands. Possibly even more important is the fact that sewage sludge would be landfilled if it was not converted to biosolids and recycled by land application. The risk assessment should include an analysis of the potential human health and ecological impacts of landfilling untreated sewage sludge.

Conceptual Model

4. EPA's definition of high-end farm family is not plausible and leads to extremely conservative estimates of risk.

The degree of simultaneous consumption of all the different varieties of home-produced food and local is an extreme overestimate. EPA has not provided sufficient support to suggest that the assumed farm family is even a remote possibility, and has developed a scenario that, in many respects, goes in the face of common sense. For example, it is considered highly unlikely that any family would locate their residence and chicken farm directly in the path of extensive sheet runoff from its farm fields, as is assumed in EPA risk assessment. Indeed, sediment control best management practices (BMPs) in many jurisdictions would prohibit substantial runoff from agricultural fields. It also seems doubtful that any family would simultaneously consume such a high percentage of homegrown foods across such a wide diversity of food groups. Further, EPA has provided no proof that the assumed farm sizes could even support the assumed level of production of fruits, vegetables, silage, beef, milk, chicken and eggs. This is particularly an issue for the smaller farm sizes assumed in the analysis. Almost 20% of the farms assumed in this analysis are between 20 and 50 acres; another 24% are between 50 and 100 acres.

EPA must investigate the reasonableness of this scenario and move forward with one that is plausible and representative of potential high-end users. To support this evaluation, EPA should review land application permits on file with the States to identify what types of land use, in fact, does occur near biosolids application sites, or provide some other alternate data to support their theoretical construct. Once information on land-use is

compiled, EPA should include some factor in the exposure assessment that takes into account the probability that any one of these uses (and associated exposure pathways) could occur.

EPA also must provide additional data to support the demographics of its assumed farm family. For example, agricultural statistics from the most recent survey conducted by the National Agricultural Statistics Service (NASS)[4] indicate that 42% of all individual or family landlords are >65 yrs old, another 56% are between 35 and 64; only 2% of the farm families had individuals below 35 years of age. Based on this, it appears that a very high percentage of farm families contain adults that are unlikely to have young children, or nursing infants, as is assumed for all farm families included in EPA's assessment.

5. EPA's conceptual model and exposure scenarios do not take into account harvesting and land-use restrictions under the 503 Rule.

EPA's 503 rule[5] establishes restrictions limiting harvesting of crops and turf from biosolids-applied land for a specified period of time following application. For food crops with harvested parts that touch the biosolids/soil mixture, the harvesting restriction is 14 months. For food crops with harvested parts below the land surface where biosolids have been incorporated into the soil within 4 months of application, the harvesting restriction is 38 months. Given these restrictions, ingestion of some of the assumed diet items would not occur until 14 to 38 months after the last biosolids application (e.g., after up to 40 years of application). EPA must develop a conceptual model and exposure scenario that is representative of required harvesting restrictions.

6. EPA's conceptual model does not take into account stream and other land-use setbacks that are mandated under the federal 503 Rule and State programs.

EPA's 503 rule dictates that Class B biosolids cannot be applied to land within 33 feet of a stream. Some State programs require greater distances. For example, Wisconsin dictates no land application within 150 to 200 feet of the stream[6]. These factors do not appear to have been factored into EPA's conceptual model. In fact, the size of the buffer does not appear to have been included at all as a parameter in the modeling. EPA should include assumptions about buffer distance to the stream as dictated by the federal and State Rules.

Similarly, EPA should factor in other land-use setbacks in its conceptual model. For example, Wisconsin regulations[7] dictate that no residence can be located within 250 feet. EPA must consider these types of restrictions for its assumed scenarios to be representative. We regard this as similar to the Agency's attempts to gain regional specificity with respect to, among other things, farm size and meteorology.

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[4] NASS. 1997. Census of Agriculture. Volume 3. Special Studies. Department of Agriculture. Washington, D.C.

[5] 40 CFR, Part 503.

[6] Wisconsin Administrative Code. 1996. Chapter NR 204. Domestic Sewage Sludge Management.

[7] Ibid.

7. EPA's model does not take into account other restrictions to land application under applicable State programs.

Several states have developed regulations that restrict the conditions under which biosolids can be applied. Wisconsin, for example, states that biosolids cannot be applied to slopes greater than 12%[8]. California requires erosion control plans for application sites over 10%[9]. Though it is not clear from the TBD, it appears that EPA has assumed that biosolids can be applied to lands with slopes greater than 24% (TBD page 4-20).

Other states may prohibit land application of biosolids with certain characteristics. California, for example, prohibits application of biosolids with a moisture content of less than 50%[10]. Though this is unclear from the discussion in the TBD, it appears that EPA has assumed that biosolids applied to agricultural land can have a moisture content of less than 40%.

8. EPA's conceptual model does not take into account agronomic rates for different crops and different regions.

Biosolids application is limited by the nitrogen requirements of the crops to which it is applied[11]. Crops differ in their nitrogen requirements and their nitrogen use. In addition, soils differ in their ability to retain nitrogen. Collectively, these factors determine the agronomic rate for a given crop at a given location. EPA has assumed that all crops and pasture on a farm and throughout the various regions of the United States will have the same agronomic requirements. This is highly unlikely to be true, and very likely, will result in overestimates of the amount of biosolids applied to land, at least for some crops and some regions. EPA should verify that the agronomic rate it assumes for all crops and pastures is, in fact, appropriate

Exposure and Risk Modeling

9. EPA should address variability in biosolids organic matter content in its modeling.

EPA has assumed that the foc of biosolids is 0.4. Biosolids commonly have organic matter content well above this, with foc values above 0.7 not uncommon[12]. This factor is important for characterizing chemical mobility and should be addressed probabilistically, as are other modeling parameters.

In addition, the Agency should modify its soil-column partitioning model to first include an equilibrium partitioning between the biosolids and the soil, which would be governed primarily by the different organic carbon contents of these matrices, and so would tend to favor PCDDs/Fs remaining bound to the biosolids matrix.

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[8] Ibid.
[9] California. State Water Resources Control Board. Water Quality Order No. 2000-10-DWQ.
[10] Ibid.
[11] EPA 1995. Land Application of Sewage Sludge and Domestic Sewage: Process Design Manual. EPA/625/R-95/001.
[12] Sullivan. 1998. Fertilizing with Biosolids. Oregon State University. PNW 508. June.

10. EPA should take into account biodegradation, hydrolysis, and photodegradation in its modeling.

EPA assumes that degradation rates in soil, sediment, and surface water are zero. This approach should be modified to include some loss from degradation processes. Since biosolids are by their very nature a highly biologically active matrix, it is likely that degradation of PCDD/Fs will be even more rapid in soil treated with biosolids compared to untreated soil. This has shown to be the case with other chemicals (e.g., alkylphenols) that are relatively stable in sludge and soil, but that biodegrade rapidly in soil that has been treated with biosolids.

A change with respect to degradation is needed to make the TBD assessment consistent with exposure assessments conducted under other EPA programs, such as waste combustion risk assessments conducted under RCRA. EPA's combustion risk assessment guidance[13], for example, includes degradation rates for dioxin congeners. Secondly, a change is needed because the model-calculated congener half-lives are significantly greater than those reported in the literature. EPA presents a summary of model-calculated half-lives for congener's in soil, and most of these values are in the range of 30 to 40 years. Literature-reported half-lives for dioxin congeners in soil indicate half-lives on the order of 10 to 15 or 20 years. EPA claims this level of difference is not significant. However, this degree of difference is significant when it is considered in the context of the lengths of the exposure that are assumed in this assessment, which can be less than 15 or 20 years.

Degradation in air also is not included in the assessment, even though EPA provides data in the TBD and the dioxin reassessment indicating that it occurs.

11. EPA should clarify the units associated with its congener-specific values, and verify the overall accuracy of the parameter values listed.

EPA describes many congener-specific chemical values as unitless, when in fact, there are explicit or implicit units associated with these parameters. Organic carbon partition coefficients (koc) have units of ml/g, though it is referred to as unitless in the Appendix D tables. Bioconcentration factors also have units associated with them (generally ppm in the *organism* per ppm in the *abiotc medium*). Failure to include proper units with the exposure factors creates confusion and complicates calculations to verify the accuracy of model predictions.

EPA also uses confusing terminology for some parameters. A parameter called Kow is listed in appendix D tables for each congener, but is termed soil:water partition coefficient (typically referred to as Kd). This is confusing because Kow commonly refers to the octanol-water partition coefficient.

12. EPA should verify that its risk distributions are stable at percentiles above 95th percentile.

[13] EPA. 1998. Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities, Peer Review Draft. July 1998. EPA 530-D-98-001A. (including August, 1999 Errata).

Probabilistic simulations based on 3000 iterations may be unstable. Lognormal outputs from Monte Carlo distributions are very sensitive to the shape of the curve and the extent and quality of the data. The extreme tails are most sensitive to this instability. EPA should verify that 3,000 iterations of its Monte Carlo runs produce risk distributions that are stable at percentiles above 95th percentile. Alternatively, EPA should not use any risks for percentiles above the 95th, which was the upper end of the distribution that it verified as stable.

Ecological Risk Assessment

13. EPA should not assume congener accumulation in terrestrial invertebrates is linear.

The report from which EPA derives the bioaccumulation factor used in the TBD provides analyses indicating that dioxin accumulation in earthworms is not a linear process. As a result, the report recommends that a regression model be used to assess accumulation, rather than static BAF. EPA ignores this recommendation and uses a BAF to estimate uptake. This is incorrect scientifically. The ecological risk assessment should be modified to predict accumulation in terrestrial invertebrates using a regression model.

14. **EPA should provide additional support for the assumption that all congeners accumulate in the food chain to same degree as TCDD.**

This is an important assumption and has not been supported nor discussed adequately.

15. The toxicity data for ecological receptors is not appropriate

EPA used an injection study to characterize dose-response in avian receptors, but did not adjust the toxicity reference value to account for differences in absorption following dietary exposures. This will result in overestimates of the avian toxicity of ingested TCDD.

16. The ecological uncertainty analysis is inadequate.

The uncertainty analysis contained in the ecological risk assessment is cursory, at best. This section should be expanded considerably to address the significance of the numerous uncertainties inherent in the ecological assessment.

Monitoring Standard

17. There is no risk-based support for a monitoring concentration criterion of 30 to 300 ppt TEQ.

EPA states that the monitoring requirements would be to catch short-term spikes in dioxin congener concentrations, but the health and ecological consequences of these "short-term spikes" are unexplored. The risk assessment clearly showed that removing concentrations > 300 ppt TEQ from the dataset had no impact on estimates of chronic risk, and EPA did not conduct an acute risk analysis to determine what concentrations are of significance for short-term exposures. Any concentration that is necessary to protect short-term exposures will, however, be substantially higher than the currently proposed monitoring triggers of 30 to 300 ppt TEQ. EPA should withdraw its proposed monitoring

requirements, explain that they are based on factors other than risk, or provide substantially more risk analysis to support a particular criterion.

High Uncertainty Concerning Dioxin Migration from the Sludge Matrix

18. EPA's pathway analysis relies heavily on volatilization of dioxin from soil estimates that are uncertain and result in conservative over-estimation of risk

The NODA did not present a real discussion on how chlorinated compounds in biosolids migrate from a fairly solid matrix when applied via controlled application. So much of the modeled risk depends on the assumption that dioxins volatilize from the soil to the leaf and enters the food chain, but this mechanism is poorly understood. The net result is a very imprecise and overly conservative quantitative contribution to risk estimates.

Dioxin and related compounds are bound tightly to the biosolids due to the high organic content present. When biosolids are added to soil an additional organic host is present. The combined effects of the organic content of the biosolids matrix and the receiving soils provide a distinct impediment to dioxin migration. The fate and transport models used to estimate how dioxin and dioxin-like compounds migrate from the biosolids matrix and soil host rely on limited and imprecise data and assumptions.

The NODA states that volatilization from the top two centimeters of biosolids-amended soil to the leaf surfaces of crops consumed by animals and humans is the principal mechanism by which dioxins are transported from sewage sludge applied to the land."[14] Relying on assumption rather than clear explanation, the Agency ignores the importance of the 3-4 percent organics in average soil and the 50 percent or greater organic content of biosolids that are land applied. Dioxins exhibit an affinity for binding to organic surfaces; so much so that dioxin is often described as "hydrophobic" and "lipophilic". This raises questions about how much dioxin will really volatilize from a richly organic environment, and how much bio-transfer in the food chain, and bioaccumulation in humans or animals really occurs.

Another concern about the model is the implausible assumption that there is no loss of dioxin from pasture surface sprayed with land applied biosolids. The NODA and TBD assume that the biosolids applied to pasture remains permanently in the top two centimeters of soil and is not diluted over time, (in CFR 67:113 at 40567). The NODA acknowledges the inconsistency with estimates of volatilization and transfer to plants, which require a loss of dioxin TEQ from the surface of the soil. A model that incorporates preservation of matter and relies on dissipation of that matter at the same time is not valid, and should be corrected.

[14] 67 Fed. Reg. at 40567 1st col.

General Concern over the Objectiveness and Accuracy of the TBD

19. **The TBD in its present form raises serious concerns regarding compliance with information quality requirements.**

Based on the above points, the TBD does not appear to comply with the information quality principles in the recently promulgated OMB guidelines, particularly the principles of objectivity and transparency/reproducibility. We look forward to EPA's promulgation of its own information quality guidelines, but it is doubtful that the current TBD draft will meet those requirements either. Given the many substantial uncertainties and data gaps in the TBD, it is unlikely that a new TBD can comply with the information quality principles, unless perhaps the TBD or NODA clearly acknowledges those uncertainties and the very high degree of conservatism that has been applied in the attempt to quantify risks.