

To: Docket ID No. EPA-HQ-ORD 2008-0547

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**Re: Problem Formulation for Human Health Risk Assessments of
Pathogens in Land-Applied Biosolids**

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Introduction

Since 1993, when the CFR 40 part 503 sludge rule went into effect, hundreds of sludge-exposed people have reported serious adverse health effects. Human deaths have been linked to land application. Groundwater has been impacted. Agricultural soils degraded. Livestock died after ingesting forage grown on sludged sites. Adverse health and environmental effects have been documented in the peer reviewed scientific literature. Many towns and counties across the nation have restricted or banned the practice. There is growing public opposition to land application, reinforced by scientists, major environmental, health, and farm organizations, all requesting that land application of sewage sludge should be phased out and replaced with safer and more sustainable ways of managing sludge disposal.

Individuals at EPA's Office of Water, responsible for sludge regulations, have forged a powerful well-funded alliance with the waste industry and gatekeeper scientists that profit from land application. This alliance continues to ignore the many reported and documented problems linked to land application, claims that the practice is safe, and has historically ignored or covered up sludge "incidents." Recent court rulings confirm that agency individuals have worked with other scientists to publish papers that included "fudged" and fraudulent data to "prove" that the current policies are adequate and could not have caused deaths or illnesses. The EPA alliance has consistently discredited other scientists and citizens who report or document health concerns linked to sludge exposure, while, at the same time, funding scientists that support and defend the practice. (http://biosolids.org/docs/IJOEH_1104_Snyder.pdf)

The 2002 *Biosolids Applied to Land* and EPA Response to the NRC Recommendations

When it became increasingly obvious that the 503 sludge rule did not appear to protect human health and the environment, EPA asked the National Academy of Sciences' National Research Council (NRC) to convene a panel to examine the scientific basis of the current land application policies. Not only EPA, which had formed an alliance with the very entities it is supposed to regulate, but several panel members were conflicted. Before the report was released in 2002, a panel member, violating NAS procedures, inappropriately deleted all references to the research by David Lewis and his co-workers, that documented and explained, for the first time, how sludge exposure could make people ill. Even though the report incorporated many of his ideas and recommendations, deleting the references to his published papers, enabled the EPA alliance to continue to claim that there was "no documented scientific evidence" that anyone ever got sick from sludge. However, the panel warned that the scientific underpinnings of the 503s were outdated or lacking and made dozens of recommendations, the primary one being that there is an urgent need to study, monitor, and track the health of people exposed to land applied sludge.

EPA's response to the NRC recommendations was to rule out doing health studies "because they were too expensive" and instead, to depend on one of its alliance partners, the Water Environment Federation, as well as on scientists associated with the National Institute of Health's Water Quality Center (WQC), to focus on quantitative health risk assessment. Ian Pepper, who had been a member of the NRC panel, chairs the WQC at the University of Arizona.

The National Science Foundation Water Quality Center at the University of Arizona

WQC receives its funding from various federal and state agencies, industries, trade-groups, and individuals. What kind of research, and how this research is carried out, is determined by the votes of its industrial members. The number of votes a member gets, depends on membership level fees, at ten votes for every \$3000. Full membership costs \$30,000, so a full member gets a hundred votes to decide the choice and direction of a particular research project. The WQC brochure lists another key benefit for members: the results and recommendations of industry-chosen and industry-directed research will be “more credible” when it is generated at a “prestigious university” and under the aegis of the National Science Foundation.

Many WQC members are corporations, trade-groups, state and municipal agencies, who either directly or indirectly benefit from the land application of sewage sludge. For example, Synagro, the nation’s largest sludge broker, as well as the Pima County Waste Water Management Department, both are full members, with 100 votes each to choose sludge-friendly projects. Enhanced Associate members include the County Sanitation Districts of Los Angeles County, the Northwest Biosolids Management Association, the Orange County Sanitation District, and the Resolution Copper Mining Company, all who have 50 votes each to choose projects that promote land application as safe.

Symptoms of sludge-exposed individuals reported across the nations are strikingly similar and appear to be primarily linked to the interaction of irritant chemicals and pathogens that make some sludge-exposed individuals more susceptible to infection. As the first ground breaking dose-response research was beginning to be published in the peer reviewed scientific literature, documenting and explaining this route of exposure (Lewis et al, later confirmed by another team of researchers, Khuder et al), it was essential for EPA to find industry-friendly researchers to engage in new aerosol emissions research at several land application sites that would rule out this exposure route. It came as no surprise then, that EPA asked WQC researchers to measure and model aerosol emissions at several land application sites, that hopefully would show that inhalation concerns were groundless and could not sicken people.

Between 2002, after the release of the NRC report and the publication of David Lewis’ *Interactions of Pathogens and Irritant Chemicals in Land Applied Sewage Sludges*, and 2005, the WQC conducted six industry-funded sludge related research projects. Four, dismissed sludge aerosols as a serious health problem. One downplayed the risks of emerging pathogens. And another (Rusin, Pepper, et al 2003) attempts to discredit the Lewis et al research in a paper entitled *Evidence of the Absence of S.aureus in Land Applied Biosolids.* Lewis’ published response to this paper, not included in the references, is printed below.

In May 2004, a University of Arizona press release from Ian Pepper, based on two of the six WQC funded studies stated “the WQC has documented that the use of sewage sludge as fertilizer is unlikely to expose humans and the environment to disease-causing microorganisms [because] human exposure exists for less than a minute and only in the vicinity of equipment that spreads biosolids on agricultural fields.”

The scientific underpinning of this Problem Formulation draft depends almost entirely on recent WQC research. And that research ignored that pathogens can be transported long distances by dust particles. The draft ignores a large body of scientific literature that documents respiratory problems caused by exposure to various airborne pollutants, such as dusts, gases, and endotoxins from decomposing organic wastes. Pages 8-10 of our comment lists some of the missing relevant literature, including an EPA fact sheet on pathogen transport by dust particles.

Quantitative Risk Assessment

Risk assessment models are one tool used by industry and agencies to help determine whether or not a product or practice is reasonably safe. It is not a very reliable tool, because it is based on assumptions that can vary from assessor to assessor. For example, when a group of EPA scientists used four accepted models to calculate the cancer risk posed by trichloroethylene in drinking water, their risk estimates varied by a factor of 100 million. (Thorne J) If risk assessments for one chemical in one medium can yield such different results, how can it be a reliable tool to identify the various environmental and health risks from such a complex and unpredictable mixtures as sewage sludge, spread on complex terrestrial ecosystems, affecting a variety of living organisms with varying susceptibility to infections? With so many unknowns, with stressors that have not even been identified, much less characterized, for which we do not yet know all the modes of action, and all the various potential synergistic interactions between chemicals and chemicals and pathogens, which we are just beginning to identify, any quantitative risk assessment will be an exercise in futility. The more complex a system, the more the uncertainties and the variables, the more unreliable are mathematical models used to assess risks.

Land application of sludge is wrought with uncertainties. Experts estimate that sludge generated in industrialized urban centers-- and most land-applied sludge is generated in these areas—contains not only pathogens and toxic metals, but thousands of anthropogenic chemical compounds for which there are not even basic toxicity data. Many known unregulated sludge pollutants are carcinogenic, persistent, and/or toxic.; endocrine disrupting chemicals can damage living organisms in parts per trillion. Pathogens are evolving and becoming more virulent. Only a very few *E.coli* 0157:H7 bacteria, as little as ten, can cause life-threatening disease. Making it impossible to determine what pathogen level in sludge is safe, especially since people's susceptibilities to infectious agents differ and they are exposed to other stressors from other sources.

Essential to any valid risk assessment is to describe the amount and effects of the components in a complex mixture. With sludge, this cannot be done. Depending on risk assessment alone will never explain why sludge-exposed people are getting sick.

The NRC panel recognized this difficulty in the sections of the report that deal with human exposure to complex and unpredictable mixtures, warning that even if we knew every constituent in sludge and its hazard, a reliable risk assessment based on agent-specific analysis would still be impossible because of various pathogen-pathogen, and pathogen-chemical interactions. “It is not possible to conduct a risk assessment at this time (or ever) that will lead to risk management strategies to protect human health, unless there is ongoing surveyance and monitoring . This degree of uncertainty requires active health and environmental tracking”(page 328).

Specific Comments about the Problem Formulation Draft

2.1.3 Page 6: The draft's description of biosolids-amended soil is simplistic, misleading and inaccurate. To only focus on changes in physical soil properties, and ignore biological and chemical soil impacts, as well as ignoring that sludge is a complex mixture of pollutants, assumes that land application is beneficial, when in fact, repeated sludge applications can lead to the gradual degradation of agricultural soils eventually reducing yields.

Page 7-8: The assumption that treatment requirements and site restrictions meet standards is highly questionable; as is the assumption that the current standards protect human health and the environment.

2.2.1.9 Page 15: The exclusion of *Staphylococcus aureus* from consideration is not based on facts. It is based on a paper by Rusin et al which ignores EPA's own fact sheets and other scientific information that indicate the presence of *S.aureus* in processed sludges. It appears that the Rusin paper was commissioned and cited in an attempt to discredit David Lewis' published sludge exposure studies. Although Rusin's reply to Lewis's published comment is included in the referenced literature, Lewis' and Gattie's comment, is not; so we include it here in its entirety:

Comment on “ Evidence for the Absence of *Staphylococcus aureus* in the Land Applied Biosolids.”

Rusin et al. (1 and in ref 2) dismissed processed sewage sludges as a source of *Staphylococcus aureus* infections and inferred that we proposed that processed sewage sludges are a primary source of *S. aureus*. In our studies (3, 4), we concluded that chronic irritation of the eyes, skin, mucous membranes, and respiratory system by irritant chemicals associated with sewage sludge (e.g., bacterial toxins, lime, organic amines, ammonia) rendered residents prone to infections from all sources, community and environmental. Rusin et al. (1) therefore improperly concluded that they disproved our hypothesis by showing that processes used to treat sewage sludge effectively eliminate *S. aureus*.

While reporting that they could only recover 8.7% of the *S. aureus* added to sewage sludge samples, Rusin, et a. (1) failed to recognize the significance of this finding. They assumed that the 91% of unrecoverable *S. aureus* cells were as susceptible to disinfection as the recovered cells. In fact, most of the *S. aureus* they added was unrecoverable because cells become embedded in organic matter, lipid particles, and other components of the sludge from which they are difficult to recover.

For the same reason most *S. aureus* cells cannot be recovered by standard isolation techniques, they are also less exposed to chemical and physical disinfection processes. We discussed this problem in *Envir. Sci. Technol.* and elsewhere (4-7). The authors, in other words, only tracked the easily extractable *S. aureus* cells from the exposed surfaces of organic aggregates, which are most susceptible to disinfection. Like trichinae embedded in pork, it is oftentimes the difficult-to-extract pathogens associated with organic matter taken into the body and released during digestion or other bodily processes that lead to infection.

Establishing the absence of an organism is difficult by any means. Looking at the easily extractable portion of a population in small volumes of sludges and extrapolating the results to millions of tons of the material produced each year provides little, if any, insight.

Finally, Rusin et al. (1) concluded that staphylococci found in processed sewage sludges by other researchers were probably non-aureus. They offered no explanation, however, as to why *S. aureus*, which is adept at survival in the environment, should be more susceptible to disinfection than any other *Staphylococcus* species when subjected to any of the very dissimilar processes used to treat sewage sludge.

Literature cited

- (1) Rusin, P. A.; Maxwell, S. L.; Brooks, J. P.; Gerba, C. P.; Pepper, I. L., Evidence for the Absence of *Staphylococcus aureus* in Land Applied Biosolids. *Environ. Sci. Technol.* **2003**, 37 (18), 4027-4030.
- (2) Renner, R. *Staphylococcus* not found in sludge, but controversy continues. *Envir. Sci. Technol.* **2003**, 37 (19), 344A.
- (3) Lewis, D. L.; Gattie, D. K.; Novak, M. E.; Sanchez, S.; Pumphrey, C. Interactions of pathogens and irritant chemicals in landapplied sewage sludges (biosolids) *BMC Public Health* **2002**, 2 (11), (28 Jun).

- (4) Lewis, D. L.; Gattie, D. K. Pathogen risks from applying swage sludge to land.

Environ. Sci. Technol. **2002**, 36, 286A-293A.

- (5) Lewis, D. L.; Gattie, D. K. Ecology of quiescent microbes, *ASM News* **1991**, 57, 27-32.

- (6) Lewis, D. L.; Gattie, D. K. Effects of cellular aggregation on the ecology of microorganisms. *ASM News* **1990**, 56, 263-268.

- (7) Lewis, D. L.; Arens, M. Resistance of microorganisms to disinfection in dental and medical devices. *Nat. Med.* **1995**, 1, 956-958

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2.2.4 Pages 22-23: The assumption that endotoxin levels in Class B biosolids are “similar to concentrations in animal manure and compost” is a broad generalization and questionable. Levels can vary greatly depending on a number of factors. The assumption that endotoxin levels resulting from a tractor driving across an [unsludged] field are identical to aerosolized endotoxin levels at land application sites is not supported by credible data. Endotoxins are produced when gram-negative bacteria break down. Even without lime that facilitates this process, levels of endotoxins at sites where sludge is top dressed and/or stockpiled—depending on many other variables, including the moisture content of sludge—can be extremely high (cf. Dowd et al 2000).

Page 25: To misrepresent research by the first scientists who established the link between adverse health effects and sludge exposure and then brand their published peer reviewed work as “speculative” is irresponsible. See the response to Rusin cited above.

3. Page 26: To exclude consideration of secondary transmission of infection, contrary to the recommendation of the NRC panel, will produce a defective risk assessment.

Page It is unreasonable to assume that there is no link between sludge exposure and adverse health effects because “ a causal association has not been documented.” Considerable evidence, some of which has been documented, suggests such a link and explains the link.

3 Page 29: The decision to delete certain routes of exposure (e.g. human consumption of dairy products from cattle that are grazing on sludged pastures) is neither “too indirect or too hypothetical.” This exposure route should be included in the Problem Formulation draft.

3.1 Page 29: Enough data exist to question the assumption that “all treatment technologies are operating as intended.”

Page 30: Legally, sewage sludge can be stockpiled for two years and not just “during winter months, inclement weather, or because equipment breaks down.” Sludge is stockpiled whenever disposal sites cannot be found. Haulers get paid to remove sludge from treatment plants. After that, there are no incentives for them to use best management practices, such as immediate incorporation into soil. Stockpiling, topdressing, and over -application are the three most risky management practices and have been linked to adverse environmental and human health effects. The assumption that stockpiles are contained in “barriers” that prevent off-site dispersion of pathogens is totally contrary to facts.

Page 32 et passim: The assumption that surface application permits ultra violet light to attenuate pathogens may not be true in other areas of the country or for pathogens transported in dusts. UV attenuation may also be more applicable to pathogens in water rather than those in land-applied sludge.

The assumption that surface application is limited to sites with less than 7% slope may be part of a state regulation, but is contrary to what is actually happening at most sites.

Page 33: Agronomic rate determination is not an exact science since nitrogen mineralization rates depend on many variables. A few states, including New Hampshire, have science-based regulations that measure and estimate agronomic rates. But to assume that across the country “biosolids are applied at a rate equal or less than the agronomic rate” is contrary to facts and will skew any risk assessment conclusions.

Page 34: The assumption that “most applications are performed when plants are ready to use the nitrogen, so as to minimize leaching” is based neither on regulations nor on facts. Waste water treatment plants and haulers need to get rid of their daily sludge. They apply sludge during all times of the growing season, regardless of crop uptake. Often sludge is applied to sites that don’t even grow crops.

Page 36: Figure 2 is misleading because it is based on the false assumption that sludged soil contains only indigenous microflora.

Page 37, Table 4 falsely assumes that there are only 5 parameters affecting pathogen survival.

3.3.2.4. Page 41, also pages 124 and 130 et passim: The draft repeatedly assumes that ground water has not been contaminated by sludge because “there are no studies” documenting such contamination. The 503s do not require ground water monitoring at sludged sites. There is evidence that EPA and state agencies have ground water contamination data in their files and there are many reports of sludge- polluted wells, so this assumption is questionable. The draft also fails to point out one of the most important factors that determines ground water impact from sludge: the depth of the water table which can vary at application sites from over 50 feet to just a few inches.

3.3.3 It is unreasonable to assume that vectors, such as flies and pets do not transport pathogens resulting in exposure that might cause disease.

Page 44: It is unreasonable to assume that the risks from accidentally ingesting sludge contaminants while swimming are greater than drinking or bathing in well water that has been contaminated by sludge pollutants.

3.4.3. Page 47: Likewise, is it unreasonable to assume that swimming in surface waters is a dermal exposure route, while walking or biking through a sludged field, is not.

3.8.1 Page 55: See **3.1** page 29.

3.8.2 The current rules do not require that sludged sites are securely fenced. This scenario should include the possibility that children and pets (not just workers) could track contaminants into residences. Another exposure route from airborne contaminants, ignored in this draft, is open windows at nearby residences.

4. Page 63. There is no credible scientific basis for assuming that endotoxins and *S. aureus* should be screened out “because they are unimportant” This appears yet another obvious attempt to discredit the published research that has suggested a plausible explanation of why sludge exposure can cause serious and life threatening adverse health effects. It illustrates how risk assessment models can be skewed to help industry win lawsuits and defend flawed regulations, rather than providing useful information that might reduce human health risks from land application.

5.3.6.4 Pages 80-83. After enumerating some of the many difficulties of using models and measuring airborne pollutants and admitting that airborne mixtures and interactions can not be modeled, it seems bizarre that this draft nevertheless concludes that airborne pollutants can be ruled out as a cause of illness.

Missing from this draft is one of the most significant stressors, namely odor. The odor generated at sludged sites, as this biologically active material decomposes, is not only a serious quality of life issue, often forcing exposed residents to stay like prisoners in their homes, but also a health issue. None of the relevant peer reviewed literature that documents and discusses this stressor, is included in the draft’s references and literature review.

Missing from this draft is the fact that much land applied sludge is treated with lime. Lime is an irritant chemical. Although it is used to inactivate pathogens, ironically it can also be a contributing factor for causing infections. (cf. Lewis et al). Most reported illnesses and the reported sludge-related deaths occurred at sites where limed sludge was top dressed or stockpiled.

Missing from this draft is the NRC recommendation that affected stakeholders should be included throughout the risk assessment process. “ Stakeholders can provide information and insights into the use of biosolids in practice and the potential health problems, which are particularly important in the development of exposure assessment.” (page 332).

Missing from the draft is the NRC recommendation that secondary transmission of disease needs to be considered in any quantitative pathogen risk assessment.

Missing from the draft is the NRC caveat, based on the Presidential/Congressional Commission on Risk assessment and Risks Management (1997) to not rely so much “on assumption-laden procedures for arriving at agent-by-agent and medium-by-medium mathematical estimates of risk” but instead to “focus at particular exposures and health end points, clarified by stakeholder input.”(page 334).

Conclusion

A quantitative pathogen risk assessment based on this Problem Formulation could provide some useful information to reduce some of the risks associated with land application, but only if it is based on supportable assumptions, a much broader research base, and, most importantly, on research generated by entities and scientists who are not funded by industry or conflicted in other ways.

It is hard to imagine how the current draft in its present form can result in a scientifically defensible risk assessment that will protect human health or be relevant for U.S. EPA’s decision needs.

Instead of focusing on risk assessment, we suggest that EPA ask non-conflicted scientists to put in place mechanisms to monitor and track health complaints, do health studies, and “ perform the needed research that will synthesize existing information on potential interaction of chemicals and pathogens that might be associated with biosolids exposure and lead to an increased susceptibility to infection, particularly by inhalation”(NRC page 332).
