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September 10, 2002

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

Secretary
Donnie R. Wheeler
General Manager
Hampton Roads Sanitation
District
Virginia Beach, VA

Re: *Standards for the Use or Disposal of Sewage Sludge; Notice of Data Availability; 67 Fed. Reg. 40554 (June 12, 2002)*

Executive Director
Ken Kirk

Dear Sir or Madam:

The Association of Metropolitan Sewerage Agencies (AMSA) is pleased to provide comments on the U.S. Environmental Protection Agency's (EPA's) *Standards for the Use or Disposal of Sewage Sludge; Notice of Data Availability (NODA)*. Founded in 1970, AMSA represents the interests of over 270 of the nation's publicly owned wastewater utilities (POTWs). AMSA members serve the majority of the sewered population in the United States and collectively treat and reclaim over 18 billion gallons of wastewater every day. As generators of treated sewage sludge, or biosolids, AMSA's members are responsible for finding environmentally safe and cost effective ways to manage millions of tons of biosolids every year. Land application continues to be one of the most viable and environmentally sound management options for many communities in the United States.

AMSA commends EPA for taking further comment before making a final regulatory decision on dioxins in land applied biosolids. The additional time has allowed the Agency to collect and evaluate new data and to perform additional risk assessment analyses using that data. The information in the *NODA* provides a current picture of the issues surrounding dioxins in biosolids and a solid foundation upon which to base a regulatory decision.

AMSA's comments focus on whether a national numeric limit for dioxin in land applied biosolids is appropriate and respond to a number of issues on which the

Agency solicited input. Based on a thorough review of the Agency's new risk assessment, AMSA's comments also highlight a few areas where additional review is needed as EPA works toward final action. AMSA's comments on the *NODA* are outlined below.

No Action Warranted for Dioxin in Land Applied Biosolids

The *NODA* presents extensive new information regarding the presence of dioxins in land applied biosolids. Based on the information presented in the *NODA*, AMSA believes that a national numeric limit for dioxins in land applied biosolids is not warranted. The *NODA* makes some key observations regarding EPA's new information that support a no action decision:

- **Current concentrations of dioxins in biosolids are low and do not present a significant risk to human health or the environment.** Results from surveys of dioxin concentrations in biosolids conducted by both EPA and AMSA over the last two years demonstrate that the average concentration of dioxins in biosolids is very low. EPA's 2001 Dioxin Update Survey found an average or mean concentration of dioxins of 31.6 ppt TEQ (toxic equivalents) (expressed with non-detects at ½ the detection limit). AMSA's 2000/2001 Survey of Dioxin-Like Compounds in Biosolids¹ found a mean concentration of 48.5 ppt TEQ (expressed with non-detects at ½ the detection limit). As outlined in the *NODA*, these concentrations do not appear to pose a significant risk to human health or the environment, even when EPA's highly conservative risk estimates are applied to the exposure assessment used in the *NODA*.
- **Dioxins concentrations in biosolids have been and continue to significantly decline, which will likely ensure further future reductions in potential risks.** A comparison of the results from EPA's 2001 Survey with the results of EPA's 1988 National Sewage Sludge Survey (NSSS) reveals that concentrations of dioxins in biosolids appear to be declining. EPA states that the significance of these differences is not certain due to changes in the sampling procedures and analytic methods. However, the results of AMSA's survey revealed similar trends when the 2000/2001 results were compared with a survey conducted in 1994 and 1995. The observed trend in decreasing dioxin concentrations in biosolids is consistent with the generally observed decreases in dioxin levels in other media and biological organisms, including humans. As dioxins decrease in the environment and humans, the amount of dioxin entering POTWs is expected to decrease – resulting in continued decreases of dioxins in biosolids.
- **Dioxin “spikes” in sewage sludge are transient.** The new data presented reveal that to the extent a “spike” (i.e., higher concentration) in dioxin levels is detected in a POTW's sewage sludge, that effect is transient. No POTWs have consistently high levels of dioxins in their biosolids. The biosolids samples that had the highest levels of dioxins in either the 1988 NSSS or the 2001 EPA Survey displayed the largest fluctuations in dioxins concentrations. Because any dioxin spikes tend to be transient, it is unlikely that biosolids from any one POTW will pose an unusual threat to human health or the environment.

¹ AMSA's 2000/2001 Survey of Dioxin-Like Compounds in Biosolids is available at <http://www.amsa-cleanwater.org/advocacy/dioxin/dioxin.cfm>.

The *NODA* also presents the results of EPA's screening ecological risk analysis (SERA) and a new probabilistic risk assessment for human health risks. These results also support a no action decision for dioxins in land applied biosolids:

- **Low probability of adverse ecological effects.** While the SERA does not establish definitive estimates of risk, it does provide insight into the potential for ecological risk. Using a two phased approach, the SERA first identified any habitats, receptor categories, and exposure routes that may be of concern. EPA then conducted a number of deterministic assessments for representative receptor categories (species) in two major habitats: terrestrial and waterbody margin habitat. None of the values obtained from these assessments exceeded the protective ecological benchmark (Hazard Quotient = 1), demonstrating with a "high level of confidence that there is a low probability of adverse effects to ecological receptors" resulting from dioxins in land applied biosolids (67 *Fed. Reg.* 40570).
- **Incremental human health risk is minimal.** The results of EPA's new probabilistic risk assessment suggest that the incremental increase in individual lifetime risk of developing cancer due to exposure to dioxins potentially present in biosolids is minimal. Using the Agency's current cancer slope factor, the high-end individual excess lifetime risk to the highly exposed modeled population could range from 2×10^{-5} to 1×10^{-6} (two in one-hundred thousand to one in one million) for exposure by multiple pathways. These excess risk levels fall within the range of risks considered acceptable by the Agency, 1×10^{-6} to 1×10^{-4} , and are lower than the risk level used for Round 1, 1×10^{-4} . Furthermore, EPA uses highly conservative slope factors, which provides additional assurance that dioxins in biosolids do not pose an unacceptable risk.

Any regulatory limit or control placed on dioxins in biosolids must reduce the risk posed by the land application of those biosolids. EPA initially proposed a limit of 300 ppt TEQ as the key threshold for minimizing the risk posed by dioxins in biosolids. When the new data are evaluated and the risks calculated, however, the need for such a numeric limit or threshold is not evident. Although the baseline level of risk may change slightly (with a change in cancer slope factor or other adjustment in the exposure or risk assessment), EPA found that there is no quantifiable decrease in risk when biosolids with greater than 300 ppt TEQ dioxins or even greater than 100 ppt TEQ dioxins are restricted from land application. Because the concentrations of dioxins in biosolids are so low (i.e., there are very few biosolids samples with levels above 100 ppt TEQ), a regulatory limit or threshold that restricts the application of biosolids with dioxins concentrations above these levels would have little or no impact on decreasing the overall risk. Therefore, placing such a regulatory limit on biosolids may cause a misallocation of limited agency and public resources for no gain in protection of human health.

EPA also found that the continual application of biosolids with significantly higher concentrations of dioxins than currently measured would be necessary to predict quantifiable increases in risk. Given the already low levels of dioxins, the demonstrated decline in dioxin concentrations over time (in human tissues and the environment, and consequently in biosolids), and the observed transient nature of elevated dioxin concentrations, such a scenario seems unlikely.

AMSA's Review of the New Risk Assessment

In light of the importance assigned to the results of EPA's new probabilistic risk assessment, AMSA conducted a careful review of the Agency's methodology to ensure it is consistent with sound risk assessment practices. AMSA's review revealed a number of very conservative assumptions, methods, and parameter values used by EPA that likely lead to overestimates or overstatements of risk. Below is a brief list of those elements that may have resulted in an overstatement of risk. Additional detail on these items including an estimate of the impact they may have on the risk estimates and suggested remedies is provided in Attachment 1. AMSA notes that despite these numerous conservative assumptions and other sources of overestimation, the resulting incremental human health risk calculated for the *NODA* is still within the Agency's range of acceptable risks. This should provide the Agency further assurance that a no action approach will be protective of human health and the environment.

Potential Sources of Overestimate/Overstatement

1. Common to All Pathways

- *Field versus farm size*
EPA incorrectly assumes that a field and a farm are equivalent, so that if biosolids are used on a field, they are used everywhere on that farm. In particular, for the major pathways EPA assumed that biosolids are used wherever they could affect the cows or steers contributing to milk or beef eaten by the farmer.
- *Period of biosolids use*
EPA appears to assume that any farm that uses biosolids will continue to use them regularly for long periods (it is not clear how the distribution for application period and the distributions for exposure periods interact). This affects the distribution of results – it is likely that a larger farmer population than calculated is exposed, but they are affected less on average, while the extremes of the distribution are less affected.
- *Method used to estimate the total number of cancers*
EPA does not use the mean value of the variability distribution to calculate total numbers of cancers. Using the upper-end values, as given in the *NODA*, gives a very large overestimate of expected cancers. The *NODA* uses as examples the 90th, 95th and 99th percentiles of risk, the last of which is 10 times the mean value.
- *Estimates of the size of the population modeled*
EPA's estimates of the size of the population affected appear to be based on the total number of farmers. This fails to take into account that not all farmers eat home-produced beef (about 39% do) or drink home-produced milk (only about 13%) and, therefore, overestimates exposure.

- *Carcinogenic potency*

EPA's dioxin risk estimates presented in the *NODA* are based on highly conservative slope factors. Many in the scientific community have argued that the available evidence suggests that dioxin poses no human cancer risk at the low levels encountered in the environment. Further, EPA appears to have staked out a highly conservative position on dioxin's potential cancer risks that is inconsistent with other federal and international bodies. The Agency for Toxic Substances and Disease Registry (ATSDR) recently published an overview concerning how different Federal and international bodies assess the potential risks posed by dioxin.² Whereas EPA relies solely on a conservative linear default model to quantify dioxin cancer risks, other federal and international bodies (e.g., ATSDR, the European Commission Scientific Committee on Foods (EC), the Joint FAO/WHO Expert Committee on Food Additives (JECFA)) have determined that a threshold model is more consistent with the science concerning dioxin's carcinogenic action.³ According to ATSDR, this has led to a "world-wide convergence" on an acceptable dioxin exposure of 1 to 4 pg/kg/day. This is in contrast to EPA's determination in its draft Dioxin Reassessment that a one in a million cancer risk exists at approximately 0.001 pg/kg/day. ATSDR observed that EPA's dioxin reassessment "may place too much confidence in the ability to accurately predict cancer risks at low doses. This approach dramatically increases cancer risk estimates that are not based on compelling new data but rather on the application of statistical models . . . [that] are not yet fully validated" (Pohl, 2002).

Despite EPA's highly conservative approaches for estimating the potential cancer and non-cancer risks posed by dioxin, it is important to note that the *NODA* states that using either EPA's current cancer slope or the one presented in its Draft Reassessment, the dioxin risks calculated for biosolids are below or around 10^{-4} . Despite the acceptable risk estimates for biosolids presented in the *NODA*, as a general matter AMSA believes that EPA should take into account the conservative nature of its risk estimates and the likelihood that use of those estimates overstate the potential risks posed by dioxins when managing biosolids.

- *Exposure frequency*

EPA incorrectly assumes all exposures on a farm continue for 350 days a year. However, periods away from the farm are likely to exceed two weeks a year.

² Pohl, HR, *et al.* 2002. Public Health Perspectives on Dioxin Risks: Two Decades of Evaluations. *Hum. Ecol. Risk Assess.* 8(2):233-250.

³ In a recent comparison of EPA's Dioxin Reassessment and the World Health Organization's dioxin cancer assessment, the U.S. General Accounting Office concluded that a "major difference in the organizations' assessments concerns whether there are threshold levels below which exposure to dioxins would pose negligible risk of cancer." While EPA assumes there is no safe threshold level for cancer effects, the WHO assumes there is. U.S. General Accounting Office, April 2002, "Environmental Health Risks, Information on EPA's Draft Reassessment of Dioxins," GAO-02-515.

- *Concentrations of dioxins in biosolids applied to land*
EPA treats the contaminant distributions measured in the biosolids survey as a variability distribution between fields for long-term average concentration. Since any single field will effectively receive many “samples” of biosolids over a long period (so that variation between such samples will tend to average out), this overestimates the upper percentiles of long-term average concentration.
- *Exposure duration for those initially exposed as children*
EPA bases the distribution of exposure duration for those initially exposed as children not on farmers, but on the general population and may well overestimate exposures for children on farms.
- *Concentration trends in biosolids*
EPA fails to account for future decreases in dioxin concentrations. EPA has undertaken many highly successful efforts over the last two decades to manage releases of dioxin to the environment. Through effective controls on dioxin sources and emissions, levels of dioxin in humans and the environment (important sources of dioxins in biosolids) have dramatically decreased. As those levels of dioxins decrease, concentrations of dioxins in biosolids can reasonably be expected to decrease. Indeed, EPA’s and AMSA’s survey data indicate such a decrease. EPA should expect to observe further future decreases in dioxins in biosolids. EPA’s failure to take those expected decreases into account leads to an overestimation of future risks posed by dioxins in biosolids.

2. Major exposure pathways (beef, milk, maternal milk)

- *Soil vapor emission model*
The soil vapor emission model as described has three principal failures affecting dioxin and PCB emissions from soil – it applies an incorrect solution of the diffusion equation at the soil surface (effectively ignoring the stated boundary condition); it fails to account for the boundary layer of air just above the soil surface; and it fails to account for infiltration of rainwater at short times after tilling, when the majority of emission occurs. The first reduces estimates of emission rates, the second principally affects very involatile materials (like the higher chlorinated dioxins) and results in overestimates of emission rates, and the last affects more volatile materials (like TCDD and PCBs), again resulting in an overestimate of emission rates.
- *Food preparation losses*
Food preparation losses for beef are based on observed weight losses during cooking and post-cooking operations. However, EPA does not account for the preferential loss of fat (in which dioxins and PCBs are primarily concentrated) in such preparation losses.

- *Correlations between milk and beef consumption*

The correlations between milk and beef consumption are not considered. This omission principally affects distribution shapes, rather than averages, and results in some overestimation.

3. Minor pathways of exposure

- *Worst-case farm layout*

EPA's adopted scenario appears to correspond to approximately the worst possible case, with all runoff from biosolids affecting the same area that happens to be used for other purposes (e.g., raising chickens), and all affecting the same stream, used by the farmer for fishing. Use of this scenario overestimates potential exposures.

- *Soil erosion modeling*

The soil erosion modeling likely overestimates soil erosion to areas that then act as source terms to the minor pathways of exposure and may, therefore, overestimate exposure.

- *100% fraction of contaminated fish*

EPA's assumption concerning the fraction of contaminated fish may lead to an overestimation of exposure.

- *100% contaminated fraction for ingested soil*

EPA's assumption concerning the fraction of ingested soil that may be contaminated may lead to an overestimation of exposure.

- *Soil ingestion rates*

EPA uses the standard regulatory assumptions of 100 mg/day for young children, and 50 mg/day thereafter. Available evidence indicates that these regulatory assumptions overestimate actual average ingestion rates.

- *Food preparation losses*

Food preparation losses are estimated from weight losses during food processing, but losses of dioxins/PCBs sorbed to the surfaces of foods (particularly root vegetables) will be higher, so the loss is underestimated and the risk overestimated.

- *Soil mixing depth*

The fixed, small, soil mixing depth in the barrier area results in an overestimate of risk.

- *Correlations between food ingestion rates*

Food ingestion rates are treated as uncorrelated for different foods.

AMSA's review did reveal some potential errors in EPA's risk assessment that might understate estimates of risk.

Potential Sources of Underestimate/Understatement

- *Soil column model*
The soil column model appears to overestimate dispersion of contaminants in the soil from the mechanisms considered (although it omits a possible mechanism, bioturbation). Therefore, it may underestimate surface soil concentrations in the field where the biosolids are applied.
- *Vapor dispersion modeling*
The vapor dispersion model used omits the principal physical effects (it evaluates dispersion of vapor above the grass layer and from some distance away, omitting the diffusion of vapor up from the contaminated soil immediately beneath the grass), resulting in a possible underestimate of vapor concentrations around plants, which may ultimately impact the estimated dioxin concentrations in milk and beef.
- *Vapor uptake by plants*
The vapor uptake estimates are based on the measured ratio of concentration in grass to the concentration in vapor dispersed above the grass in field conditions. This approach might underestimate the uptake from an equal concentration of vapor in the immediate vicinity of the grass leaves (as would be obtained from vapor diffusing up from the soil directly below the grass). This is because the resistance to diffusion of vapor from the plume above the grass is higher than the resistance to diffusion of vapor adjacent to the grass leaves.
- *Maternal milk route*
A scoping calculation using the model applied in the Technical Background Document (TBD) demonstrates that infant exposure to breast milk might contribute a larger fraction to EPA's risk estimates (the TBD assigns a negligible contribution). However, EPA's approach in the *NODA* appears consistent with its extensive consideration of breast milk risk outlined in its draft Dioxin Reassessment, which concluded that dioxins in breast milk generally do not pose an unreasonable risk to nursing infants.
- *Fraction home-produced*
The intake equation for foods (including beef and milk) erroneously includes a "fraction home-produced." The distributions for intake quantity are already of the home-produced component of food components only, so such factors are not needed.

AMSA continues to believe that EPA's decision regarding dioxins in land applied biosolids must be based on sound science. For this reason, AMSA strongly recommends that EPA strengthen the underlying foundation of the information presented in the NODA by further investigating the issues

outlined above concerning the risk assessment and addressing them as appropriate and in accordance with sound risk assessment practices as the Agency works toward final action.

No Regulatory Action Does Not Mean "No Action"

Should EPA conclude that the risk assessment and other scientific data dictate that no federal regulatory action is appropriate for dioxins in land applied biosolids, AMSA notes that this does not mean that nothing will be done at POTWs to monitor and reduce the presence of dioxins in biosolids. In fact, many of the nation's wastewater treatment agencies already monitor for dioxins in biosolids, despite the lack of a regulatory requirement, to address local concerns and issues. These practices are unlikely to change in the event that EPA decides not to regulate dioxins in land applied biosolids. AMSA is confident that voluntary monitoring will continue to demonstrate that dioxins in biosolids do not pose an unacceptable risk to human health or the environment. That monitoring may also demonstrate the anticipated decrease of dioxins in biosolids.

Response to Specific Comment Requests

Below are AMSA's responses to the 12 issues on which EPA sought comment in Section XIII of the *NODA*.

1. Request for Comments

The significance of the differences in dioxin concentrations in sewage sludge measured at facilities with wastewater flows greater than one MGD (million gallons per day) compared to dioxin concentrations in sewage sludge at facilities with wastewater flows less than one MGD.

AMSA Response

The data in Table 2 suggest that the concentrations of dioxins in biosolids at small facilities (less than one MGD) are lower than concentrations at large facilities. However, EPA 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 AMSA 2000/2001 survey also examined the mean concentrations of dioxins in biosolids from small and large facilities to determine if there was a significant difference. Although AMSA's survey was not conducted according to the same statistical procedures as EPA's survey, the *t*-tests conducted for the AMSA survey did not suggest any significant difference between the mean TEQ mass fractions of small and large facilities.

2. Request for Comments

The significance of the differences in dioxin concentrations in sewage sludge measured in the EPA 2001 dioxin update survey compared to dioxin concentrations in sewage sludge measured in the 1988 National Sewage Sludge Survey.

AMSA Response

As stated above, AMSA believes this difference is significant. Although AMSA's dioxin surveys were not conducted according to the same statistical procedures as the EPA surveys, the data from the AMSA surveys (1994/1995 and 2000/2001) provide further support for this trend of decreasing dioxin concentrations over time. Both the overall low

concentrations of dioxins in biosolids and the decline in those concentrations over time suggest that controls on dioxins in other regulatory programs are having a noticeable effect on releases to the environment. Although data is not provided for PCBs, it would not be unreasonable to assume that PCBs would show the same decreasing trend with time.

3. Request for Comments

Choice of the highly exposed farm family as the modeled population for the revised risk assessment and the assumptions related to this choice of modeled population.

AMSA Response

We believe that the assumptions used to define the farm family lead to an overestimation of exposure and risk estimates. EPA has used a highly exposed individual (HEI) concept to define exposure. The recently completed National Research Council (NRC) study *Biosolids Applied to Land: Advancing Standards and Practices* 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 NRC 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.

Attachment 1 provides a more comprehensive list of the issues AMSA identified in the Agency's risk assessment.

4. Request for Comments

All of the assumptions related to exposure, fate and transport used in the revised risk assessment, including the specific assumptions related to the farming and grazing practices used by the modeled farm family.

AMSA Response

Attachment 1 provides a more comprehensive list of the issues AMSA identified in the Agency's risk assessment, but a few of the assumptions are worth highlighting:

- No distinction is made 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. AMSA recommends that EPA consider an application distribution that more closely approximates actual operating practices. One possible approach would be to assume that one third of the fields within a farm receive biosolids in any given year and that application rotates between fields from year to year.
- EPA assumes that the farmer does not rotate the pasture to grow row crops where tilling of biosolids in the soil would mitigate dioxin volatilization transport. EPA should more closely consider actual farming practices and factor in some level of crop rotation.

- 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. AMSA believes the exposure assessment should use a distribution where a small, but conservatively defined percentage of the farms are assumed to 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 AMSA believes 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. 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.

5. Request for Comments

The treatment of non-detects in the revised risk assessment and the effect on estimating risk.

AMSA Response

AMSA agrees with EPA's treatment of non-detects in the revised risk assessment. Because of the sensitivity and limits of detection achieved by the analytical procedures used in EPA's 2001 survey, the reported dioxin congener values are relatively unchanged and there is no quantifiable difference in risk if non-detects are treated as zero, one-half the detection limit, or at the detection limit. AMSA's 2000/2001 survey treated non-detects in the same manner.

6. Request for Comments

The assumptions and values used to estimate how much dioxins are being transported to individuals in the modeled farm family (e.g., the sources [store-bought versus farm-produced], types and dioxin contamination levels of poultry feeds.)

AMSA Response

See Response to Comment 4 and Attachment 1.

7. Request for Comments

The methodology and data used for the screening ecological risk assessment, and the results derived from the screening ecological risk analysis.

AMSA Response

AMSA believes EPA has taken a reasonable approach to evaluate the ecological risk posed by dioxins in land applied biosolids. Calculation of relative ecological risks using a hazard quotient (HQ) approach is consistent with other EPA programs.

Some of the biosolids concentrations used for the Screening Ecological Risk Analysis (SERA) are likely overestimates (the first screen assumed the ecological receptors were exposed to the raw biosolids). The concentration estimates were derived from the human health risk assessment and used as surrogates for ecological receptors, an approach that needs further evaluation. This approach leads to some overestimates that are not identified in the Technical Background Document. For example, earthworms were effectively assumed continuously exposed to soil concentrations calculated to be present in the top 20 cm, 2 cm, or 1 cm of the soil column (in cropped areas, pasture, and in the buffer, respectively), although such an assumption is not valid.

See also discussion above “No Action Warranted for Dioxin in Land Applied Biosolids”

8. Request for Comments

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.

AMSA Response

The finding that a 300 ppt TEQ limit would make no detectable difference in the risk of cancer is a function of the fact that very few biosolids samples from EPA’s 2001 survey exhibited dioxins concentrations over 300 ppt TEQ. The same is true if a limit of 100 ppt TEQ is assumed. If the Agency decides to establish a numeric limit, that limit should be risk based and consistent with the risk level used in Round 1 (1×10^{-4}).

See discussion above “No Action Warranted for Dioxin in Land Applied Biosolids”

9. Request for Comments

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

AMSA Response

See discussion above “No Action Warranted for Dioxin in Land Applied Biosolids”

10. Request for Comments

The proposed monitoring schedule and the threshold concentration of dioxin 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.

AMSA Response

Assuming EPA decides that a numeric limit for dioxins in biosolids is necessary, and develops a risk-based limit or ceiling concentration using the 1×10^{-4} risk level, AMSA believes that all POTWs subject to the rule should be required to conduct an initial test to establish a baseline dioxins concentration. POTWs already monitoring for dioxins would be able to rely on existing data. If the baseline concentration is lower than the ceiling concentration, POTWs would be required to monitor dioxins concentrations once every five years. If the baseline concentration exceeds the ceiling concentration, AMSA would suggest a two-step approach. The initial step would consist of a confirmatory test. If the test confirms the elevated dioxins concentration, the POTW would be required to investigate the source of the dioxins using the methodology suggested by EPA in the *NODA*. In the event that a source can not be identified and controlled, and as long as the dioxins concentration remains above the limit, the POTW would not be permitted to land apply its biosolids.

EPA also requested comments on whether a monitoring requirement in lieu of a numeric limit should be considered. Unfortunately, a monitoring regimen without some sort of action level is meaningless. Any requirement to monitor biosolids for elevated dioxins concentrations would have to be accompanied by some sort of guidance as to what levels are elevated, what levels are “safe”, and at what level should land application be halted. Without this information, POTWs would be required to establish their own action levels, which would likely make the monitoring requirements more burdensome and potentially less effective than a national numeric limit.

11. Request for Comments

Excluding small entities from the limits for dioxins in sewage sludge to be land applied.

AMSA Response

Given that the total amount of land applied biosolids generated by small POTWs accounts for less than eight percent of total biosolids land applied, and the extremely small probability that this small amount of biosolids could unreasonably increase the health risk for any individual, AMSA agrees with EPA that small entities could be subject to less stringent requirements or completely excluded without a measurable increase in risk. The apparent difference between dioxins concentrations at small and large facilities (small facilities having lower concentrations on the whole) observed in the EPA survey data, suggests that a different regulatory scheme may be warranted. EPA notes that the significance of these differences may be difficult to assess due to a variety of factors, including a small sample size, and the AMSA survey did not find a significant difference between these two groups (see response to Comment 1). Nevertheless, when the costs of regulating these small facilities are compared to the minimal risk posed by the small quantity of biosolids generated by these facilities, an exclusion appears warranted.

12. Request for Comments

A methodology to assist communities in voluntarily identifying and reducing or eliminating sources of dioxins entering wastewater treatment plants that contribute to elevated levels of dioxins in sewage sludge.

AMSA Response

EPA should develop guidance to provide additional details and explain how communities can utilize this voluntary methodology. Although eliminating the elevated concentrations of dioxins does not measurably change the risk to individuals exposed to land applied biosolids, it will be beneficial to have some means by which to track down the sources of those elevated levels. In addition, communities will be able to evaluate the potential for their biosolids to have elevated dioxin levels without having to conduct expensive tests.

EPA's Final Action

AMSA believes that given the information presented in the *NODA*, including the current data on dioxins in biosolids and the results of the Agency's new probabilistic risk assessment, a no action decision is warranted. As noted above, AMSA continues to believe that EPA's decision regarding dioxins in land applied biosolids must be based on sound science. Accordingly, AMSA strongly recommends that EPA strengthen the underlying foundation of the information presented in the *NODA* by further investigating the issues we have identified concerning the risk assessment and addressing them as appropriate as the Agency works toward final action.

We appreciate the opportunity to comment on the *NODA*, and look forward to continued discussions with the Agency on this matter. If you have any questions about our comments, please do not hesitate to contact me at 202/833-4653 or via email at kkirk@amsa-cleanwater.org.

Sincerely,



Ken Kirk
Executive Director

ATTACHMENT