

September 5, 2002

W-99-18 NODA Comment Clerk
Water Docket (MC-4101)
USEPA
1200 Pennsylvania Ave., NW.
Washington, DC 20460

Subject: Comments on Part 503 NODA

The Madison Metropolitan Sewerage District (Madison, Wisconsin) has reviewed the above referenced NODA and associated documents. Comments on each of the 12 specific areas called out by EPA in the NODA are attached.

The risk calculations as presented in Table 5 of the NODA show that the lifetime carcinogenic risk to the highly exposed adult population modeled by EPA ranges from 4×10^{-5} to 1×10^{-6} . This would indicate that no regulation is warranted since the risks are lower than the 1×10^{-4} risk level used in Round 1.

However, we believe that the exposure assessment in the NODA and supporting documentation contains multiple errors, which are discussed in greater detail in the attached comments. In some cases the errors lead to an overestimate of exposure and resultant risk, while in other cases they appear to underestimate exposure and resultant risk. In addition, we note that EPA has yet to make a decision on whether or how it will address potential non-cancer endpoints. It is difficult for us to determine what net impact multiple changes to the exposure assessment (including a potential change in the cancer potency factor) would have on the resulting risk calculation.

We encourage EPA to carefully consider all comments that are received and to confirm that appropriate exposure assumptions have been used. EPA should recalculate the Table

5 numbers following any necessary revisions to the exposure assessment. If the net result is that there is no significant increase in risk levels compared to the current Table 5 values, then we would support a “no regulation” alternative. If however, risks increase and fall within the 1×10^{-4} risk range, then we would support development of a risk based regulation at a carcinogenic risk level of 1×10^{-4} . This risk level is consistent with the risk level used in developing numeric limits for Round 1.

We also believe that it would be prudent for EPA to discuss in the preamble why the regulatory approach focuses on 29 specific dioxin, dibenzofuran and co-planar PCB congeners, but doesn't address the remaining congeners.

Finally, while EPA has not officially asked for comment on the concept of a voluntary self monitoring program as an alternative to regulation development, we believe that it is appropriate to comment on this concept. We support and encourage voluntary monitoring and source identification/reduction programs. Many agencies already go well beyond existing regulatory requirements as it relates to these activities. However, we have a major concern about presenting a voluntary approach as a viable alternative to more traditional regulatory approaches. Our concern is that the “voluntary” approach in essence would become a pseudo regulation, with strong expectations on the part of state/federal regulatory agencies that “voluntary” activities be adopted by most, if not all operating agencies. EMS programs would be the logical vehicle used to encourage development and implementation of voluntary self monitoring and source identification/reduction programs. Thus, we believe that endorsing the “voluntary” self monitoring concept would represent a major step towards making adoption of an EMS a regulatory requirement. The EMS concept has been promoted by EPA, AMSA and WEF as being a voluntary initiative. We do not believe that these agencies should endorse an approach that may move the wastewater treatment industry closer to the mandatory development of an EMS program.

We appreciate the opportunity to provide comments on the NODA and associated documents. If you have any questions regarding the attached information, please feel free to contact me directly at 608-222-1201, ext. 276.

Sincerely,

David S. Taylor
Director of Special Projects

Enc: as stated

Response to EPA's Request for Public Comments (Section XIII of the NODA)

1) The significance of the difference in dioxin concentrations between small facilities (≤ 1 MGD) and larger facilities (> 1 MGD). It is our understanding that EPA followed a statistically relevant procedure in selecting facilities to participate in the most recent EPA dioxin survey. However, we are unsure whether the study was statistically designed to test the hypothesis that there may be a difference in concentrations between small and large facilities. The data in Table 2 appears to indicate that the concentrations for small facilities are lower than for larger facilities, although EPA correctly points out that the significance of these differences may be difficult to assess due to a variety of factors, including a small sample size. The more important question based on this and other information contained in the NODA is whether small facilities should be exempt from regulation, should regulation be deemed necessary (see comment 11).

2) The significance of the differences in dioxin and furan concentrations in biosolids measured in the EPA 2001 survey compared to dioxin concentrations measured in biosolids in the 1988 NSSS.

Changes in sampling procedures, analytical protocols and associated detection limits have occurred between these two sampling periods, which can confound comparisons of the datasets. However, it is clear based on the EPA database and earlier AMSA biosolids surveys that the concentrations of dioxins and furans have decreased with time. This is not unexpected given the history of use associated with these compounds and regulatory initiatives directed at these parameters. Although data is not provided for PCBs, it would not be unreasonable to assume that PCBs would show the same decreasing trend with time. This is significant in that it demonstrates that exposure to dioxin and dioxin like compounds will decrease with time, and should give regulatory agencies and the general public confidence that regulatory decisions based on current datasets will be adequately protective under reasonably anticipated future conditions.

3) Choice of the highly exposed farm family as the modeled population and the associated exposure assumptions.

We believe that the assumptions used to define the farm family lead to an overestimate of exposure and resultant risk. EPA has used a highly exposed individual (HEI) concept to define exposure. The recently completed NAS study recommends the use of a reasonable maximum exposure (RME) approach when conducting risk assessments as opposed to characterizing exposure to a maximally exposed individual (MEI) or a highly exposed individual (HEI). The NAS report stated that use of a RME will result in a more accurate characterization of exposure/risk, minimizing the compounding effect of overly conservative assumptions associated with the MEI or HEI approach. We encourage EPA to redefine exposure to the farm family using assumptions that are more consistent with a RME approach.

Specific areas where EPA appears to have overestimated exposure include:

- ? There is no distinction between a field within a farm and the farm itself. In other words, EPA appears to assume that biosolids are applied to the entire farm (except the buffer area). In addition, all fields within a farm appear to have biosolids applied at the same rate and frequency. This is certainly not how Madison has operated its land application program and we doubt whether this practice is followed by other programs around the country. We recommend that EPA consider an application distribution that more closely approximates practices that actual operating programs are following. One possible approach would be to assume that 1/3rd of the fields within a farm receive biosolids in any given year and that application rotates between fields from year to year (e.g. the entire farm is covered over a three year period).

- ? All farms are assumed to have a fishable stream immediately adjacent to the farm, with the stream always located downhill from the farm. The stream therefore receives runoff from the biosolids amended fields. The farmer is assumed to catch fish from these streams and consume the fish, which have some level of dioxin contamination. This description may fit a **very limited number** of farms, but it is clearly not appropriate to use this assumption to describe all farms. We believe that the exposure assessment should use a distribution where a small, but conservatively defined percentage of the farms are assumed have a layout similar to the above description.

- ? All farms are assumed to raise beef cattle, dairy cattle and free range chickens for direct consumption. All of these animals are assumed to consume dioxins through direct ingestion of the biosolids-soil mixture and/or through consumption of plant products that have accumulated dioxins through plant uptake or volatilization/re-deposition. While we believe that the potential routes of dioxin intake are appropriate, assuming that 100% of the farmers would raise beef cattle, dairy cattle and free range chickens for direct consumption is unrealistic. The percentage of home produced products does not appear to be consistent with earlier EPA estimates or other data that we are aware of. We encourage EPA to use a more realistic assumption regarding the percentage of home produced animal products.

- ? The concentration of dioxins in biosolids is assumed to remain constant over the period of application. In addition, dioxins are not assumed to degrade in the soil environment with time. The EPA exposure assessment should reflect dioxin degradation and should also reflect some variation in dioxin concentration in the source material over time.

- ? The exposure frequency of 350 days per year appears to be excessive and does not appropriately model time spent away from the farm.

- ? 100% of the ingested soil is assumed to be contaminated with dioxin and all soil within a farm is assumed to have the same level of dioxin contamination. More realistic assumptions need to be made in this regard.
- ? 100% of the fish caught and consumed by a farmer are assumed to come from a stream that has been impacted by biosolids applied to adjacent soils. This again is clearly a worst case assumption and a more realistic assumption is warranted.
- ? We are aware of other errors identified by AMSA's contractor (Cambridge Environmental, Inc.) and encourage EPA to fully consider and address those errors.

4) All of the assumptions related to exposure, fate and transport, including the specific assumptions related to farming and grazing practices used by the modeled farm family.

See the above comments for areas where we believe EPA may have overestimated exposure. We also believe that there may be instances where EPA has underestimated exposure. These areas are identified below. We encourage EPA to take a closer look at these areas and to make modifications in cases where they feel changes may be appropriate:

- ? There appears to be something incorrect about exposure through the maternal milk route. Based on our understanding of this route, we would expect a higher level of exposure than that shown by EPA.
- ? The soil column model may overestimate dispersion of dioxin within the soil column and therefore may underestimate dioxin concentrations in surficial soils.
- ? The vapor dispersion model may lead to an underestimate of vapor contamination.

5) The treatment on non-detects in the revised risk assessment and the effect on estimating risks.

Use of 1/2 the detection limit is a well established practice. It has been used previously by EPA and other agencies and is consistent with the RME concept addressed in previous comments. Clearly, use of 1/2 of the detection limit will increase the estimated exposure and resulting risk vs. use of zero (0) for non-detects. However, given the extremely sensitive analytical protocols used in the biosolids survey and the resultant low detection limits, we do not believe that use of 1/2 the detection limit value will significantly alter risk calculations. We would not support use of the full detection limit value in cases where non-detects were reported.

6) The assumptions and values used to estimate how much dioxins are being transported to individuals in the modeled farm family.

See comments 3 and 4.

7) The methodology used for the screening ecological risk assessment (SERA) and associated results.

We believe that EPA has taken a reasonable approach in conducting the ecological risk assessment. Calculation of relative ecological risks using an HQ approach is consistent with other EPA programs. The guidelines used in selecting representative ecological receptors were appropriate. All trophic levels and relevant feeding guilds were represented. The screening assessment is responsive to comments that the agency received in response to the December 1999 proposal and represents an improvement over the 1999 proposal.

8) The significance of the finding that setting a 300 ppt TEQ limit would make no detectable difference in the risk of cancer to the highly exposed farm family.

It is not surprising that setting a limit at 300 ppt TEQ would make no detectable difference in the risk of cancer to the highly exposed farm family when compared to setting a limit at 100 ppt TEQ. This is simply a function of the distribution of concentrations found in the EPA dioxin survey (e.g. few samples were above this limit, therefore there was no significant change in risk).

EPA may be looking for confirmation that it would be appropriate to set a limit at 300 ppt TEQ. We believe that if a limit is deemed necessary, it should be risk based and consistent with the risk level used in Round 1 (1×10^{-4}).

9) Taking no action with respect to regulating dioxins for land application.

We have reviewed the NODA and supporting documentation. The risk calculations as presented in Table 5 of the NODA show that the lifetime carcinogenic risk to the highly exposed adult population modeled by EPA ranges from 4×10^{-5} to 1×10^{-6} . This risk range is based on use of the existing cancer potency factor of 1.56×10^{-4} /PG TEQ/kg-d. These risks fall below the 1×10^{-4} risk level that was used to develop criteria in Round 1 of the Part 503 rule. The annual number of excess cancer cases ranges from 0.0002 to 0.006. By definition, the risks to the highly exposed population are much greater than the risks to the general population. A reasonable conclusion based on the above information is that the risk level does not warrant a regulatory response.

However, we believe that the exposure assessment contains multiple errors, which are discussed in greater detail in earlier comments. In some cases the errors lead to an overestimate of exposure and resultant risk, while in other cases they appear to underestimate exposure and resultant risk. It is difficult for us to determine what net impact multiple changes to the exposure assessment (including a potential change in the cancer potency factor) would have on the resulting risk calculation.

We encourage EPA to carefully consider all comments that are received and to confirm that appropriate exposure assumptions have been used. EPA should recalculate the Table 5 numbers following any necessary revisions to the exposure assessment, which may include use of a revised cancer potency factor. If the net result is that there is no significant increase in risk levels compared to the current Table 5 values, then we would

support a “no regulation” alternative. If however, risks increase and fall within the 1×10^{-4} risk range, then we would support development of a risk based regulation at a carcinogenic risk level of 1×10^{-4} . This risk level is consistent with the risk level used in developing numeric limits for Round 1.

10) The proposed monitoring schedule and threshold that would allow for less frequent monitoring, and specifically, on whether other schedules which would require more or less frequent monitoring would be more appropriate.

EPA’s December 1999 proposal called two years of initial monitoring. Those facilities with concentrations between 30 and 300 ppt dioxin TEQ’s would subsequently be required to monitor annually. Those facilities with two consecutive years of data showing concentrations below 30 ppt would be able to reduce their monitoring frequency to once every five years.

We support a tiered monitoring strategy similar in concept to that outlined in the original proposal. However, we believe that the upper or “ceiling” concentration should be risk based (using a risk level of 10^{-4}). In all likelihood, the upper concentration would be significantly higher than 300 ppt. We would support a lower concentration being established at 10% of the ceiling concentration. We suggest that 3 data points be collected in the initial sampling year and be used as the basis for establishing a sampling frequency in subsequent years. For facilities that have concentrations less than 10% of the ceiling concentration, monitoring frequency could be reduced to once every five years. Facilities with concentrations between the ceiling concentration and the 10% value would be required to monitor annually.

11) Excluding small entities from the limit for dioxins in sewage sludge to be land applied.

We do not believe that there should be a regulatory exclusion for small facilities. However, it would be appropriate to look for opportunities to lessen the burden for these facilities. One possible method would be to reduce the monitoring requirements for small facilities to a frequency of once every five years (e.g. once during every NPDES permit cycle).

12) A methodology to assist communities in voluntarily identifying and reducing/eliminating sources of dioxin that contribute to elevated levels of dioxin in sewage sludge.

We support this concept. There are many cases where facilities have chosen to pursue pollution prevention/source reduction activities for other parameters, even though their biosolids concentrations are well below any regulatory action level. We believe that the same will be true for dioxin and dioxin like compounds. Guidance on how to approach such activities for dioxin and dioxin like compounds would be extremely useful, particularly if there is not a heavy reliance on upstream sampling, which would be extremely expensive and perhaps prohibitive for many facilities.