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Via Regular Mail and Email (OW-Docket@epamail.epa.gov)

W-99-18 NODA Comment Clerk
Water Docket (MC 4101)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Subject: Comments on Notice of Data Availability for Proposal to Amend the Standards for the Use or Disposal of Sewage Sludge to Limit Dioxin and Dioxin-like Compounds (67 Fed. Reg. 40554 *et seq*., June 12, 2002)

The following comments address principally the extremely high uncertainties in the cancer risk assessment for the subject proposal, and the bias in assumptions, used to overcome those uncertainties, which has led to probable exaggeration of the quantitative estimates of such risk. These comments also focus on how the draft risk assessment is deficient under the principles of objectivity, transparency/reproducibility, and consideration of all available scientific data required by the information quality rules issued recently by the Office of Management and Budget, which are binding on EPA.

The major conclusions we have reached as a result of review of the issues discussed below are that (1) the cancer risks are unrealistically overstated – and are certainly in the range of the "high end of the high end" as indicated in the NODA – and (2) there is insufficient objective scientific support for presenting a quantitative estimate of risk or for supporting the proposed monitoring standards.

We believe that it is indisputable that the NODA and Draft Technical Background Document ("DTBD") must be considered "influential" information under the OMB information quality guidelines, and therefore must meet higher standards of information quality, including transparency/reproducibility. The two subjects of risks from dioxin and related compounds and use of biosolids are each important and controversial issues; and when combined, as in this case, the combination is sure to be even more influential.

1. Major Uncertainties and Policy Biases Embedded in the Underlying Draft Risk Assessment for

Dioxin and Related Compounds.

The cancer risk estimates in the NODA depend largely on conclusions, assumptions, and quantitative estimates contained in the latest version of the EPA draft risk assessment for dioxin and related compounds.[1] (EPA 2000.) The EPA Science Advisory Board has reviewed this draft and has issued a final report[2] (SAB 2001) which finds that there are a number of key points on which the assessment's findings are not scientifically objective and supportable. These SAB findings must therefore be considered in evaluating the validity of the NODA and DTBD and the degree of conservatism built into their cancer risk assessments.

1. <u>Use of TEQ and Characterization of the Dioxin-related Compounds and Mixtures as "Likely Human Carcinogens"</u>

The quantitative cancer risk estimates in the NODA and DTBD are based on TEQ – *i.e.*, the sum of estimated exposure from all 29 compounds after adjusting each compound by its TEF (toxic equivalency factor). The single compound known as "dioxin" (2,3,7,8-TCDD, or "TCDD") accounts for only approximately one-tenth of the TEQ in foodstuffs, while the 16 dioxin-like PCDDs and PCDFs account for more than half of the TEQ, and the 12 PCBs account for approximately one-third.[3] However, the NODA and DTBD do not contain information on the relative concentrations of TCDD, the other dioxins and furans and PCBs in Class B biosolids, or their relative contribution to concentrations in foodstuffs.

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[1] Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. EPA/600/P-00/001Bg (Sept. 2000 "SAB Review Draft").

[2] Dioxin Reassessment – An SAB Review of the Office of Research and Development's Reassessment of Dioxin. EPA-SAB-EC-01-006 (May 2001).

[3] *E.g.*, EPA 2000, Tables 4-8 and 5-1, pp. 119 and 121.

Not only did a majority of the SAB find that it could not support EPA's classification of "dioxin" as a (known) human carcinogen[4]; it also found it could not support EPA's classification of the dioxin-like PCDDs and PCDFs, and TEQ mixtures, as "likely" human carcinogens.[5] In addition, the International Agency for Research on Cancer (IARC) reviewed evidence concerning the possible carcinogenicity of TCDD and other dioxins and furans in 1997, and it concluded that the evidence was "inadequate" for carcinogenicity of the other dioxins and furans and placed them in its Category 3 – "not classifiable" as to carcinogenicity.[6] With regard to PCBs, both IARC and the National Toxicology Program have concluded that while there is sufficient evidence of carcinogenicity in animals, there is inadequate evidence for carcinogenicity in humans.[7]

These SAB, IARC, and NTP findings regarding the non-TCDD (and TCDD) component of the TEQ introduce massive uncertainty into the Agency's draft risk assessment for dioxin and related compounds, since it is not possible to quantify objectively the cancer risk from substances which are not even regarded as likely to cause cancer. Moreover, since information on the relative concentrations of the TEQ compounds in biosolids and their relative contributions to foodstuffs is not provided, the uncertainty relating to this point is even greater. EPA's proposal to treat the 28 "dioxin-like" compounds (non-TCDD PCDDs, PCDFs, and PCBs) "as if" they had a carcinogenic potential similar to TCDD is based solely on "inference" and "logic" and represents an intrusion of policy bias into scientific assessment.[8] And the uncertainty regarding the human cancer potential of TCDD as the reference substance further weakens such "inference" and "logic".

2. The Cancer Slope Factor (or "potency factor")

The attempt by the draft dioxin risk assessment to quantify a cancer slope factor ("CSF") in the face of such great uncertainty regarding carcinogenicity of TCDD and the related compounds magnifies the above uncertainties. Not only does the CSF assume that TCDD and all of the related compounds are carcinogenic, it also adds to this uncertainty by adopting a linear extrapolation modeling approach to obtain this quantitative measure of risk. The SAB could not concur that such a dose-response assessment was scientifically supportable:

> Some Members of the Panel believe that the default assumption of a linear dose response for cancer may not be the best choice because dioxin is primarily a cancer promoter rather than an initiator. Other Members do not believe that sufficient data are available to justify

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4 SAB 2001 at 4 & n.6.

5 *Id*. at 46.

6 IARC Monograph 69 (1997). Polychlorinated Dibenzo-*para*-dioxins and Polychlorinated Dibenzofurans.

7 9th Report on Carcinogens (2000).

8 EPA 2000, Part III at 30.

> an over-ride of the linear dose response default and point out that EPA's cancer risk assessment guidance makes it clear that linear defaults should be over-ridden only when sufficient data exist to overcome the default.
>
> **The Panel agreed that the actual shape of the low-dose exposure response relation couldn't be determined from the available data.** For this reason, the Agency used a linear dose extrapolation model to derive an upper bound cancer potency factor. . . . . . . **[T]he Panel cannot reach consensus on a single value for a dioxin potency factor.**

At 6, 37 (emphasis added).

> About half of the Members . . . believe that the estimated cancer risks at small doses are bound to be lower with the receptor-mediated process than with the linear model.

At 55.

> **The actual shape of the low-dose exposure response relation cannot yet be determined from the available data.** . . . For example, the Kociba (1978) study actually showed a deficit for all tumors combined in all dose groups in comparison to the controls. That finding is statistically significant for the lowest two dose groups, and deficits in uterine, mammary, and pituitary tumors in female rats and pancreatic and adrenal tumors in male rats are statistically significant in the highest dose group. . . . Without the highest dose, the Kociba experiment would have been judged negative. . . . **EPA should acknowledge the possibility that reducing current body burdens of TCDD might lead to no change at all in cancer incidence, or even a net increase. Given the uncertainty in the data, the Panel agrees that choice of complex models cannot be justified at this time.**

At 49-50 (emphasis added).

It is clear that EPA's proposed choice of a linear low-dose extrapolation model is based on policy rather than science, and thus introduces a substantial conservative bias into the risk assessment. Those uncertainties and the conservative bias are not described and discussed in the NODA or DTBD.

3. <u>Quantification of cancer potency is not scientifically supportable, and the potency factor proposed in EPA's latest draft reassessment for dioxin and related compounds clearly represents a policy choice rather than an objective scientific assessment.</u>

The NODA posits a choice between the old (1986) EPA cancer potency factor and its latest potency factor. The difference between the two factors is approximately six-fold. Neither quantification is scientifically supportable. The great uncertainty regarding any human carcinogenicity, particularly for the non-TCDD PCDD/Fs, combined with the great uncertainty regarding a supportable dose-response model, make it inappropriate to attempt to quantify cancer potency. It is clear that the current cancer potency factor is based largely on policy inputs. The SAB has recommended that if the Agency is going to adhere to this policy-biased approach, it should at least also provide a quantified estimate of uncertainty, which it has not done, and which it most likely cannot do. The SAB concluded:

> [I]n light of the considerable uncertainties in the cancer potency factor and of the accuracy of individual TEFs for many of the dioxin-like chemicals (e.g., the PCBs), the majority of Panel Members have concerns about Agency cancer risk estimates associated with current population exposures and feel that it was not appropriate for the Agency to characterize the risk in such a quantitative manner without providing a similar quantitative estimate of uncertainty.

At 6.

The use of a single-point cancer potency factor in the latest draft reassessment for dioxin and related compounds has masked huge uncertainties in the reassessment. Those uncertainties should not be carried over into the Round II risk assessment for Class B biosolids. If a point estimate of cancer risk is to be provided and used, it should be made clear that the estimate is not based on science, but rather is a policy artifact designed to be inherently exaggerated in the interests of attempting to protect persons who may be highly exposed in the face of presently insurmountable gaps in scientific knowledge.

4. Selection of a percentile of risk for the highly-exposed population

The NODA presents a range of percentile risk from the 50th to the 99th percentile. At 40566 and 40569. The uncertainties and conservative bias described in these comments make a strong case for using the 50th percentile. To use a higher percentile would be piling on clearly excessive conservatism. Even confining this view to the uncertainties and policy biases in the underlying dioxin reassessment, this was the view of the SAB:

> About half of the Members . . . believe that the estimated cancer risks at small doses are bound to be lower with the receptor-mediated process than with the linear model.
>
> . . .
>
> **The Panel** recommends that complete reliance on the upper confidence limit (based on EPA's standard models and defaults) for quantitative risk assessment of cancer risks needs to be tempered. . . . The summary might also point out that **with a receptor mediated cancer process, the best estimate of risk from the linear non-threshold model is already an "upper limit".**

At 55 (emphasis added). Note that this Panel recommendation was made even allowing for use of a linear non-threshold model, although the scientific evidence was viewed as probably not supportive of use of such a conservative model. In other words, the view of the SAB was that, for the dioxin reassessment, the 50th

percentile (or another form of "best estimate") would be equivalent to use of an upper bound and would still be very conservative, and that use of a higher percentile would be excessive.

5. Failure to consider anticipated future reductions in dioxin emissions contributing to the TEQ in biosolids

EPA is anticipating that its current regulations on many combustion sources will result in further emission reductions in the years ahead. While the new sewage sludge survey data utilized in the NODA and DTBD are relatively up-to-date, the risk analysis and discussion do not point out that any risks will almost certainly be reduced in future years even if no further regulatory efforts are put in place (and it is likely that any such risks have already been reduced significantly during the last two years).

II. Additional Major Uncertainties in Deriving Food TEQs from Biosolids TEQs.

The TEF/TEQ approach was designed to be used at the point of exposure. The quantities of TCDD and related compounds are measured in the lipid fraction of blood or tissue in beef, poultry, fish, fruits, and vegetables, and then a TEQ is determined by applying the TEFs. Even with all the uncertainties regarding the TEQ approach described above, however, the biosolids risk assessment presents a far more complex problem. The overall quantities of TCDD and related compounds in various foodstuffs can be measured with some precision, but those measurements tell us nothing about whether those foodstuff concentrations came from combustion sources and related atmospheric deposition of particle-bound or vapor-phase compounds, or from transport of TEQ compounds emanating from biosolids applied to land.

Attempting to determine whether, or the extent to which, dioxin and related compounds are transported from biosolids-amended soil to foodstuffs rather than from atmospheric deposition is a far more complex and uncertain exercise than measuring at the point of exposure. The NODA and DTBD attempt to solve the obvious fate and transport problems by presenting and employing a series of theoretical equilibrium equations, with little or no discussion of the inherent uncertainties, or how the values used in the equations were selected and validated. The DTBD is extremely opaque in this regard, and there is almost no discussion of these issues in the NODA. Also lacking is any discussion of empirical studies and whether they are consistent with the values used and the results of the theoretical modeling. For some aspects of attempting to determine fate, transport, and exposure, it appears that empirical studies were neglected in favor of theoretical calculations. In any event, there is no discussion of empirical studies, as there was in earlier versions of the DTBD.

The WHO working group (van den Berg et al. 1998), whose publication is the primary source for the current TEF/TEQ approach, warned explicitly of such problems and uncertainties:

> PCDDs, PCDFs, and PCBs exist in environmental and biological samples as complex mixtures of various congeners whose relative concentrations differ across trophic levels. These differences are caused by environmental degradation, which refers to the different environmental fates of congeners with different solubilities, volatilities, and rates of

degradation/metabolism. As a result, these mixtures change spatially and temporally into [sic] the environment and are very different from the technical mixtures originally released into the environment.

. . .

[I]n relation to [*i.e.*, concerning] the use of TEFs for abiotic compartments, the biological meaning of these [TEF] values is obscure. This is caused by the fact that the assumed biological or toxicological effect is influenced by many physicochemical factors before the actual uptake of the compounds by the organism takes place.[9]

When biosolids are added to soil, the dioxin and related compounds are bound tightly to the biosolids as a function of the high organic content of the biosolids and the natural organic content of the soil. The biosolids are then either mixed into the soil, or they are left on top and gradually work their way into the soil. To eventually estimate the cancer risk that any dioxin and related compounds in the biosolids might pose as a result of ending up in the edible portion of foodstuffs, their fate and transport must be determined/estimated through a number of extremely difficult steps.

The NODA and DTBD assume that transport can occur either in the form of vapor-phase compounds or compounds bound to particles. Each of these modes of transport presents distinct and difficult problems. In the case of determining vapor-phase transport and fate, one must determine whether, or the extent to which, the compounds can be volatilized from the complex organic matter and soil matrix. Assuming a specific quantity is volatilized from its extremely tight bond to the organic matter, the vapor will then be subject to some degree of photolysis. Photolysis may also occur in the top layer of amended soil at the same time that volatilization occurs, in the atmosphere after any volatilization occurs, or when amended soil particles are deposited on the surfaces of vegetation. If the compounds are not volatilized, or are photodegraded before they are ingested by humans or animals (which become foodstuffs), the binding to the particles will reduce their bioavailability before they can be measured in the lipids portion of human blood or in foods. Finally, even once the compounds are present in the lipids of foods, they will be subject to degradation and elimination while at the same time possibly bioaccumulating. How the NODA and DTBD have calculated these steps and accounted for these variables is far from transparent and appears to lack validation. With regard to some steps, it appears likely that the theoretical calculations are not consistent with empirical studies, as discussed below, and tend to exaggerate the amount of TCDD and related compounds which is likely to be transported into the edible portion of foodstuffs.

The DTBD admits that the fate and transport modeling has not been validated, but it does not explain how it was decided what values to use for the model inputs:

Although **the source model used in this risk assessment to simulate chemical**

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[9] *Env. Hlth. Persp*. 106(12):775-92, at 775, 776 (1998).

> **releases from and soil concentrations within the agricultural field receiving biosolids** has been extensively verified, it **has not been validated**. Verification is the process of confirming, through testing, sensitivity analysis, or benchmarking against other models, for example, that a model performs as it was intended by the modelers; that is, its functionality is verified. **Validation is the more rigorous process of confirming that a model's predictions are in fact in reasonable agreement with phenomena observed in nature.** Model validation requires extensive, and appropriate, data on observed emission rates and soil concentrations, as well as model calibration activities, neither of which were feasible for this modeling study primarily for the practical reason that the sites modeled are in a large sense hypothetical.

DTBD at 5-9 (emphasis added). This lack of validation introduces significant uncertainty into the estimates of fate and transport.

1. <u>Uncertainty, and apparent over-estimation, of volatilization and uptake of TEQ compounds from biosolids-amended soils</u>

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."[10]

A distinct feature of biosolids is their high *foc*, organic carbon content. Ordinary soil may be in the range of 3 or 4 percent; whereas Class B biosolids are likely to have a *foc* of 50-70 percent.[11] This is important because it is generally recognized that dioxin and related compounds bond tightly to soil, and the higher the *foc*, the tighter the bond. The very high organic content of biosolids raises a serious issue regarding the extent to which TEQ compounds can volatilize from biosolids-amended soil, and the extent to which such compounds are bioavailable to crops or if ingested by animals or humans from the air or the surfaces of vegetation.[12] The fate and transport behavior of TEQ compounds are likely to be influenced more by the characteristics of the particle matrix to which they are bound than by their physicochemical properties.[13]

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[10] 67 Fed. Reg. at 40567 1st col.

[11] Table 4-1, p. 4-2, of the DTBD indicates that a *foc* value of 0.4 was used. No source is given for this value.

[12] O'Connor GA. 1996. Organic compounds in sludge-amended soils and their potential for uptake by crop plants. *Sci Total Environ* 185:71-81.

[13] Smith KEC, Green M, Thomas GO, and Jones KC. 2001. Behavior of sewage sludge-derived PAHs on pasture. *Environ Sci Technol* 35:2141-50.

An earlier version of the DTBD contained a discussion of studies attempting to measure actual volatilization and/or photodegradation from sludge-amended soils. The discussion concluded that such "loss processes" are "minimal". It is noteworthy that the discussion quoted below is not able to differentiate volatilization from photodegradation, and refers to them jointly as "loss processes". To the extent that loss from biosolids-amended soil occurs through photodegradation, or compounds are photodegraded after volatilization, they will not eventually result in exposure. The 1999 draft of the DTBD stated:

> Several studies have investigated **loss** of dioxins and dibenzofurans. Initial losses to photodegradation **and/or** volatilization from the soil have been shown within the first six months of application to soil (DiDomenico et al., 1982 as cited in U.S. EPA, 1994a). However, studies that specifically measured volatilization or photodegradation in sewage-sludge amended soil did not find any significant losses over 30 days or six weeks (Schwartz and McLachlan, 1993, as cited in U.S. EPA, 1999; Cousins et al, 1996, as cited in U.S. EPA, 1999). Photodegradation is generally limited to the soil surface; below a few millimeters, this loss process is not significant. McLachlan et al. (1996) (cited in U.S. EPA, 1999) measured the presence of chlorinated dioxins and furans 18 years after biosolids were applied to soil. The authors found that dioxins and furans had similar half lives of about 20 years each.
>
> Other studies indicate that most loss processes are minimal. One study found insignificant loss of these compounds due to vertical migration, volatilization, or degradation over an eight year period (Hagenmaier et al., 1992 as cited in U.S. EPA, 1994a). Yanders et al. (1989, as cited in U.S. EPA, 1994a) investigated the effect of natural conditions on contaminated soil samples and found that no appreciable losses occurred during a four year period. Although some biodegradation of dioxins and dibenzofurans in media other than soil has been shown to occur, an experiment most closely related to the condition of adding sludge to soil (i.e., organic compost added to soil) and another study in soil found only minimal degradation (Camoni et al., 1982 and Quensen and Matsumura, 1983, as cited in U.S. EPA, 1994a).[14]

The EPA draft reassessment for dioxin and related compounds also contains discussion of these and other studies, and concludes that any losses due to volatilization and/or photodegradation are difficult to predict and are likely to be insignificant. Following are some pertinent excerpts from the dioxin reassessment, which are not discussed (and mostly not referenced) in the DTBD:

> Upon deposition of CDD/CDFs onto soil **or plant surfaces**, there can be an initial loss due to photodegradation **and/or** volatilization. The extent of initial loss due to volatilization **and/or** photodegradation **is difficult to predict** and is controlled by climatic

[14] Abt Associates, Dec. 14, 1999, at 11-12 (emphasis added).

> factors, soil characteristics, and the concentration and physical form of the deposited CDD/CDFs (i.e., particle-bound, dissolved in solvent, etc. . . . . Schwarz and McLachlan (1993) observed no significant changes in CDD/CDF concentrations in sewage sludge amended soil that was exposed to natural sunlight for six weeks in the late summer/early fall in Germany. Similarly, Cousins et al. (1996) detected no volatilization from sludge amended soils through which air was pumped for 30 days.

At 2-33 to 2-34.

> Hagenmaier et al. (1992) collected soil samples around two industrial plants in Germany in 1981, 1987, and 1989 at the same site and from the same depth, using the same sampling method. There was no indication . . . of appreciable loss of CDDs and CDFs by vertical migration, volatilization, or degradation over the 8-year period.

At 2-36.

> The absence of any changes [observed in the study by Schwarz and McLachlan, 1993, *supra*] indicates that neither photodegradation nor volatilization are important mechanism in the fate of CDD/CDF in sewage sludge following agricultural applications.

At 2-50.

The only such study referenced in the current DTBD is a 1996 study by McLachlan et al. At 5-11, Table 5-2. The DTBD concludes that this study and two others seem to corroborate the half-lives used in the DTBD fate and transport modeling, and therefore give a measure of credibility to the modeled results. At 5-11. However, the DTBD does not reference the other studies discussed in the dioxin reassessment, and the McLachlan et al. study is the only study referenced which examined TEQ compounds other than TCDD in sludge-amended soil. The DTBD fails to mention that the authors of that study concluded that the observed half-lives were likely to reflect principally physical removal rather than volatilization and/or degradation.[15]

Three other more recent studies, not referenced or discussed in the DTBD or the draft dioxin reassessment, are worthy of note. Molina et al. (2000)[16] attempted to assess the "evolution" of PCDD/Fs from sludge-amended soil over four years in both laboratory and field experiments. The laboratory experiment showed no evolution in any sample. The field experiment also showed no evolution or loss of

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[15] However, this conclusion by the authors is noted in the 2000 dioxin reassessment at 2-35.

[16] Molina L, Diaz-Ferrero J, Coll M, Marti R, Broto-Puig, Comellas L, Ridriguez-Larena MC. 2000. Study of evolution of PCDD/F in sewage sludge-amended soils for land restoration purposes. *Chemosphere* 40:1173-78.

the PCDD/Fs, but the variability in results was so high that the authors felt conclusions could not be drawn. The extreme variability was attributed to lack of homogeneity in the field plots.

Sinkkonen and Paasivirta (2000)[17], estimated half-lives for PCDD/Fs and PCBs in air based on atmospheric chemistry. Their estimates illustrate the difficulty in assuming that volatilized TEQ compounds are all taken up by vegetation or humans. The estimated half-life for TCDD was approximately 8 days; for 1,2,3,7,8-PeCDD it was 15 days; and for the hex- and hepta- dioxins it was 31 days. PCBs were estimated to have longer half-lives in air – in the range of two to four months for many. Half-lives for TEQ compounds adsorbed to soil were estimated to be higher. In connection with these conclusions, it should be noted that the portion of the DTBD which addresses air dispersion modeling of TEQ compounds which might be lost from biosolids-amended soil states that the model "does not include photochemical reactions or degradation of a chemical in the air, which results in additional model uncertainty." It should be added that in the DTBD this uncertainty appears to have been resolved in the direction of an over-estimation of deposition and exposure.

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[17] Sinkkonen S and Paasivirta J. 2000. Degradation half-life times of PCDDs, PCDFs and PCBs for environmental fate monitoring. *Chemosphere* 40:943-49.

Rappe et al. reported on a study of uptake of TEQ compounds into wheat and rape at two farms in Sweden Sampling and analysis of the wheat and rape from control and biosolids-amended plots was conducted in 1993 and 1994. It was found that the TEQ content of the rape from biosolids-amended soil had increased, while the TEQ content of the wheat had decreased. However, it was noted that there were distinct differences in the congener concentration profiles for the biosolids-amended soil in which the rape was grown and in the rape. This led the authors to conclude that "there is no transfer from the biosolids to the growing plants."[18]

2. <u>Mixing height for volatilized and particulate emissions from amended soil</u>

Although there is mention of mixing height in the sections explaining the air dispersion modeling, we could not find the value used. A significant portion of the human dietary exposure considered is from various fruits. While we could not find a complete list of the specific fruits which comprised the dietary exposure, the DTBD gave as examples apples, peaches, pears, and berries. Except for some berries, all of these fruits are orchard crops, which means that any TEQ compounds volatilized or dispersed from the amended soil would have to reach a considerable height (much higher than for any of the vegetables) to be taken up. The greater the height, the more likely that vapor-phase or particle-bound TEQ compounds would be dispersed, diluted, and/or degraded partially or completely, before reaching the fruits. This is true of course also for other common fruits not mentioned, such as bananas, oranges, grapefruits, and apricots (although most bananas are imported).

3. <u>The inconsistent assumption of no loss from pasture surface</u>

The NODA and DTBD assume that the biosolids applied to pasture remain permanently in the top two centimeters of soil and are not diluted over time. NODA at 40567 1st col. The NODA then acknowledges that this assumption is inconsistent with the estimates of volatilization and transfer to plants, which require a loss of TEQ compounds from the surface of the soil. The NODA is obviously correct in commenting that "this assumption is likely to contribute to an overestimation of risk." Volatilization will continuously deplete the TEQ in the surface layer of the amended soil, and this depletion will then make less TEQ available for volatilization – assuming, as discussed above, that any significant volatilization occurs,

[18] A summary of the Swedish study is contained in a report by the United States Conference of Mayors' Urban Water Council, "Biosolids Land Application – The Dioxin Situation" at pp. 33-34 (June 1999), which was presented to EPA. The body of the report was prepared by C. Rappe, L. Oberg, C. Nilsson, and C. Håkansson. The Swedish study summarized in the report was presented at Dioxin "97 and published as Rappe C, Andersson R, Nilsson C, and Nilsson P. 1997. A field study on the use of sewage sludge as soil amendment. *Organohalogen Compd* 32:45-50.

which also appears to contribute to an overestimation of risk. Losses will also occur due to atmospheric dispersion of soil particles.

The assumption of a constant TEQ at the top of the soil is also inconsistent with the assumption, in the model farm scenario, that biosolids erode into the buffer from the pasture and crop land. Such erosion cannot occur without depletion of the TEQ in the upland topsoil.

4. Uncertainty of bioavailability from biosolids

Bioavailability of TEQ compounds due to inhalation or ingestion of soil particles by humans and animals varies depending on the tightness of the bond between the compound and soil, which in turn is affected by the organic carbon content. TEQ compounds bound to biosolids can be expected to have a significantly lower bioavailability than bioavailability from unamended soil. It does not appear that this was considered in the DTBD.[19]

The fate and transport portion of the DTBD provides uptake equations for beef, milk, poultry, and eggs. Those equations use a "B_s" factor to account for "Bioavailability of contaminant on the soil vehicle relative to the vegetative vehicle (unitless)". It is not clear what this means – *i.e*., whether the "soil vehicle" means unamended soil or biosolids. The value given for this factor is 0.65. This value appears also in Appendix I to the DTBD as a value used in the food chain algorithms. There, in Table I-2, is a parameter B_s of 0.65, described as "Bioavailability for soil (unitless)". These appear to be the only references to bioavailability in the DTBD, and they do not indicate that lower bioavailability from biosolids (*i.e.*, matter with a much higher organic carbon content than soil) was accounted for. It does not appear that such data exists for many of the individual congeners. Without bioavailability data, it is also not possible to determine bioaccumulation, and ultimate human exposure. Thus, lack of consideration of bioavailabity of TEQ compounds from biosolids, as opposed to soil, appears to introduce yet another significant uncertainty into the DTBD, and it appears to result again in a upward bias of risk.

III. Unrealistic Conservatism in the "High-end" Model Farm Exposure Scenario

EPA risk characterization policy guidance cautions that even "high-end" or "conservative" risk estimates must be realistic. When the current risk characterization guidance was announced in 1995, then-Administrator Browner stated: "While I believe the American public expects us to err on the side of protection in the face of scientific uncertainty, I do not want our assessments to be unrealistically conservative."[20] Several aspects of the NODA/DTBD appear contrary to this policy, and, as a result, the risk characterization in the NODA/DTBD is most certainly accurately characterized as a "high end of a high end", particularly when the following factors are added to those discussed above.

[19] If it was considered, it appears that the *foc* value used throughout was 0.4, but, as noted previously, no source is given for this value.

[20] This policy memorandum, which was issued as a cover letter to the EPA risk characterization handbook, can be found at www.epa.gov/osp/spc/rccover.htm.

1. Unrealistic model farm layout

The draft's generic farm layout locates the farm family's house, yard, and chicken yard in the buffer zone downslope of the crops and pasture, where it supposedly receives loadings of TEQ from the upland cropland and pasture via erosive sheet flows. As a result, it is assumed that children playing in the yard next to the house ingest a certain amount of biosolids in the soil, and that the free-range chickens also ingest a certain amount of biosolids TEQ in the soil.

This aspect of the layout/exposure scenario seems highly improbable, and is not supported by any data. People do not locate their residences in the path of runoff sheet flows; they try to locate them on terrain that is higher and drier than that surrounding the residential area. Even if a residential area were subject to erosive sheet flows, it is unlikely that a family would tolerate intrusion of runoff from biosolids amended soils, and would arrange some sort of diversionary structure in the form of a ditch or berm to protect the house, yard, and nearby structures (such as the chicken coop and yard).

2. Unrealistic combined dietary intake of home-grown meats, fruits, and vegetables

The NODA and DTBD assume that the model farm family raises, grows, and consumes all of the various types of meat, poultry, eggs, milk, vegetables, and fruits on its farm, where they are exposed to biosolids. The realism of this model appears greatly suspect. Peer reviewer Dr. Curtis Travis pointed this out and cited a number of agricultural statistics to support his view that it was extremely unlikely that any significant number of farm families, or even any single family, would concurrently raise and consume all of those dietary items on their farm. The limited statistics cited by Dr. Travis indicate that a great many farms do not concurrently raise or grow certain significant dietary items. In the face of such statistics, and the importance of the issues raised, the Agency is obligated to demonstrate that these dietary assumptions are realistic.

The model farm scenario assumes the farm is the median size for each of the 41 climate regions. A good number of those median sizes are under 100 acres, and more than half are under 150 acres. EPA has not included in the NODA or DTBD any analytical data to support the notion that farms of such small size could concurrently be used to raise and grow feed cattle, dairy cattle, poultry, and a great variety of fruits and vegetables, while maintaining a buffer zone and a residential area within the acreage.

3. Unrealistic home-caught fish consumption

While it might not have a significant impact on the overall assessment, the dietary intake for the adult recreational fisher appears overestimated and is another example of unrealistic conservatism in the DTBD. It appears that year-long consumption is estimated; but the small third-order stream used in the conceptual farm layout would not be productive all year-long. In roughly the upper half of the U.S., such a stream would be frozen or dormant for fishing purposes for at least four to five months of the year, and at other times, weather events such as flooding or drought would influence productivity. In addition, many such streams would produce unpalatable varieties of fish, such as carp and bullheads. Furthermore, fish populations usually do not reside and feed in one area of a stream consistently, and if they did, consistent fishing of such a small stream segment by a recreational fisher would quickly deplete the population.

IV. Non-compliance with the new Data Quality legislation and OMB's Implementing Rules

EPA must issue by October 1 Data Quality rules which are consistent with the rules issued by OMB.[21] Agencies are responsible for complying with the OMB guidance as a matter of law under 44 U.S.C. §§ 3506 and 3516, as well as § 515 of the FY2001 Consolidated Appropriations Act.

The legislation and the OMB guidelines require that, under the agency-specific conforming guidelines due out October 1, risk assessments must be "objective" and "unbiased", and must also conform to the risk assessment principles in the 1996 amendments to the Safe Drinking Water Act ("SDWA"). The SDWA principles require that risk assessments in support of regulations identify each significant uncertainty and any studies that would assist in resolving the uncertainty, and identify any peer-reviewed studies known to the agency that support, are directly relevant to, or fail to support any risk estimate, and the methodology used to reconcile inconsistencies in the scientific data. These principles are relevant here because the NODA and DTBD fail to identify and discuss many of the uncertainties described above, and fail to identify and discuss many studies and data that bear on those uncertainties.

The OMB guidelines also require a higher standard of quality for "influential" information. The biosolids risk assessment contained in the NODA and DTBD is undoubtedly influential information. One of the higher standards of quality specified by OMB is that influential information must be so transparent as to be "substantially reproducible". As noted above, many key value inputs into the biosolids risk assessment (*e.g.*, bioavailability factors for dioxin and related compounds adsorbed to biosolids particulates, mixing height for vapor-phase and particulate emissions, agricultural statistics supporting the cumulative dietary intake scenario) cannot be found and the uncertainties involved in the equations and values are not discussed.

Both the underlying draft dioxin reassessment and the proposed biosolids risk assessment clearly incorporate numerous biases based on policy. This is non-compliance with the requirement that risk information must be objective and unbiased and presented in an objective an unbiased manner. Scientific information can be presented in an objective and unbiased manner, and policy positions can be presented in an objective and unbiased manner; but if the two are mixed together so that they cannot be disentangled – as is the case here – the intermingled presentation is not objective and unbiased. The scientific appraisal must be presented in an objective and unbiased manner by being completely separated from any policy biases. This means, for example, that if the objective science will not support a single quantitative "best

[21] 66 Fed. Reg. 49718 (Sept. 28, 2001); amended 67 Fed. Reg. 369 (Jan. 3, 2002). Technical corrections to the Jan. 3, 2002 notice were published at 67 Fed. Reg. 5365 (Feb. 5, 2002) and 67 Fed. Reg. 8452 (Feb. 22, 2002). Although both OMB and EPA have labeled these as "guidance", the label is not significant, since they satisfy the definition of a "rule" (or regulation) in the Administrative Procedure Act, 5 U.S.C. § 551.

estimate" of risk, the presentation must say so, as recommended by the SAB. If, as a matter of policy, it is then decided to use policy-driven assumptions to quantify an upper-bound, or "high-end" risk, it should be clear that such a numerical estimate is based on policy rather than science, and the elements of policy bias should all be clearly identified.

One of the indicators of objectivity specified by OMB is peer review. If information has been peer-reviewed, it is presumptively objective. This presumptions can be rebutted, however. Presumably, if the peer reviewers have disagreed with portions of the information, and the agency has not complied with the peer reviewers views, the presumption of objectivity does not apply. In this case, the underlying dioxin risk assessment was peer-reviewed by the SAB, and the SAB disagreed with EPA on some of the most significant points, as described above. The dioxin reassessment therefore cannot be regarded as objective and unbiased, and the uncertainties described by the SAB must be described in the risk assessment. The latest version of the biosolids DTBD has not been peer-reviewed; however, the peer-reviews of previous versions of the DTBD raised criticisms that have not been dealt with in the current DTBD. An example is Dr. Travis' critique of the cumulative dietary intake scenario.

If the above data quality problems with the NODA and DTBD are not corrected, it might be necessary to file a petition for correction or a judicial challenge based on failure to follow the OMB and agency rules.

V. The Proposed Limit of 300 ppt and the Proposed Monitoring Standard of 30 ppt Are Not Supportable.

The NODA states that "[n]o 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." At 40567 3d col. The NODA does not indicate what numerical TEQ threshold would result in a significantly higher risk. Thus, the proposal for a 300 ppt limit and a 30 ppt monitoring level are both unsupported.

VI. Summary

- The use of the latest draft of the reassessment for dioxin and related compounds (EPA Sept. 2000) introduces massive uncertainties and policy biases into the biosolids risk assessment. Those uncertainties and biases include:

  – assuming all of the TEQ compounds are carcinogenic ("likely human carcinogens") when such an assumption is not scientifically defensible, as found by the SAB, so that TEQ cancer risk cannot be realistically quantified as has been done

  – use of a cancer slope factor that is based on the above assumption and which is therefore not supportable, as well as use of a default linear no-threshold dose-response model that is not scientifically defensible, as concluded by the SAB

– quantification of risk based on the cancer slope factor, when the SAB concluded that there was insufficient scientific basis for quantification, and if any quantification were presented, it should be presented along with a quantification of uncertainty

· If risk is quantified as proposed in the 2000 draft reassessment for dioxin and related compounds, an appropriately conservative risk estimate would be at the 50^{th} percentile for the highly-exposed population.

· The biosolids risk assessment also contains major uncertainties and fails to provide sufficient information and data to support its conclusions. These uncertainties and gaps include:

– the extent to which TEQ compounds volatilize from biosolids and biosolids-amended soil, which have a very high organic carbon content which binds the compounds even more tightly than to non-amended soil

– the extent to which photodegradation reduces the amount of volatilized or particle-bound TEQ compounds which can be transported into food sources and humans

– uncertainty concerning the mixing height for volatilized or dispersed TEQ compounds and impact on fruits

– the assumption of no loss from the surface of amended pasture soil, which is inconsistent with the calculations of vapor and particle loss to air and the buffer zone

– apparent failure to consider the lower bioavailability of TEQ compounds bound to biosolids

· The model farm layout and dietary consumption assumptions are unrealistically conservative. This is a result of the following factors, among others:

– location of the residence and chicken yard in the path of sheet runoff from biosolids-amended cropland and pasture is highly improbable

– assuming the any significant number of farm families will consume cumulatively all of the assumed dietary fractions of meats, dairy products, eggs, fruits, and vegetables from their own farm appears highly improbable and is not supported by data

– the assumption that the farm size in many of the climate regions is sufficient to produce all of those dietary items is likewise unsupported and improbable

– the assumption that edible/palatable fish can be caught consistently from the hypothetical small stream segment next to the farm appears unrealistic

· The proposed 300 ppt limit and 30 ppt monitoring threshold are not supported by data indicating that such levels pose any significant risk.

- Both the dioxin reassessment and the NODA/DTBD are not in compliance with the Data Quality legislation and OMB rules (and therefore must be assumed to also not be in compliance with the forthcoming EPA rules) because –

  – the risk assessment is not objective and unbiased because it relies on many policy biases which are intermingled with the scientific data, and many of these biases have been highlighted, and not concurred with, by the Agency' peer review body, the SAB

  – the risk assessment does not sufficiently describe and discuss many significant uncertainties, nor the studies or reviews that bear on those uncertainties

  – the risk calculations are not transparent enough to be reproducible, as required for "influential" information

VII. Conclusions

1. Both the dioxin reassessment and the biosolids risk assessment are seriously flawed and incorporate many unsupported and unrealistic policy biases that exaggerate the risk estimates, contrary to the Data Quality legislation and rules.

2. The regulatory proposals are not supported by the risk assessments, even as they are now.

3. The Agency should issue a *Federal Register* notice describing the high level of unsupportable conservatism in the current risk assessment and concluding that there is insufficient basis for any regulatory action.

Thank you for considering these comments.

Sincerely,

Jim J. Tozzi
Member, CRE Advisory Board