BLUE RIDGE ENVIRONMENTAL DEFENSE LEAGUE

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To: The USEPA, c/o Kate Schalk Kate.Schalk@erg.com and ORD.Docket@epa.gov

Re: Draft Problem Formulation for Human Health Risk Assessments of Pathogens in Land-Applied Biosolids, Docket ID No. EPA-HQ-ORD-2008-0547

From: Susan Dayton, Statewide Coordinator
NC Healthy Communities
Blue Ridge Environmental Defense League

Dear Ms. Schalk:

Please consider accepting these late comments concerning the EPA DRAFT. They are late due to the death of a close friend.

The Blue Ridge Environmental Defense League represents over 2,500 individual members and over 40 member chapters located in the southeast United States. I submit to you the following brief, observations concerning the Draft Problem Formulation:

Comments on the Proposed DRAFT Problem Formulation for Human Health Risk Assessments of Pathogens in Land-Applied Biosolids

2. Stressor Characterization. The report states that it will address a "problem formulation and analysis plan relating to uncertainties associated with conducting quantitative microbial risk assessments on land-applied biosolids." Pathogens are one constituent of concern found in sewage sludge. Illnesses may not result from exposure to a single pathogen or combinations of pathogens, but in response to synergistic effects from a number of factors.

Other constituents found in sludge may have an affect on the body's immune system. The antimicrobial agent, triclosan, has been found to degrade into dioxin when exposed to ultraviolet light ("Effects of ultraviolet intensity of wavelength on the photolysis of triclosan," H.S. Son et al, Water Science and Technology, Vol. 55, No. 1-2, pp. 209-216). Dioxins, even in minute quantities, pose a risk to humans. The degradation of certain compounds into more toxic forms, such as the case of triclosan, may occur either during ultraviolent treatment at a wastewater treatment plant or in the field upon application when exposed to the sun. The implications of interactions between various constituents in sludge, and the creation of new and potentially toxic compounds and their potential effects on the human immune system, should be carefully considered in any human health risk study (See section: 2.2.6. Multiple Stressors).

2.1.5. Site Restrictions. The report notes that site restrictions are required to reduce [human] contact with Class B biosolids. It is important to note that not all states abide by these public access restrictions nor do they enforce them. For example, the State of North

Carolina further regulates sludge under the state's 2T Rules. The Rules state that public access to land that is not a contact site (i.e., a farmer's field) must be restricted for 30 days (NC Administrative Code Title 15A, DENR/DWQ, subchapter 2T, 15A NCAC 02T.1109 (b)(2)(B)). However, the rule fails to provide a means of enforcement for this regulation. Only recently has the DENR Division of Water Quality made a change in the 2T Rules which will state that end users "may use signs" to limit public access to fields. Still, there exists no enforcement. Without a means to limit public access to sludged areas, there might as well be no rule.

2.2 Pathogens. The report cites a reference (Straub et al) that has concluded the types and levels of pathogens in biosolids are determined by the incidence of infection within a community. While this may seem to be a logical conclusion, but in the case of sludge, it is not. Sludge is primarily applied to farmlands in rural areas, and distances to nearby residences vary from feet to miles. Pathways of exposure need to be considered, and little is known about the long-term, chronic effects of exposure to low levels of pathogens and other emerging contaminants, and in combination with each other.

The report lists a number of pathogens which should be tested for in sludge, but fails to mention the presence of prions, a class of fatal neurodegenerative diseases which can affect a variety of both animals and humans. One study found that prions are highly resistant to degradation and disinfection procedures at wastewater treatment systems and can survive conventional wastewater treatment (Persistence of pathogens prion protein during simulated wastewater treatment processes, G.T. Hinckley et al, Environmental Science Technology, July 15; 42(14): 5254-9, 2008).

Additionally, the report concludes that Staphylococcus aureus, a bacterium that can cause serious and fatal infections, is uncommon in treated sewage sludge, thus Staph aureus should not be tested for. However, additional studies that examine the associations between sludge exposure and Staphylococcus aureus are recommended due to the deaths of at least two people exposed to sludge who died of Staph aureus (http://pubs.acs.org/subscribe/journals/esthag-w/2003/aug/science/rr_staph.html).

2.2.6. Multiple Stressors. There is a scant three lines give to this topic that conclude there is no evidence to suggest that pathogens and chemicals (i.e., metals) in biosolids have "interactive effects" in humans. The effects of metals such as mercury, copper, zinc, cadmium, chromium, selenium, vanadium, and molybdenum, on animals are well known (Veterinary Toxicology: Basic and Clinical Principles, by Ramesh C. Gupta, p. 297, 2007. See: http://books.google.com/books?id=NgMX__L3q40C&pg=PA296&lpg=PA296&dq=metals,+effects+on+immune+systems&source=web&ots=wqtzamUo4d&sig=t-X4SZOT36x0RkyEjZ9oBXmfftI&hl=en&sa=X&oi=book_result&resnum=8&ct=result#PPP1,M).

The report fails to mention the known impacts of toxic metals on the human immune system, even at low levels ("The effect of heavy metals on the immune system at low concentrations," E. Martha et al, International Journal of Occupational and Medical Environmental Health, 14(4):375-86, 2001). Research on human cells has also indicated that the toxicity of some metals is enhanced by combinations of others. For example, in one study, mmercury toxicity was increased by lead and cadmium at low levels. Exposure to a variety of metals present in sludge could lead to increased susceptibility of people to bacterial, viral, fungal and parasitic disease agents ("Immunotoxicity of

metals," Fournierl et al, Science and Research, 2002, http://www.hc-sc.gc.ca/sr-sr/finance/tsri-irst/proj/metals-metaux/tsri-44-eng.php).

3. Development of Conceptual Models. Pathways of exposure should also include human consumption of food grown on sludge applied land, not because it is an "important issue for stakeholders," but because these pathways may play an important role in transmission of illnesses. One recent example is the contamination of milk from dairy cattle that grazed on sludge-applied land in Georgia. The milk was pulled from grocery store shelves because it was found to contain, among other chemicals, thallium at levels 120-times levels above safe drinking water standards (http://chronicle.augusta.com/stories/030908/met_190330.shtml).

Pathways of exposure should also include contamination of surface waters. For example, some rural residents in NC use surface water directly for their drinking water needs. Although federal regulations require that buffer zones be implemented with standards set for distances from sludge application to surface wasters, runoff occurs in many instances, especially after heavy rains and inclement weather (http://www.youtube.com/watch?v=GdvfWUEEOpo). Since both federal and state (NC) regulations do not require that sludge spreading cease before a predicted inclement weather event, such as a hurricane, runoff into surface waters could be potential pathways for exposure.

3.2.3 Timing of Land Application of Biosolids. The report assumes that heavy rains and windy conditions are avoided when land application is considered. This is false. Here are no regulations for land application during windy conditions, and while regulations require that spreading not take place during a precipitation event or within 24-hours following a rainfall event of 0.5 inches or greater in a 24-hour period (NC Administrative Code Title 15A, DENR/DWQ, subchapter 2T, 15A NCAC 02T.1109 (b)(F)) there are no rules that require sludge spreading to stop prior to an inclement weather event, as seen in the video above.

The report makes the conclusion that the number of people affected by pathogens in biosolids varies regionally, and exposures to biosolids increase as the density of people increases. This conclusion is simplistic and dos not consider multiple pathways for exposure. Since land application is usually restricted to rural areas, small and isolated groups of people are involved. Health studies of transmission rates are few and far between, and conclusions such as these are premature.

3.3.2.4 Leaching to Groundwater. The report states that there has been no microbial contamination to groundwater from biosolids. There have been numerous instances of contamination to groundwater from nitrates as a result of sewage sludge spreading. While it may not be practical or possible to analyze for all pathogens, better methods, such as testing for Salmonella and Fecal coliform, should be used as indicators which could identify the potential presence and quantity of additional pathogens. http://ewr.cee.vt.edu/ewr/environmental/teach/gwprimer/landappl/sewer.html

3.6 Factors That Affect Infection and Disease. The psychological effects associated with sludge spreading and its links with disease has not been addressed in this section. There have been hundreds of reports from people from across the nation reporting negative experiences associated with land application (http://www.sludgevictims.net/). Many of these reports include a decreased quality of life due to sewage sludge spreading. Complaints include (but are not limited to) general anxiety and depression associated

with fears of contracting illnesses related to sewage sludge spreading, threats to the environment, and decreased property values. This aspect of the spreading of sewage sludge has not been addressed in any study. While these relationships are complex, research points to the solid links between stress, and physical illness and chronic disease (http://www.medicalnewstoday.com/articles/85162.php).

5.4.4.1 Risk Assessment Model. When considering sewage sludge, one must know the entire suite of contaminants contained in sludge. No risk assessment is capable of dealing with the extensive modeling and fundamental uncertainties inherent in sewage sludge disposal practices that addresses the realities of this complex system.

Bottom line: no two sludges are alike. Constituents in sludge vary from city to city; wastewater treatment processes vary from place to place; climate conditions vary regionally; groundwater depth varies from place to place, as does the locations of surface waters, types of crops grown, and methods of domestic animal production. Populations of people may represent the largest variable. Does the EPA plan to conduct risk assessments at each and every land-applied sludge field across the country?

Risk assessments have a number of fundamental flaws. Risk assessments do not ask whether the activity is needed or if the activity is ethical. Nor does risk assessment consider the cumulative impacts of other damaging activities to people that may be located in the observed area. With this in mind we offer the following:

- Risk assessments are the basis of all permits and registrations for hazardous activities and products;
- Activities practiced by industry are largely taken as "givens" in most risk assessments;
- Risk assessments give industry the aura of being "scientific" about the safety or insignificance of its activities;
- The complexity of most risk assessments and the room for debate regarding appropriate assessment assumptions allow interminable haggling;
- Risk assessments fail to acknowledge or include stakeholders in a meaningful way and communicate using language that is unrecognizable by the people who are the subjects of the risk assessment. To read or debate a complicated risk assessment requires technical expertise, as well as a skeptical eye.

("Making Better Environmental Decisions; an Alternative to Risk Assessment," by Mary O/Brien, Cambridge, Mass.: MIT Press, 2000. ISBN 0-262-15051-4. See power point: http://www.esm.ucsb.edu/academics/courses/286/Brief%20Introductory%20Topics/OBrien%20overview%20presentation.ppt#256,1,Making Better Environmental Decisions: An Alternative to Risk Assessment Mary O'Brien, MIT press).

"Risk assessment data can be like a captured spy: if you torture it long enough, it will tell you anything you want to know."

- William Ruckelshaus, first EPA Administrator

While we commend the EPA for its willingness to conduct a "human health risk assessment for pathogens in land-applied biosolids," given the complexity of this issue, we find that such an assessment would only serve to further fuel uncertainties associated with land application of sewage sludge. In lieu of a risk assessment, we recommend that the EPA support the following measures based on the precautionary principle:

- Convene a roundtable group of distinguished and independent experts from various disciplines, with input from citizens and representatives of non-governmental organizations, to research cleaner and safer alternatives to land application of sewage sludge;
- Until an alternative is found, develop and implement health surveillance programs to help identify problems associated with sludge applications as they emerge;
- Require that municipalities generate Class A sludge instead of Class B sludge for use as a commercial fertilizer for land application;
- Provide a mechanism for implementing statewide pharmaceutical take-back programs with stakeholders, counties, federal and state regulatory agencies;
- Support state partnerships with county governments, with citizen stakeholders, to enforce existing regulations and increased monitoring of states' residuals management programs;
- Conduct epidemiologic studies of communities located near areas where sewage sludge is land applied;
- Require that private appliers post performance bonds to mitigate any harm that may surface as a result of land application;
- Require that farmers using sewage sludge as a fertilizer are provided information about the potential risks associated with sludge;
- Promote green chemistry in producing products that ultimately end up in our waste streams.

Thank you very much for your consideration of our comments. We hope that the many citizens of this country who have suffered, and who continue to suffer from the big business of biosolids, are given due consideration in requesting your help in finding an alternative to an outdated system of ridding society of its waste through spreading it on precious farmland, a practice that, without question, poses a threat to our health and environment.

Sincerely,

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