

September 10, 2002

W-99-18 NODA Comment Clerk
EPA Water Docket
EPA West
U.S. Environmental Protection Agency
1301 Constitution Avenue, N.W.
Washington, DC 20460

Subject: Rhode Island Department of Health
Comments on Notice of Data Availability
Standards for the Use or Disposal of Sewage Sludge
Federal Register Vol. 67, No. 113/ June 12, 2002

Dear Madam/Sir:

The Rhode Island Department of Health (HEALTH) respectfully submits comments on the Notice of Data Availability (NODA), Standards for the Use or Disposal of Sewage Sludge. HEALTH's comments are based on a review of the above-referenced Federal Register notice and the document entitled *Exposure Analysis for Dioxins, Dibenzofurans, and Coplanar Polychlorinated Biphenyls in Sewage Sludge, Technical Background Document* (Draft, May 2002). Also reviewed were the National Research Council's document entitled *Biosolids Applied to Land: Advancing Standards and Practices* (advance copy, July 2002) and various peer reviews of the December 23, 1999 proposed rule for the same standard, available on U.S. EPA's web site.

In the attached submittal, HEALTH first presents its understanding of the risk assessment approach and conclusions, in part to set a framework for later comments. Specific comments are then presented in subject groupings but not necessarily in order of importance. Recommendations are include with the comments.

We appreciate the opportunity to comment on this NODA. Any questions on these comments can be addressed to the undersigned.

Sincerely,

Walter S. Combs, Jr., Ph.D.
Executive Director
Division of Environmental Health
Rhode Island Department of Health
3 Capital Hill, Room 209
Providence, Rhode Island 02908-5097

Summary of Proposed Rule

The Notice of Data Availability (NODA) contains a revision to the December 23, 1999 proposed rule for Standards for the Use or Disposal of Sewage Sludge to limit dioxin and dioxin-like compounds (“dioxins”) in sewage sludge applied to the land. The NODA applies to 29 compounds: seven 2,3,7,8-substituted congeners of polychlorinated dibenzo-p-dioxins, ten 2,3,7,8-substituted congeners of polychlorinated dibenzofurans, and twelve coplanar polychlorinated biphenyl congeners, collectively referred to as “dioxins.” The NODA proposes a numeric limit of 300 parts per trillion (ppt) dioxin toxic equivalents (TEQs) for sewage sludge applied to the land. This numeric limit is the same limit proposed in the 1999 proposed rule. The purpose of the standard is to prohibit land application of sewage sludge containing dioxin TEQ concentrations above the numeric limit to protect the health of highly exposed individuals and the general population. The NODA also proposes to exclude from the numeric limit and monitoring requirements treatment works with a flow rate equal to or less than one million gallons per day, based on the small amount of sewage sludge generated by these facilities.

The NODA contains a revised risk assessment that assesses the potential carcinogenic health risks associated with land application of sewage sludge. The NODA revised risk assessment uses a probabilistic approach, in which certain values, such as dioxin TEQ sludge concentrations, sludge application rates and duration, and exposure conditions, are varied to produce a distribution of exposures over multiple iterations of the exposure model. These exposure ranges are then used to derive a range of risk values. The risk assessment used sewage sludge data collected in the 2001 Dioxin Update of the Sewage Sludge Survey from 94 randomly selected publicly owned treatment works. An exposure analysis consistent with that used in the Draft Dioxin Reassessment (U.S. EPA 2000) and exposure data from the 1997 Exposure Factors Handbook were also applied. Receptor groups assessed were members of a farm family residing in a buffer zone adjacent to fields used for cattle grazing and crop production onto which sludge with dioxin was applied. The farm family also raised chickens in the buffer zone and caught fish from an adjacent stream. Receptors were assessed for exposure through the following pathways:

Exposure Pathway	Adult Farmer	Child of Farmer	Infant of Farmer
Inhalation of ambient air (vapor and particle)	✓	✓	-
Ingestion of soil	✓	✓	-
Ingestion of above- and below-ground vegetation	✓	✓	-
Ingestion of beef and milk	✓	✓	-
Ingestion of poultry and eggs	✓	✓	-
Ingestion of fish	✓	-	-
Ingestion of breast milk	-	-	✓

Data from 41 climatic regions across the continental United States were used to define farm size, soil type, meteorological conditions, and other factors. Source partitioning and fate and transport models were used to estimate dioxin concentrations in soil, air, and food. U.S. EPA’s current cancer slope factor for 2,3,7,8-tetrachlorodibenzo-p-dioxin of 0.15 pg/kg-day was used, rather than the more stringent, proposed revised cancer slope factor of 0.001 pg/kg-day applied in the Draft Dioxin Reassessment. The WHO 1998 toxic equivalent factors (TEF) scheme was used to derive toxic equivalents (TEQs) for dioxin-like compounds.

At the 95th percentile level, the risk assessment estimated a cumulative cancer risk of 2×10^{-5} (a risk of two in one-hundred-thousand) for adults, 1×10^{-5} for children, and 1×10^{-8} for infants. The exposure pathways contributing the greatest amount to this cumulative risk were ingestion of beef (1×10^{-5} and 5×10^{-6} for adults and children, respectively) and ingestion of milk (6×10^{-6} and 5×10^{-6} for adults and children, respectively). Risk estimates were also derived excluding dioxin TEQ concentrations above 300 ppt and 100 ppt, and remained the same. Because the resultant risks fell within the U.S. EPA's acceptable risk range of 10^{-4} to 10^{-6} , the proposed numeric limit of 300 ppt was retained.

HEALTH Comments on the NODA and Risk Assessment

Comments on Probabilistic Approach and Risk Characterization

While a probabilistic risk assessment can provide valuable information on the distribution of risks and variability of assumptions, HEALTH questions its practical utility as applied in this risk assessment in setting numeric limits. A numeric limit typically represents a concentration that poses a maximum acceptable risk level, above which the risks would be deemed unacceptable. That is not the case with the 300 ppt limit. In individual iterations of the assessment, the probabilistic model selected dioxin TEQ concentrations from a single municipal wastewater treatment plant out of the 94 treatment plants sampled, with the probability of selection weighted by the quantity of sludge produced. Dioxin TEQ concentrations up to 718 ppt were applied. It is not known whether the maximum 95th percentile risk of 2×10^{-5} represents a reasonable maximum exposure to 300 ppt dioxin TEQs, but likely it does not. The Agency should clearly demonstrate that a reasonable maximum exposure to 300 ppt dioxin TEQs will not result in an unacceptable risk because, in practice, a facility will be able to apply this concentration to land with no restrictions. The risk assessment should be revised to include a scenario with a fixed dioxin TEQ concentration of 300 ppt to evaluate how variability in other parameters affects the distribution of risk.

Use of a probabilistic approach and a range of national data also make it difficult to evaluate how assessment assumptions compare with the risk approaches presented in the Rhode Island Remediation Regulations. It is not possible to determine whether Rhode Island, with its small farms and colder weather, falls in the 25th or 99th percentile or somewhere in between, making it difficult to assess the relevancy of a 300 ppt sewage sludge limit in Rhode Island.

HEALTH also has concerns with setting the numeric limit in the center of the acceptable risk range (at least, as best as HEALTH can determine), with no consideration of other chemicals that may be present in the sludge. It is not uncommon for chemical-specific limits to be set at a more protective level (e.g., a risk level of 1×10^{-6}) to indirectly account for risks posed by other constituents, such that cumulative risks fall within the acceptable risk range. U.S. EPA used this approach in setting Soil Screening Levels (U.S. EPA 1996), as has Rhode Island Department of Environmental Management in its Remediation Regulations. By not considering risks contributed by other constituents present in sludge or setting the limit at a more protective risk level, the potential exists for cumulative risks to exceed the acceptable risk range. If other

constituents in sludge are not going to be considered, the numeric level should be based on the 1×10^{-6} point of departure risk level.

Site Conceptual Exposure Model Assumptions

The NODA revised risk assessment limited the assessment to members of a farm family, representing highly exposed individuals. Adult exposure to soil occurred only in the crop field (where dioxin-containing sludge was tilled to a depth of 20 cm) and child exposure occurred within the buffer zone (where dioxin-containing sludge was not directly applied, but where dioxins migrated from the crop field and pasture, as well as from atmospheric deposition). No direct exposure to pastureland, where dioxin-containing sludge was directly applied but soil was not tilled and where the highest predicted soil concentrations were estimated, was assumed. The risk assessment did not consider the potential for the farmland to succumb to development; an occurrence that is, unfortunately, too common here in the northeast. In this scenario, it is conceivable that untilled pastureland could become someone's backyard garden, a school, or a sports field. This could result in higher exposure levels than are estimated in the risk assessment (although the beef and dairy pathways are less likely to be relevant). The risk assessment should look beyond land use by a farm family and assess other potential future land uses, to ensure that those uses will be protected by the numeric limit. Alternately, some limitation on future use of sludge-amended lands should be considered. This issue is particularly relevant for dioxins owing to their environmental persistence.

Hazard Evaluation Issues

The NODA revised risk assessment applied the current "EPA-sanctioned" dioxin TEQ cancer slope factor of 1.56×10^{-4} (pg/kg-day)⁻¹, rather than the cancer slope factor of 1×10^{-3} (pg/kg-day)⁻¹ that was recommended and used in the Draft Dioxin Reassessment. This newer value is about six times higher than the current value and would result in risk estimates six times higher, as well. The newer number was reportedly not used because it is still under review and subject to change. However, the possibility of an increase in the cancer slope factor should have been addressed in the risk assessment; either through explicit assessment and proposal of an alternate numeric limit, should the cancer slope factor become finalized, or through postponement of the numeric limit until such time as a consensus is reached on the slope factor. It makes no sense to promulgate a numeric limit based on the current cancer slope factor when EPA itself has recommended an alternate value.

The NODA revised risk assessment assessed the cancer toxicity endpoint only and did not consider potential non-carcinogenic effects, the rationale being that only the cancer endpoint had sufficient data to support the assessment for all the dioxin-like congeners. This limitation of the assessment is a concern because of the apparent wide range of non-carcinogenic effects of dioxins, including effects on development, reproduction, immunity, and other systems. While the available data may not be optimal, it would be useful to apply a draft reference dose or a range of possible reference doses to evaluate, in broad terms, whether the cancer slope is protective of other endpoints. This would be of particular importance in children with shorter duration exposures for whom cancer risks are "diluted" by the conventional lifetime averaging.

Biosludge Use Assumptions

The basis of sludge application rates applied in the assessment (5 to 10 tons/hectare, one application every 2 years for up to 40 years) is unclear and should be clarified. Are they based on loading limits for metals or nitrogen, using corresponding sludge dioxin data or are they simply assumptions? Is 20 applications a reasonable upper estimate? It would be useful to have further discussion and perhaps assessment on the range of possible application scenarios.

Exposure Pathways

The exclusion of relevant exposure pathways; listed below, limits the completeness of the NODA revised risk assessment:

Dermal exposure was not considered for any receptor. A farmer would be expected to have dermal contact with soil on a regular basis; not only directly, but also through the handling of farm equipment and crop material. It has been estimated that as much as three percent of an applied dose in soil may be absorbed dermally (U.S. EPA [1991] Dermal Exposure Assessment). This pathway, because it is reasonably expected to occur, should be included in the assessment.

Infant exposure was characterized separately and not combined with childhood exposure. However, it is reasonable to assume a scenario wherein a child is born, breast-fed, weaned to farm food as assessed for children, and remains on the farm until adulthood. Breast-fed infants should be combined with child and adult receptors as part of the overall risk characterization. *In utero* transfer from the mother to the fetus should also be explored.

Consumption of fish was only assessed for the adult farmer, but it is reasonable to assume that other farm family members may also consume fish caught by the farmer/fisherman. Fish consumption should be included in the child assessment.

Assessment of dioxin accumulation into trophic level 3 and 4 fish was incomplete because it did not consider food chain transfer, only sediment-to-fish transfer. Food chain transfer is expected to be of more importance than is sediment-to-fish transfer, and should be incorporated into the risk assessment.

Exposure Factors

The soil ingestion rate of 50 mg/day applied to adult farmers is not reflective of soil intake by gardeners or farmers who have frequent and intense contact with soil. A higher value (between 100 mg/day and 500 mg/day) is more appropriate. The Exposure Factors Handbook discusses use of 100 mg/day soil ingestion rate for agricultural scenarios.

Exposure Point Concentrations

Adults were assumed exposed to soil only in the crop field and children were assumed exposure to soil only in the buffer zone. It is reasonable to expect that the adult farmer would have exposure to all three areas (perhaps pastureland less, but buffer soils while at home and as indoor

dust) and children are likely to have some degree of exposure to crop fields and pastureland, as well. The soil exposure point concentration should be weighted by the estimated time spent in each area.

It is not clear whether the fat content in cattle represents fat content in edible muscle or is a whole body number that includes lipid-rich organs, such as the liver and brain.

The assumed 4% milk fat content is most applicable to pasteurized whole milk. Alternate risk values could be generated assuming consumption of low-fat or non-fat milk, or non-homogenized milk where the high milk fat cream naturally separates from the milk. Use of alternate milk fat values could lower the risk from milk ingestion.

It was not clear whether the fraction of organic carbon assumed in the soil /sludge mixture was a weighted average of the sludge and soil organic carbon content, or whether only soil values were used. This assumption affects the partitioning of dioxins from soil to vegetation, and should reflect the expected soil/sludge organic carbon content.

It appears that certain loss processes, such as leaching and volatilization, were considered for tilled soils but not considered for buffer zone soils. If so, the discrepancy should be discussed or consideration of those processes included for buffer zone soils.

The beef cattle diet was assumed comprised of 48% feed, 48% pasture forage and 4% soil, suggesting that soil intake is 12% of pasture forage intake. The dairy cattle diet was assumed comprised of 90% feed, 8% pasture forage, and 2% soil, suggesting that soil ingestion is 40% of pasture forage ingestion. Assuming that forage and soil intake are related, the soil ingestion percentage seems high for dairy cattle.