Comments on "Standards for the Use of Disposal of Sewage Sludge: Agency Response to the National Research Council Report on Biosolids Applied to Land and the Results of EPA's Review of Existing Sewage Sludge Regulations"

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NOTE: These comments are those of the author and do not represent the views of Cornell University.

Included in this submission are these comments, a list of references cited or used in preparing these comments. Please consider those references to be part of this submission for the record.

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General comments

Thank you for this opportunity to comment on EPA's proposed response to the National Research Council (NRC) recommendations. As a member of the NRC Biosolids committee, I am intimately familiar with the report and its recommendations. Since reports can end up sitting on a shelf, it is helpful to have this public airing of the ways in which EPA plans to respond to the recommendations. The involvement of the EPA Office of Research and Development in the response is a positive step.

In general the proposed EPA response is disappointing. The NRC report raised many concerns and detailed many recommendations. However, EPA seems to be basically endorsing the status quo and proposing little that is new or responsive.

These are the most glaring failures to address the NRC recommendations:

1. Human Health: Failure to commit to studies of health at sites where people reporting illness. Failure to commit to health surveillance at land application sites.

2. Failure to recognize the serious limitations of the NSSS regarding limits of detection so that when "failure to detect" is used to eliminate chemicals from consideration, chemicals may be eliminated due to the flawed survey rather than due to absence of the chemical in sludges.

3. Failure to commit to engaging stakeholders in risk assessment and research.

4. Failure to commit to revising risk assessment to include multi pathway aggregate risks; risks to sensitive populations; risks to children and fetuses; interactions between contaminants and pathogens.

5. Failure to require bulk EQ sludges to meet nutrient and site restrictions

6. Failure to commit to establishing regulations protective under reasonably anticipated high risk conditions.

7. Failure to suggest increased emphasis on/resources for the sludge program.

One aspect of concern in addressing any recommendations is that EPA continues to use the same staff in the Office of Water who have been involved in the development and defense of the current sludge rules and program. I recognize that these are the people in the agency with relevant knowledge, but it is not surprising that a fresh and objective view is unrealistic to expect of people with such a long and vested interest in the status quo.

In responding to the NRC recommendations regarding updating the risk assessment, ORD and not OW should be engaged. This would both help to involve people with a fresh perspective, but would also involve people with greater expertise in risk assessment. It would also promote more consistent risk assessment between the sludge program and other EPA programs.

EPA mentions an incident investigation team that would respond to reports of problems at land application sites. Unfortunately, they appear to be using these same staff for that team. The investigative reports by EPA of incidents to date have not given the people claiming harm from sludge applications confidence in the EPA's objectivity. The incident reports are viewed as "white washes." That makes it highly unlikely that complainants will cooperate with EPA in the future. There needs to be an independent group established to investigate complaints, one not comprised of government agencies or professional associations at the federal, state or local level that have a stake in the regulation of sludges. There are many qualified people who would likely serve on such a body. I, for one, would be willing to serve on and help to organize such a group.

Cronyism is another major concern. EPA mentions a number of current and recent research and outreach efforts in the April 9 document. A "State of the Science" conference to be held in Florida in January provides an example (p.17387). EPA did not undergo a competitive process to determine who to fund to do the conference. In discussions with OW staff prior to EPA's determination of who to fund to work on such a conference, I had volunteered to be involved in

organizing such an event. Not only was I not given the opportunity to "bid" on the project, I was not even included in any way in the planning (though I had volunteered to serve on a planning committee). The conference organizers and many of the speakers represent persons that EPA has worked with closely on the sludge issue and most have a relatively "pro" land application viewpoint. The speakers were not identified through an open solicitation, but rather were hand picked by the conference organizers. This same propensity of EPA to go to "like-minded" people for research and other activities can be seen in their funding of research through WERF or by their selecting researchers directly (as in the Pennsylvania project discussed below). EPA should work through ORD to develop a competitive, peer reviewed process to fund research on sludge. A competitive peer-reviewed process should also be used by EPA to support outreach activities.

Research

It was not possible through reading the April 9 document to evaluate how well the research mentioned addresses the NRC recommendations because there was only cursory description of the several projects. The document should and could have included a much more detailed description of the research which is mentioned since conducting additional research is an important recommendation of the NRC report.

I followed up with EPA and with U. Arizona to try to get a better understanding of the projects mentioned in the April 9 document. There are only a few, and they leave most of the NRC recommendations unaddressed.

The Region 8 study proposal was forwarded to me by Bob Brobst. It is a brief proposal dealing with some soil impacts of one or two applications of a sludge on range land experimental plots. After more than a month of trying, I was able to get some information on the other EPA project. This came as an email dated May 7 from Steve Wright at ORD forwarded on May 8 by Terry Simpson which described a possible ORD study the fate of indicator bacteria through the wastewater treatment process and land application at an unspecified number of WWTPs. The email indicated that the study is likely to be delayed due to work on the Pennsylvania project

> Stephen Wright
> 05/07/2003 05:10 PM
> To: Terry Simpson/DC/USEPA/US@EPA
> cc:
> Subject: Summary of Planned Local Biosolids Investigation
>
> Terry,
>
> In response to your request for information (specifically a Quality Assurance Project Plan) related to biosolids research at EPA, the following is a summary of planned research at ORD Cincinnati. The research has not progressed to the point that a QAPP has been prepared or is practical (or required), but a QAPP currently being prepared for a biosolids project in Pennsylvania that we are involved in will be relevant and applicable, at least in part, to the study outlined below.
>
> The biosolids research at EPA will investigate the level of indicator and pathogenic microorganism reduction that can be expected as sewage sludge is processed to meet 40 CFR Part 503 Class B requirements utilizing anaerobic digestion, and what additional microorganism reduction is achieved following land application of the resulting biosolids (processed sludge). Additionally, historical operating

records of the municipal wastewater treatment plants (WWTP) producing the biosolids will be reviewed to determine possible correlations between plant operations and pathogen reduction.

The studies will be conducted using WWTPs located within an approximate 100 mile radius of our Cincinnati facility. The selected WWTPs will employ anaerobic digestion for biosolids processing, produce material meeting Class B requirements, and beneficially utilize (land apply) the resulting biosolids. Samples will be collected for microorganism analysis as the sludge is processed through the various stages of the digesters, also following dewatering, and for a period of time following land application. Samples will be analyzed for fecal coliform (indicator) organisms. Additional analyses of pathogenic organisms such as Salmonella sp., enteric viruses and helminth ova will be performed as budgets permit.

This is intended to be an initial study, with future studies building on the results. As noted previously, this study will investigate the level of indicator and pathogenic microorganism reduction that is achieved utilizing anaerobic digestion processes, and what additional reduction occurs following land application. Anaerobic digestion and resulting Class B biosolids are being selected for this initial study since the majority of biosolids are processed using these techniques. The WWTPs will be selected within the 100 mile radius to allow greater utilization of our staff. The microorganisms are selected to coincide with what is currently required for monitoring under 40 CFR Part 503 (Class A and Class B), and because analytical techniques and methodology are well established. The frequency of sample collection, both at the WWTPs and the land application sites, is expected to be quarterly with a duration of one year. Both the frequency and duration may change depending on initial results (e.g., after two quarterly sampling events at a land application site, if microorganism are no longer detected, they may not be sampled the following quarter. If, however, the microorganisms are still detected after a year of sampling, continued sampled may occur).

We are still in the initial stages of this investigation. Currently, most of our resources have been shifted to a collaborative study of biosolids in Pennsylvania. This will delay the initiation of this project, however, it will allow the results of the Pennsylvania study to be incorporated into this effort as appropriate, and as limited resources permit.

Please contact me if there is any additional information I can provide.

Sincerely,

Steve Wright
U.S. EPA
Office of Research and Development
National Risk Management Research Laboratory
Cincinnati, Ohio
(513) 569-7610

Finally I also obtained some information on the U. Arizona Water Quality Center research which is mentioned in the April 9 document. There are several studies planned or underway that

involve monitoring of air, water and sludges for selected pathogens at several sites around the US.

The other research mentioned in the April 9 document is the Pennsylvania/USDA/EPA project. EPA cites the PA study and lists objectives that appear to go beyond what that study will accomplish (p17386 CFR) as I know from my participation in the Information Sharing Group (ISG). I am very familiar with that project since I have been participating in the ISG. I have reviewed the draft Quality assurance plan (US EPA, June 2003) twice and participated in numerous conference calls and one face-to-face meeting involving the research teams as well as ISG participants. This project is multi-faceted and complex. However, as pointed out in the draft QAPP and in the comments on the draft QAPP, there are many significant limitations (see Harrison comments on draft QAPP, Appendix A to this document).

A recent email from John Walker at EPA to the ISG participants summarized some of those limitations: Email from John Walker re ISG Concerns

> Date: Wed, 02 Jul 2003 08:57:47 -0400
> X-PH: V4.1@hermes3
> From: Walker.John@epamail.epa.gov
> Subject: Re: EPA view of ISG
>
> I know that there many of the ISG participants have very valid concerns about the potential representativeness of the data that will result from this study. Further, I know about the belief that the levels of potential pathogens, odor levels, endotoxin levels and particulate levels will be too small to be of a potential problems to the public. There is also a concern that the proper things are not being measured or the samplers are not adequate. I can assure you that I do not know of hardly any studies elsewhere that have undergone such an extensive quality assurance review. What is ultimately found remains to be seen, but there will fortunately be a lot of data collected regarding potential exposures that previously did not exist. The information gained will be useful I believe in helping direct hoped for future health studies on what to ask and what to measure in addition to measures on residents and control populations.
>
> John M. Walker, PhD
>
> Senior Physical Scientist
> Leader, Biosolids Program Implementation Team

The June 2003 draft QAPP includes this statement of limitations:

1.6 Known Project Limitations

As in any research effort there is a specified scope and the imposition for potential limitations. These limitations may exist because of both technical and financial reasons. Nonetheless, these limitations will ultimately have an impact on interpretation and usability of the data acquired.
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It is the intention of researchers to reduce these limitations as much as possible, and to acquire representative and meaningful data, and to do so by using established methods whenever possible - methods that have undergone rigorous review and in some instances have undergone extensive revisions
or modifications for improvement. Wherever possible methods with established limits will be utilized for this effort; however, it is likely that method-specific limits will be realized over the course of this

investigation in the field and in the laboratory during monitoring and analyses of samples. These limits will be identified in project records and taken into consideration by researchers when reporting and interpreting the final data.

Appropriate precautions and quality assurance and quality control (QA/QC) measures will ensure the precision and accuracy of measurements that are deemed critical for accomplishing project objectives.

Decisions to collect and conduct measurements using particular protocols or specified instrumentation have been made based on professional experience, manufacturer's literature, and the availability of published research conducted by scientists in various related career fields. In cases where literature references are not available or less is known of a particular instance, decisions will be based on logical expectation. Nonetheless, to the extent that this project's limitations are currently known, they have been identified by the researchers and are presented in the following sections. Other project limitations may be realized over time by trial and error in the field and in the laboratory and will be documented in the project records. The project researchers will evaluate all such limitations, and the consequences of such limitations, and determine potential impacts to the analytical data acquired through the course of the effort.

1.6.1 Limitations of Project Scope. Biosolids will be selected from only five sites, where there have been scarce or nonexistent historical records or data as to the constituents that are in the biosolids and whether they have ever elicited health effects. Not all chemicals are being analyzed in emissions, and therefore all chemicals that could potentially be emitted during land application will not be known. Furthermore, these are case studies and may have limited value for predicting outcomes related to emissions, exposure, odor, and irritation at other sites that utilize other biosolids.

Due to the case study approach of this effort, the sources of biosolids, application methods, agronomic application rates, weather, geographical area, and terrain will vary from site to site in this study. As a result, conclusions at a site will be confounded by other site-specific variables. It will not be possible to draw general conclusions from this data.

1.6.2 Environmental/Weather Limitations. There will be no way of knowing if the meteorologic conditions encountered during application had any impact on sampling and/or study results. Wind speed and direction could vary by application day and may have significant impacts on the sample collection and volatile emissions from the biosolids. Experience of persons living near application sites suggests that weather conditions play a major role in when problems are experienced. This study is not able to address that issue or to focus monitoring on times when these problems may be more likely.

1.6.3 Sampling and Analytical Limitations. The VOA-7 Method (TO-15 Method-revised) for measuring headspace emissions in biosolids samples is a general VOC scan developed by PADEP to analyze for specific nitrogen and sulfide compounds. The majority of compounds listed in the TO –15 can be detected using this method; however, certain compounds may not elicit a mass response that is identified in the mass spectrum library. Consequently, existing compounds may be reported as nondetectable, or may be wrongly identified as another compound.

Solid phase microextraction (SPME) analysis will only be calibrated to recognize the compounds stated in Section 7.1. Consequently, other volatile compounds that may exist in samples will not be detected by the SPME method. Furthermore, SPME is sensitive to sample integrity. All efforts will be

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made to preserve samples appropriately and to ship via overnight delivery when possible to preserve the integrity of samples for analysis. The SPME fibers that load the sample are extremely sensitive and can be prone to some decay once the sample has been loaded.

The method of solvent extraction and analysis of semivolatile organic compounds (SVOCs), PBDEs, organochlorines, and selected polychlorinated biphenyls (PCBs) using gas chromatograph/mass spectrophotometry (GC/MS) is sensitive and designed to determine low levels of these specific analytes. These compounds may be lost in the extraction process. Likewise, other halogenated chemicals may be present but not detected with these methods.

Ammonia and hydrogen sulfide detection will be measured using a handheld toxi ultra gas detector and Jerome meter, respectively. These instruments have a lower detection range of 10 parts per million (ppm). Ammonia and hydrogen sulfide could exist and not be detected if they are below this lower detection range.

The OP-FTIR spectrophotometer will be used to measure concentration of VOCs in air. The TO-16 method will be used to calibrate this unit; however, the unit is factory calibrated and simply needs to

be adjusted to account for weather conditions. The method is included in Appendix B. Because data is collected by passing a light beam through a vapor plume and a fixed path length cannot be established (necessary for quantitative analysis), definitive quantitation cannot be achieved. Therefore, OP-FTIR calibration is primarily a verification of instrument response. To conduct instrument performance verification, a target compound is typically analyzed to evaluate accuracy. Thirty days before land application, a background sample will be collected and its OP-FTIR profile will be measured. This background profile will be subtracted from all subsequent field samples, so that the target compounds, which were not present at the site before biosolids were applied, can be quantified accurately.
The OP-FTIR is an accurate instrument for the detection of VOCs in air, however compounds must pass within the FTIR beam to be detected. If the beam is not aimed across the application field in the emissions capture zone, then some compounds that are present in the air above the selected biosolids
application may not be detected.
Samples submitted for odor analysis are also prone to potential and fairly rapid decay, which may underestimate the true odor concentration in the field. The TedlarÆË bags used for the odor panel will be analyzed approximately 24 hours after collection. Therefore it is possible that the chemical composition in the bag may change over this time frame.
For odor concentration, odor panels comprised of human noses will be used. Odor panels require 'trained noses'; however, an individual's olfactory senses are unique and may vary due to illness, etc. Replication of a sample by another odor panel may not occur. Furthermore, there can be some variability amongst field odor panelists in determining the intensity of the odors exposed to the air in the field.
It is estimated that advective flux of VOCs will occur predominately in the first several hours after application, and may vary depending on the weather conditions. A total of five flux chambers will be deployed in order to gain replication of the emission capture during this time period. However, frequent startups may account for some loss of emissions and ultimately an underestimation of the true flux at the application site. In addition, the orifice of the stack on the top of the chamber will impact the rate of emissions release out of the chamber, potentially underestimating the true VOC flux.
Various air sampling methods for collecting bioaerosols, such as filter collection, impaction, and impingement, are described by the American Conference of Governmental Industrial Hygienists (ACGIH) (ACGIH, 1999, 1995), the American Industrial Hygiene Association (AIHA) (AIHA, 1996), NIOSH (NIOSH, 1994), and other available references (Willeke and Baron, 1993); (Buttner, et al., 2001) for the collection of bioaerosols.
Many of these bioaerosol collection methods may have low recovery (accuracy) for quantifying the airborne concentration of viable organisms for a number of reasons. The filter collection and impaction methods may be limited for collecting a "representative"sample because recommended sampling times for microorganisms are less than 1-2 hours. This relatively short collection period is due to issues such as viable organisms being subject to drying, or the collection medium becoming overloaded. Longer sampling times with water-based impingers such as the All Glass Impinger (AGI-4 or AGI-30) may cause lysis or reaerosolization of the bioaerosol, and evaporation of the collection water (Lin, et al., 1999).
The U.S. EPA is currently evaluating two alternative bioaerosol sampling techniques for more efficient and representative collection of bioaerosols. One sampling technique is a modified filter-holding sampler with higher aspiration efficiency, relative to other samplers (Aizenberg, et al., 2000). The other sampling technique is an oil-based impinger, with the potential of reduced impaction forces, reduced reaerosolization, and longer sampling times (Lin, et al., 1999). NIOSH evaluated the efficiency of several different air samplers, including high-volume samplers, and several different collection mediums during a health hazard evaluation at the New Jersey mail processing and distribution facility (McCleary, et. al, 2003) (Barth et. al., 2003).
Land sampling and analysis may be limited in replication, because there are only three replicate plots per site, and a maximum of 3 replicate samples/plot. The low replication and unknown variability may limit the ability to draw statistically valid conclusions.
There is a relatively short time frame (total duration at one site is 30 days for land application sampling) and sample spacing. However, the 30-day time period may not be sufficient to observe preapplication
concentrations. In addition, because postapplication samples are at 15 and 30 days, there may be poor resolution on removal or survival rates.

Many sewage treatment plants across the United States are finding little or no Helminth ova in the influent and effluent streams. It is possible none will be measured in the selected biosolids that will be used for the five Pennsylvania applications.
Fecal coliforms are being used as bacterial indicator for bacteria such as Salmonella species. No such relationship has been established, nor will be established in this study, between fecal coliforms and pathogens such as Helminth ova or viruses.

That this PA project is presented as a centerpoint of the research response to the NRC recommendations is of great concern. It is not a health study nor a study of exposure in a "real world" setting. As stated in the email above, Walker, representing EPA, has consistently stated that this limited study would be useful in helping to shape future needed studies. However, the April 9 document does not commit to further studies and seems to imply that this PA study will provide the needed research.

EPA is "considering developing and validating methods for measuring bacteria and virusus." This is a critical need. In reviewing the plans for the PA study, it became clear that existing methods not only for viruses but also for bacteria, are totally inadequate. Data presented to the group showed that samples tested under "approved" Colony Forming Unit (CFU) methods failed to detect the pathogens, while Most Probable Number (MPN) methods detected them. If research and regulatory decisions are based only on currently approved methods, we are clearing failing to monitor as needed and we may be failing to protect the public health. <u>There is an urgent need for EPA to work to develop and validate methods for detection and enumeration of bacteria and viruses in sludges, soil, water and air.</u>

Revised Risk Assessment(RA)/Exposure

NRC Recommendations:

Use aggregate exposure multi-pathway assessment.

Add exposures/risk across pathways.

Use separate exposure scenarios for different end uses (like forestry, mine reclamation, ag, etc).

Involve stakeholders (like neighbors) in RA.

Conduct exposure assessment studies of workers and public.

Assess risks for high-end populations under most sensitive conditions that reflect regional variations.

Update fate and transport and exposure assumptions and models.

Conduct research/synthesis on interactions between chemicals and between chemicals and pathogens.

Consider secondary transmission of disease.

Treat uncertainty and variability explicitly.

Some contaminants, like persistent, bioaccumulative toxics (PBTs), should not be eliminated from RA even if infrequently detected or if there are data gaps for PBT chemical. Do uncertainty assessment if data are missing.

Gather data on exposure and RA assumptions - such as proximity of receptors.

Involve those with first hand knowledge of risks in the RA process.

EPA Response

EPA makes only a vague statement regarding involving stakeholders in revising the RA and makes no commitment to do so (p 17386). Where EPA discusses the approach EPA will take to consider RA revisions, no mention is made of stakeholders (p 17387-8). EPA cites a "recent" PA study as involving stakeholders in "scenario development and regulatory processes" and mentions the role of the ISG. That statement is misleading and incorrect. The study has yet to commence so it is not a recent study. The ISG participants were not involved in scenario development. We have had very limited influence on the study design, locations or research protocols. In fact a frustration has been that the ISG was not brought in early enough to consider the appropriate research objectives. EPA should involve stakeholders from the very beginning of any research or risk assessment pertaining to sludge application. The stakeholders need to be engaged early enough to help formulate the questions that are being addressed. Since many stakeholders are volunteers, it will be necessary to find ways to support their involvement.

EPA states that it will reassess methods and data for previously evaluated and new pollutants, but makes no mention of the many specific issues raised by NRC – like treatment of uncertainty and variability.

EPA "may" consider multiple exposures, sensitive populations, and contaminant interactions. This is not adequate. EPA states that it will look at risks to children and sensitive populations in future assessments and reassessments. However, it does not say explicitly that EPA will undertake such a review for the sludge RA. EPA needs to commit to revising the RA to address multiple exposures, sensitive populations (including children and fetuses), and contaminant interactions.

EPA appears to be saying it is up to each state to determine how local conditions may increase risk and thus determine the need for more stringent regulations and enact them as they choose. Clearly under the Clean Water Act, the states have that right. However, as pointed out by the NRC, the federal rules must be protective under reasonably anticipated high risk conditions. Thus citizens and the environment in states that do not enact more stringent rules must be protected under the federal rules. This means that the risks must be assessed under reasonably worst case conditions. An example given in the NRC report is that for the potential exposure to sludge contaminants, conditions such as karst when direct flow into groundwater without travel through intervening soil must be considered in the RA. There are many such examples of reasonable "worst case" assumptions that need to be taken into account. For example, sludge application rates as high as 42 MT/hectare in Californa (see email below) rather than the. 10 MT/ha assumed in the RA done to develop the 503 rules.

> Email from Ron Liebert regarding Sludge application rates in California sent to ISG participants
>
> Subject: Response to question about California annual application rates
> Date: Mon, 9 Jun 2003 11:33:04 -0700
>
> Hello Everyone,
>
> During the 5/20 conference call, I said that in California, annual application rates of 15-20 tons/acre were occurring. I mentioned this because of my concern that the EPA's part 503 risk assessment assumed annual

application rates of 10 metric tons/hectare or approximately 4.4 tons/acre (see Leather Industries of America, Inc. v. EPA, 40 F.3d 392, 396 (1994)).

John Walker and others questioned whether my numbers referred to wet or dry tons and I said I would find out. Preliminarily, I wanted to report to the group about annual land application rates obtained by extrapolation from data provided by the City of Los Angeles in the executive summary of its "Biosolids Environmental Management System (EMS)" report (which can be found at www.lacity.org/san/biosolidsems/). In the EMS, the City states that it produces approximately 86,000 tons of dry biosolids per year (which equates to roughly 309,000 wet tons/year). Of this total, the City applies 85% to a 4688 acre farm site it owns in Kern County, CA.

Conservatively assuming the City uses every inch of the farm (which it cannot because of regulatory setback requirements, geographical features, etc), we can calculate the annual application rates as follows:

(86,000 dry tons x 85%)/4688 acres = 15.6 dry tons/acre

(309,000 wet tons x 85%)/4688 acres = 56 wet tons/acre

Since these annual application rates exceed what the EPA expected when it conducted its original risk assessment, the EPA should investigate and revise its risk assessment, as part of its response to the NRC report, to include more accurate "real world" numbers.

Ron Liebert

In response to a request from a municipality, I developed a draft municipal ordinance that addresses many of the concerns posed by the land application of sewage sludges (Harrison, 2003). I believe that EPA should enact these provisions nationally as a means to be reasonably protective of public health and the environment.

EPA states that it will review exposure information used in Rounds 1 and 2 to identify data gaps, inform future RA, assess needs for studies and will review published literature, federal and state databases, NRC report, other sources. The paragraph that follows this proposed action (p 17386) discusses studies showing that bioavailability assumptions made in current RA are too conservative. However, a recent study of snails showed that cadmium was more bioavailable than predicted (Scheifler, et al, 2003).

Noteworthy in EPA's response is that no mention is made of any assumptions that they used in the current RA that may not be adequately protective. EPA continues to assert that "the part 503 numerical standards are based on a conservative set of exposure pathway and risk assessment assumptions (p 17391). That statement flies in the face of much of the NRC report which sets forth numerous examples of assumptions in the RA that are not conservative. Previous work has also pointed out that many of the assumptions in the RA are not conservative as did a more general review (Harrison, et al, 1999).

A review of an EPA RA of dioxins in sludges documented many non-conservative assumptions (Harrison, 1999). In response to this and other criticisms, EPA contracted for a revised RA for dioxins in sludges. While a significant improvement was achieved with the use of probabilistic tools, the revised RA continued to use many deterministic values, many of which were not appropriately conservative. Some of the probabilistic assumptions were also not relevant to reasonable worst case. For example, the revised risk assessment for dioxins in biosolids addressed regional differences by relying on a database that divides the country into 41 distinct regions on the basis of climate and other factors. Meteorological data from each region were

used in the risk assessment to predict a distribution of annual average air concentrations of volatiles in air at land application sites. Average values are not appropriate in assessing the reasonable worst case exposure. Biosolids are generally spread during the growing season and not under winter conditions. Therefore, warmer temperatures and higher rates of volatilization would be expected at the time biosolids are applied. This issue will be particularly important in the valuation of short-term exposures. So, for example, for these exposures, risks posed under high-wind and high-temperature conditions should be assessed.

The April 9 document indicates that EPA's perspective continues to ignore the many non-protective assumptions. This is one reason why it would seem imperative to have ORD rather than OW undertake the review and revision on the RA for sludge land application.

Human Health

NRC Recommendations:

Need to provide some explicit and measurable measures of performance that can be monitored.

Promote and support response investigations.

Promote and support targeted exposure surveillance studies.

Promote and support epidemiological studies.

Establish a framework for approach to implement human health investigations including tracking allegations and events.

Need for ongoing health surveillance due to impossibility of adequately assessing risks.

EPA Response

The NRC report reviewed all the available literature pertaining to health studies. The report found that in studies of wastewater treatment plant (WWTP) and biosolids workers, there are a mix of results., some showing illness response and some not. At the time the NRC report was drafted there was not a single study of the health of neighbors at sites where illness was reported. The NRC committee clearly recognized that a lack of evidence does not represent evidence of a lack of effect. That is why the committee strongly endorsed investigations of the reported incidents of illness.

EPA proposes no health studies and no surveillance of health around land application sites. They propose to "conduct a dialogue with other health-based Federal agencies…on the possibility of cooperatively tracking incident reports." (p 17384).

EPA suggests that they have conducted or are conducting studies on the occurrence of disease (p. 17389),) but none have been done or are being done to my knowledge (and I have been very involved with EPA and others in this area so I would expect to know of any such studies) and none are discussed further in the April 9 document. The document refers back to the section on Risk Assessment and Human Health and states that their primary objective is "to characterize pollutants and microbial agents present in biosolids, as well as any associated human health exposure pathways…"

This is not the type of human health studies called for by NRC. EPA recognizes that "the NRC sees an immediate need for a systematic approach for investigating claims of disease or illness"

(p 17390). EPA proposes to "investigate the possibility of developing a process for "notification and tracking. This is not responsive to the NRC recommendation. Keeping track is necessary, but not sufficient. Investigating the possibility of a process is not even committing to keeping track.

In work done at the Cornell Waste Management Institute (CWMI), research was done to determine what investigation of illness reports was done by EPA and by the states and local agencies (Harrison and Oakes, 2003). The findings were that no systematic investigations of the health complaints were conducted. The results of our investigation and work published subsequent to the drafting of the NRC report (Lewis et at, 2002) make it reasonable to believe that in some circumstances neighbors are getting ill from land application of sludges. This makes the investigation of such reports imperative. Since not all land application sites seem to be causing illness, the investigations must be directed to those problem sites. One of the problems with the Pennsylvania study is that it is not addressing such sites. Rather it is an experiment, applying sludges to small areas once and these are not sites at which neighbors have reported symptoms.

The U AZ and the USDA/EPA/PA studies are mischaracterized in the April 9 document as evaluating risk (p 17390). They are simply monitoring of selected pollutants and bioaerosols.

There is a critical need to respond immediately to reported illnesses associated with land application of sludges to determine whether sludge is the probable cause. There is a need to determine what types of sludges and management practices are associated with illness. None of the current or planned research addresses these issues.

Chemicals and Pathogens to consider/survey/methods

NRC Recommendations:

Conduct a new survey of pathogens and chemicals in sludges after reviewing existing state and other data.

Conduct surveys to verify Class A and B treatment processes and field management practices perform as assumed.

Certain chemicals like pharmaceuticals, PBTs, odorants, metal species need to be investigated. Some like PBTs should not be eliminated from RA even if infrequently detected or if there are data gaps.

Research improved pathogen detection.

Research other indicator organisms.

Develop standardized methods for pathogen and indicator organisms detection and quantification and include round-robin lab testing.

Research aerosols and develop standardized methods.

Research vector transmission of pathogens and toxins.

EPA Response

EPA proposes "a less comprehensive, more targeted survey" to be accomplished by reviewing existing sources of info (published literature, state data, pubic input). It makes sense to compile existing data prior to undertaking a new survey.

In the area of toxic organic chemical concentrations in sludges, CWMI has compiled the available data from a literature survey and from reports that could be found (see Harrison and Oakes, 2003, Organics survey, unpublished data). A query to AMSA and WERF failed to locate any industry-sponsored data except for the AMSA dioxin survey. CWMI found data from a couple of states (NH and VT). A request for assistance in locating data from other states was placed with the state biosolids coordinator from Wisconsin who represents the states to EPA. So far no other state data has been brought forward.

Examination of the data which were compiled indicates that for some sludges, concentrations of particular toxic organic chemicals found in sludges exceed the Superfund soil screening levels (SSLs) (EPA, 2001). SSLs are published for 71 of the 291 toxic organics detected in the more than 58 studies that were consulted in the CWMI study. Of those 71 chemicals for which there are SSLs, 61 toxic organic chemicals were found in one or more sludges above an SSL. Thus under Superfund, a site specific RA to evaluate the need for remedial action would be triggered if the concentration of the chemical in the soil at the Superfund site was the same as the concentration found in the sludge sample. Of the 291 toxic organics reported, there were RfDs for 68. 18 had SSLs but no RfD, 18 had an RfD but no SSL. Thus there are toxicity data for a number of toxic organic chemicals detected in sludges. The fact that there are concentrations of toxic organics in sludges that exceed soil screening levels indicates a need to collect more data on the concentration of these toxic organic chemicals in sludges (a survey) and to assess the risks posed by those toxic organic chemicals in sludges.

EPA does not seem to recognize the inadequacy of the National Sewage Sludge Survey (NSSS) data (USEPA, 1990). (p.17384-5). The document, for example, fails to mention limits of detection problems with NSSS. As pointed out in the NRC report and Figures, for some of the toxic organic chemicals in the NSSS, the limits of detection for all samples were higher than the soil screening levels (SSLs were used by the NRC as a guide for what concentration might warrant examination of risks). Analytic issues resulted in non-detects for many chemicals in the NSSS and in a number of cases the limit of detection exceeded health benchmarks. Thus the basing of any regulatory measures (such as eliminating a chemical from consideration) based on the percentage of sludges in which the chemical was detected is absurd. Yet EPA continues to propose non-detect as a screen (though dropping it to "not detected in more than 1% of samples"). Rather EPA should compare limit of detection with health benchmark to see if a chemical that was not detected might nonetheless pose a health risk.

The NRC report also mentions some specific classes of chemicals like pharmaceuticals, PBTs, odorants, and metal species that that should be monitored and evaluated. EPA does not significantly address these in the April 9 document.

The NRC report addresses odorants in sludges and recognized the lack of data both on the odorant chemicals in sludges and their potential to cause symptoms. The NRC recognized that odor is not simply an esthetic issue, but can lead to symptoms including "levels of tension, depression, anger, fatigue, and confusion (Schiffman et al. 1995). Mood impairments and stress can potentially lead to physiological and biochemical changes with subsequent health

consequences (Shusterman et al. 1991; Cohen and Herbert 1986). In addition, conditioned responses (behavioral and physiological) can be developed to odors perceived to be associated with health symptoms (Bolla-Wilson et al. 1988; Shusterman et al. 1988)" (NRC, 2002, p.231). EPA needs to investigate the presence of odorants in sludges, how to minimize them, and how odors are related to illness.

Risk Management Activities

NRC Recommendations:

Do not allow Class A non-EQ to be sold in bags or containers.

Consider additional risk management practices (like stebacks).

Consider adequacy of existing management practices.

Eliminate exemption from nutrient management and site restrictions for bulk EQ sludge.

Adopt standard treatment design criteria.

Review protocols of other countries.

Increase resources devoted to sludge at EPA.

Expand EPA oversight activities.

Provide more funds to states.

EPA Response

EPA is not proposing additional management practice requirements, like setbacks from homes. NRC recommends these be considered. Application of Class B sludges containing pathogens up to property lines and thus proximate to places where children play and people spend time in their yards is poor policy. Having witnessed a child playing on a swing set behind their trailer, just feet from the edge of a field to which sludge was being applied, can anyone doubt that there is the potential for that child to be exposed to the pathogens in the applied sludge? EPA needs to commit to establishing setbacks.

EPA is not proposing to require nutrient management or site restrictions for bulk applications of EQ sludges as recommended by NRC. In fact I find no mention of this issue in the EPA response. Since nutrient contamination of waterways and groundwater is a concern, and since nutrient levels in Class A EQ sludges may be the same as in Class B, it makes no sense toexempt them from such considerations.

The EPA Office of the Inspector General first (OIG) twice investigated the EPA sludge program (USEPA, 2002; USEPA, 2000). The first report documents insufficient oversight of the sludge program by EPA. The agency clearly did not respond positively to that report, since EPA staffing levels declined dramatically in the sludge program during the 2 years between the first and second reports. There is clearly no EPA presence in most areas that would ensure that even the inadequate 503 rules are being complied with. EPA proposes to "continue" program implementation – which is not responsive to the recommendation to enhance EPA oversight and enforcement. The fact that sludges are being spread close to where families live and on lands on which we grow our food makes such a stance indefensible. A credible enforcement and

compliance assurance presence is essential. Voluntary programs which EPA supports such as the EMS system is not a replacement for oversight.

Other

The bibliography compiled and made part of the docket is helpful, but specific citations should be provided in the response document where appropriate. For example, p. 17385-6 refers to EPA research previously conducted. Citations to that work should be included.

References Cited or Consulted

Abt Associates Inc. 1994. Revision of Assessment of Risks to Terrestrial Wildlife from TCDD and TCDF in Pulp and Paper Sludge. Bethesda, MD.

Alcock, R. E., J. Bacon, R. D. Bardget, A. J. Beck, P. M. Haygarth, R. G. M. Lee, C. A. Parker and K. C. Jones. 1996. Persistence and Fate of Polychlorinated Biphenyls (PCBs) in Sewage Sludge-Amended Agricultural Soils. Environmental Pollution. 93(1):83-92.

Anderson, H. 2000. Wisconsin Division of Public Health. Personal communication.

Balzer, W. and P. Pluschke. 1994. Secondary Formation of PCDD/F During the Thermal Stabilization of Sewage Sludge. Chemosphere. 29: 1889-1902.

Bennie, D. T. 1999. Review of the environmental occurence of alkylphenols and alkylphenol ethoxylates. Water Quality Research Journal of Canada. 34(1):79-122.

Beyer, W. N., E. E. Connor and S. Gerould. 1994. Estimates of Soil Ingestion by Wildlife. Journal of Wildlife Management. 58(2):375-382.

Birmingham, B. 2000. Ontario Ministry of the Environment. Personal communication.

Bohme, F., K. Welsch-Pausch and M. S. McLachlan. 1999. Uptake of Airborne Semivolatile Organic Compounds in Agricultural Plants: Field Measurements of Interspecies Variability. Environmental Science and Technology. 33:1805-1813.

Bolla-Wilson, K., R.J. Wilson, and M.L. Bleecker. 1988. Conditioning of physical symptoms after neurotoxic exposure. J. Occup. Med. 30(9):684-686.

Brouwer, A., U. G. Ahlborg, F. X. R. van Leeuwen and M. M. Feeley. 1998. Report of the WHO Working Group on the Assessment of Health Risks for Human Infants from exposure to PCDDs, PCDFs and PCBs. Chemosphere. 37(9-12):1627-1643.

Cavalli, L. and L. Valtorta. 1999. Surfactants in sludge-amended soil. Analysis. 36 (1): 22-28

Chaney, R. L., J. A. Ryan and G. A. O'Connor. 1996. Organic contaminants in municipal biosolids: risk assessment, quantitative pathways analysis, and current research priorities. Science of the Total Environment. 185:187-216.

Cohen, S., and T.B. Herbert. 1996. Health psychology: psychological factors and physical disease from the perspective of human psychoneuroimmunology. Annu. Rev. Psychol. 47:113-142.

Cousins, I. T., A. J. Beck and K. C. Jones. 1999. A review of the processes involved in the exchange of semi-volatile organic compounds (SVOC) across the air-soil interface. Science of the Total Environment. 228(1): 5-24.

Dachs, J., D. A. Van Ry and S. J. Eisenreich. 1999. Occurence of estrgenic nonylphenols in the urban and coastal atmosphere of the lower Hudson river estuary. Environmental Science and Technology. 33(15):2676-2679.

Douben, P. E. T., R. E. Alcock and K. C. Jones. 1997. Congener specific transfer of PCDD/Fs from air to cow's milk: an evaluation of current modelling approaches. Environmental Pollution. 95: 333-344.

Drescher-Kaden, U., R. Bruggemann, B. Matthes, M. Matthies. 1992. Contents of Organic Pollutants in German Sewage Sludges. In: Effects of Organic Contaminants in Sewage Sludge on Soil Fertility, Plants and Animals. Hall, J.E., D.R. Sauerbeck, and P.L'Hermite (eds.). Commission of the European Communities, Luxembourg

Eljarrat, E., and C.J. Rivera. 2003. A Comparison of TEQ Contributions from PCDDs, PCDFs, and Dioxin-like PCBs in Sewage Sludges from Catalonia, Spain. Chemosphere. In press.

Engwall, M., B. Brunstrom, C. Naf and K. Hjelm. 1999. Levels of dioxin-like compounds in sewage sludge determined with a bioassay based on EROD induction in chicken embryo liver cultures. Chemosphere. 38(10):2327-2343.

EPA Office of Solid Waste and Emergency Response. March 2001. Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites: Peer Review Draft: OSWER 9355.4-24

Feijtel, T.C. J., A. Rottiers, G.B.J. Rijs, A. Kiewiet, A. de Nijs. 1995. AIS/CESIO Environmental Surfactant Monitoring Programme. Part 1. LAS Monitoring study in "de Meern" sewage treatment plant and receiving river "Leidsche Rijn." Chemosphere 30 (6): 1053-1066.

Field, J.A., D.J. Miller, T.M. Field, S.B. Hawthorne, and W. Giger. 1992. Quantitative Determination of Sulfonated Aliphatic and Aromatic Surfactants in Sewage Sludge by Ion-Pair/Supercritical Fluid Extraction and Derivation Gas Chromatography/Mass Spectrometry. Analytical Chemistry 64: 3161-3167.

Field, J.A., T.M. Field, T. Poiger, H. Siegrist, and W. Giger. 1995. Fate of Secondary Alkane Sulfonate Surfactants During Municipal Wastewater Treatment. Water Research 29 (5): 1301-1307

Fries, G. F. 1995. A review of the significance of animal food-products as potential pathways of human exposures to dioxins. Journal of Animal Science. 73(6):1639-1650.

Fries, G. F. 1996. Ingestion of sludge applied organic chemicals by animals. Science of the Total Environment. 185:93-108.

Fries, G. F. and D. J. Paustenbach. 1990. Evaluation of Potential Transmission of 2,3,7,8 - Tetrachlorodibenzo-p-Dioxin - Contaminated Incinerator Emissions to Humans Via Foods. Journal of Toxicology and Environmental Health. 29:1-43

Galton, D. 2000. Cornell Department of Animal Science. Personal communication.

Goldring, J. 1992. Assessment of Potential Human Health Impacts of Dioxin an Furan Contaminated Sludge Amended to Soils. Wisconsin Department of Health and Social Services.

Golet, E.M., A. Strehler, A.C. Alder, and W. Giger. 2002. Determination of Fluoroquinolone Antibacterial Agents in Sewage Sludge and Sludge-Treated Soil Using Accelerated Solvent Extraction Followed by Solid-Phase Extraction. Anal. Chem. 74: 5455-5462

Hagenmaier, H., J. She and C. Lindig. 1992 b. Persistence of Polychlorinated Dibenzo-p-Dioxins and Polychlorinated Dibenzofurans in Contaminated Soil at Maulach and Rastatt in Southwest Germany. Chemosphere. 25(7-10):1449-1456.

Hagenmaier, H., J. She, T. Benz, N. Dawidowsky, L. Dusterhoft and C. Lindig. 1992 a. Analysis of Sewage Sludge for Polyhalogenated Dibenzo-p-Dioxins, Dibenzofurans, and Diphenylethers. Chemosphere. 25(7-10):1457-1462.

Hale, R.C., M.J. La Guardia, E.P. Harvey, M.O. Gaylor, T.M. Mainor, W.H. Duff. 2001. Persistent Pollutants in Land-applied Sludges. Nature. 412: 140-141

Hale, R.C., M.J. LaGuardia, E. Harvey, and T.M. Mainor. 2002. Potential Role of Fire Retardant-treated Polyurethane Foam as a Source of Brominated Diphenyl Ethers to the US Environment. Chemosphere. 46: 729-735

Harms, H. and D.R. Sauerbeck. 1982. Toxic Organic Compounds in Town Waste Materials: Their Origin, Concentration and Turnover in Waste Composts, Soils, and Plants. In: Environmental Effecs of Organic and Inorganic Contaminants in Sewage Sludge. Proceedings of a Workshop held at Stevenage, May 25-26, 1982. D. Reidel Publishing Co.; Dordrecht, Holland and London, England

Harnly, M.E, M. X. Petreas, J. Flattery and L. R. Goldman. 2000. Polychlorinated dibenzo-p-dioxin and polychlorinated dibenzofuran contamination in soil and home-produced chicken eggs near pentachlorophenol sources. Environmental Science & Technology. 34(7): 1143-1149.

Harrad S. J and D. J. T. Smith. 1997. Evaluation of a terrestrial food chain model for estimating foodstuff concentrations of PCDD/Fs. Chemosphere. 34(8):1723-1737.

Harrison, E. Z., M. B. McBride and D. R. Bouldin. 1999. Land application of sewage sludges: an appraisal of the U.S. regulations. Int. J. Environment and Pollution. 11,1.

Harrison, Ellen Z. 1999. Review of the Risk Analysis for the Round Two Biosolids Pollutants. Accessed July 7, 2003 at http://cwmi.css.cornell.edu/Sludge/review.html

Harrison, Ellen Z. 2003. Recommendations for sludge model ordinance. Accessed July 7, 2003 at http://cwmi.css.cornell.edu/Sludge/Recommendations_EZH_sludge.htm

Harrison, Ellen Z. and Summer R. Oakes, 2002. Investigation of Alleged Health Incidents Associated with Land Application of Sewage Sludges. New Solutions, 12 (4) 387-408.

Harrison, Ellen Z. and Summer R. Oakes, 2003. unpub data.

Helleday, T., K. L. Tuominen, A. Bergman, D. Jenssen. 1999. Brominated flame retardants induce intragenic recombination in mammalian cells. Mutation Research-Genetic Toxicology and Environmental Mutagenesis. 439(2):137-147.

Henck, J. W., J. L. Mattsson, D. H. Rezabek, C. L. Carlson and R. H. Rech. 1994. Developmental Neurotoxicity of Polybrominated Biphenyls. Neurotoxicology and Teratology. 16(4):391-399.

Henderson, A. K., D. Rosen, G. L. Miller, L. W. Figgs, S. H. Zahm, S. M. Sieber, H. E. B. Humphrey and T. Sinks. 1995. Breast-Cancer Among Women Exposed to Polybrominated Biphenyls. Epidemiology. 6(5):544-546.

Hoover, S. M. 1999. Exposure to Persistent Organochlorines in Canadian Breast Milk: A Probabilistic Assessment. Risk Analysis. 19(4):527-545.

Hoque, A. A. J. Sigurdson, K. D. Burau, H. E. B. Humphrey, K. R. Hess and A. M. Sweeney. 1998. Cancer among a Michigan cohort exposed to polybrominated biphenyls in 1973. 9(4):373-378.

Hornung, M. W., E. W. Zabel and R. E. Paterson. 1996. Toxic equivalency factors of polybrominated dibenzo-p-dioxin, dibenzofuran, biphenyl, and polyhalogenated diphenyl ether congeners based on rainbow trout early life stage mortality. Toxicology and Applied Pharmacology. 140(2):227-234.

Hulster A, J. F. Muller and H. Marschner. 1994. Soil-plant transfer of polychlorinated dibenzo-p-dioxins and dibenzofurans to vegetables of the cucumber family Cucurbitaceae. Environmental Science and Technology. 28:1110-1115.

Hulster, A. and H. Marschner. 1993. Transfer of PCDD/PCDF from contaminated soils to food and fodder crop plants. Chemosphere. 27:439-446.

Jacobs, L.W., G.A. O'Connor, M.A. Overcash, M.J. Zabik, P. Rygiewicz. 1987. Land Application of Sludge: Food Chain Implications. Effects of Trace Organics in Sewage Sludges on Soil-Plant Systems and Assessing Their Risk to Humans. Ch 6.

Kelley, E.F. 1997. Vermont WWTF Biosolids Sampling Project: Final Report, June 10, 1997. VT DEC & US EPA.

Kirchmann, H. and A. Tengsved. 1991. Organic Pollutants in Sewage Sludge. Swedish J. Agric. Res. 21: 115-119.

Klopffer, W. 1996. Environmental Hazard Assessment of Chemicals and Products. Part V. Anthropogenic Chemicals in Sewage Sludge. Chemosphere. 33(6):1067-1081

La Guardia, M.J., R.C. Hale, E. Harvey, T.M. Mainor. Alkylphenol Ethoxylate Degradation Products in Land-Applied Sewage Sludge (Biosolids). 2001. Environ. Sci. Technol. 35, 4798-4804.

Langenkamp, H. and L. Marmo (eds.). 1999. Workshop on Problems Around Sludge. European Commission: Joint Research Center. Pg. 84.

Lee, H.-B. and T.E. Peart. 2002. Organic Contaminants in Canadian Municipal Sewage Sludge. Part I. Toxic or Endocrine-Disrupting Phenolic Compounds. Water Quality Research Journal of Canada. 37 (4): 681-696

Lee, H-B. and T.E. Peart. 1995. Determination of 4-Nonylphenol in Effluent and Sludge from Sewage Treatment Plants. Analytical Chemistry 67(13): 1976-1980.

Lewis, D.L., D.K.Gattie, M.E. Novak, S. Sanchez, and C. Pumphrey. 2002. , Interactions of Pathogens and Irritant Chemicals in Land-Applied Sewage Sludges (Biosolids), *BMC Public Health, 2*:11

Linz, D. G. and D. V. Nakles, editors. 1997. Environmentally Acceptable Endpoints in Soil. An American Academy of Environmental Engineers Publication. Book.

Litz, N. 2002. Some Investigations into the Behavior of Pentabromodipheyl ether (PeBDE) in soils. J. Plant Nutr. Soil Sci. 165: 692-696.

Marcomini, A., P.D. Capel, Th. Lichtensteiger, P.H. Brunner, and W. Giger. 1989. Behavior of Aromatic Surfactants and PCBs in Sludge-Treated Soil and Landfills. Journal of Environmental Quality 18: 523-528

Marcomini, A., P.D. Capel, W. Giger, and H. Hani. 1988. Residues of Detergent-Derived Organic Pollutants and Polychlorinateed Biphenyls in Sludge-Amended Soil. Naturwissenschaften. 75: 460-462.

McAvoy, D.C., B. Schatowitz, M. Jacob, A. Hauk, and W.S. Eckhoff. 2002. Measurement of Triclosan in Wastewater Treatment Systems. Environmental Toxicology and Chemistry. 21 (7): 1323-1329

McCrady, J. K. and S. P. Maggard. 1993. Uptake and photodegradation of 2,3,7,8-tetrachlorodibenzo-p-dioxin sorbed to grass foliage. Environmental Science and Technology. 27:343-350.

McLachlan, M. S. 1996. Bioaccumuladon of hydrophobic chemicals in agricultural food chains. Environmental Science and Technology. 30(1):252-259.

McLachlan, M. S. 1997. A simple model to predict accumulation of PCDD/Fs in an agricultural food chain. Chemosphere. 34 (5-7):1263-1276.

McLachlan, M. S. and W. Richter. 1998. Update and Transfer of PCDD/Fs by Cattle Fed Naturally Contaminated Feedstuffs and Feed Contaminated as a Raw Sewage Sludge Application. 1. Lactating Cows. J. Agric. Food Chem. 46:1166-1172.

McLachlan, M. S., A. P. Sewart, J. R. Bacon and K. C. Jones. 1996. Persistence of PCDD/Fs in a Sludge-Amended Soil. Environmental Science and Technology. 30:2567-2571.

McLachlan, M. S., M. Hinkel, M. Reissinger, M. Hippelein and H. Kaupp. 1993. A Study of the Influence of Sewage Sludge Fertilization on the Concentrations of PCDD/F and PCB in Soil and Milk. Environmental Pollution. 85:337-343.

McLachlan, M. S., M. Horstmann and M. Hinkel. 1996. Polychlorinated dibenzo-p-dioxins and dibenzofurans in sewage sludge: sources and fate following sludge application to land. The Science of the Total Environment. 185:109-123.

National Research Council, 2002. Biosolids Applied to Land: Advancing Standards and Practices, National Academy Press, Washington, D.C.

Nelson, S. D., J. Letey, W. J. Farmer, C. F. Williams and M. Ben-Hur. 1998. Facilitated transport of napropamide by dissolved organic matter in sewage sludge. Journal of Environmental Quality. 27(5):1194-1200.

Nelson, S. D., J. Letey, W. J. Farmer, C. F. Williams and M. Ben-Hur. 1998. Facilitated transport of napropamide by dissolved organic matter in sewage sludge. Journal of Environmental Quality. 27(5):1194-1200.

O'Connor, G.A. 1996. Organic compounds in sludge-amended soils and their potential for uptake by crop plants. The Science of the Total Environment. 185: 71-81

Orazio, C. E., S. Kapila, R. K. Puri and A. F. Yanders. 1992. Persistence of Chlorinated Dioxins and Furans in the Soil Environment. Chemosphere. 25(7-10):1469-1474.

Patandin, S., C. I. Lanting, P. G. H. Mulder, E. R. Boersma, P. J. J. Sauer and N. Weisglas-Kuperus. 1999. Effects of environmental exposure to polychlorinated biphenyls and dioxins on cognitive abilities in Dutch children at 42 months of age. Journal of Pediatrics. 134(1):33-41.

Patandin, S., C. Koopman-Esseboom, M. A. J. De Ridder, N. Weisglas-Kuperus and P. J. J. Sauer. 1998. Effects of environmental exposure to polychlorinated biphenyls and dioxins on birth size and growth in Dutch children. Pediatric Research. 44(4):538-545.

Paustenbach, D. J., R. J. Wenning, V. Lau, N. W. Harrington, D. K. Rennix and A. H. Parsons. 1992. Recent developments on the hazards posed by 2,3,7,8 tetrachlorodibenzo-para-dioxin in soil - implications for setting risk-based cleanup levels at residential and industrial sites. Journal of Toxicology and Environmental Health. 36(2):103-149.

Prats, D., F. Rutz, B. Vazquez, D. Zarzo, J.L. Berna, and A. Moreno. 1993. LAS Homolog Distribution Shift During Wastewater Treatment and Composting: Ecological Implications. Environmental Toxicology and Chemistry 12: 1599-1608

Pyor, S. A. Hay, L. Walker. 2000. Nonylphenol in Anaerobically Digested Sewage Sludge from New York State. Unpub. Data, SETAC Conference.Sludge Type:

Rinella, J. F., P. A. Hamilton, and S. W. McKenzie. 1993. Persistence of the pesticide DDT in the Yakima River Basin, Washington. U.S.G.S.

Robina, J. 1997. Results of Vermont Dioxin in Sewage Sludge (Biosolids) Test Results. State of Vermont Department of Conservation, Waste Management Division. Draft Report. Waterbury, VT

Roeder R. A., M. J. Garber and G. T. Schelling. 1998. Assessment of dioxins in foods from animal origins. Journal of Animal Science. 76(1):142-151.

Rowland, S. J. 1998. Biosolids Management in New York State. New York Sate Department of Environmental Conservation Division of Solid and Hazardous Materials.

Schecter, A. and J. R. Olson. 1997. Cancer Risk Assessment Using Blood Dioxin Levels and Daily Dietary TEQ Intake in General Populations of Industrial and Non-Industrial Countries. Chemosphere. 34(5-7):1569-1577.

Scheifler, R., Schwartz, C., Echevarria, G., De Vaufleury, A., Badot, P., and Morel, J. 2003. Nonavailable Soil Cadmium Is Bioavailable to Snails: Evidence from Isotopic Dilution Experiments. Environ. Sci. Technol. 37:81-86

Schiffman, S.S., J.M. Walker, P. Dalton, T.S. Lorig, J.H. Raymer, D. Shusterman, and C.M. Williams. 2000. Potential health effects of odor from animal operations, wastewater treatment, and recycling of byproducts. J. Agromed. 7(1):7-81.

Shusterman, D., J. Balmes, and J. Cone. 1988. Behavioral sensitization to irritants/odorants after acute overexposures. J. Occup. Med. 30(7):565-567.

Shusterman, D., J. Lipscomb, R. Neutra, and K. Satin. 1991. Symptom prevalence and odor-worry interaction near hazardous waste sites. Environ. Health Perspect. 94:25-30.

Smith, K. E. C. and K. C. Jones. 2000. Particles and vegetation: implications for the transfer of particle-bound organic contaminants to vegetation. The Science of the Total Environment. 246(2-3):207-236.

Stephens, R. D., M. X. Petreas and D. G. Hayward. 1995. Biotransfer and bioaccumulation of dioxins and furans from soil: Chickens as a model for foraging animals. Science of the Total Environment. 175(3):253-273.

Stevens, J.L. and K.C. Jones. 2003. Quantification of PCDD/F Concentrations in Animal Manure and Comparison of the Effects of the Application of Cattle Manure and Sewage Sludge to Agricultural Land on Human Exposure to PCDD/Fs. Chemosphere. 50: 1183-1191

Stevens, J.L., G.L. Northcott, G.A. Stern, G.T. Tomy, and K.C. Jones. 2003. PAHs, PCBs, PCNs, Organochlorine Pesticides, Synthetic Musks, and Polychlorinated n-Alkanes in U.K. Sewage Sludge: Survey Results and Implications. Environ. Sci. Technol. 37:462-467

Thomas, G. O., A. J. Sweetman, R. Lohmann and K. C. Jones. 1998. Derivation and field testing of air - milk and feed - milk transfer factors for PCBs. Environmental Science and Technology. 32(22):3522-3528.

Thomas, G. O., K. E. C. Smith, A. J. Sweetman and K. C. Jones. 1998. Further studies of the air-pasture transfer of polychlorinated biphenyls. Environmental Pollution. 102:119-128.

Thorton, I., and P. Abrahams. 1981. Soil ingestion as a pathway of metal intake into grazing livestock. In: Proc. Int. Conf. Heavy Metals in the Environment. Edinburgh, Scotland: CEP Consultants.

Topp, E., and A. Starratt. 2000. Rapid mineralization of the endocrine-disrupting chemical 4-nonylphenol in soil. Environmental Toxicology and Chemistry. 19(2):313-318.

Torslov, J., L. Samsoe-Peterson, J.O. Rasmussen, P. Kristensen, VKI Insititute for the Water Environment. 1997. Use of Waste Products in Agriculture: Contamination Level, Environmental Risk Assessment ad Recommendations for Quality Criteria. Ministry of Environment and Energy, Denmark: Danish EPA

U.S. Department of Health & Human Services. ATSDR. 1998. Toxicological Profile for Chlorinated Dibenzo-p-Dioxins (Update). Book.

US EPA, National Risk Management Laboratory. June 2003. Draft Quality Assurance Project Plan (QAPP) for Multi-Media Sampling at Biosolids Land Application Sites. Contract No. 68-C-00-159. Task Order 42. Richard Brenner, Manager. Prepared by Battelle.

U.S. EPA, Office of Inspector General, 2002. Land Application of Biosolids, Status Report. 2002-S-000004.

U.S. EPA, 2000. Office of Inspector General, Biosolids Management and Enforcement, Audit Report No. 2000-P-10.

US EPA, National Center for Environmental Assessment. 1999. Report of the Workshop on Selecting Input Distributions For Probabilistic Assessments. EPA/630/R-98/004.

US EPA Office of Research and Development. National Center for Environmental Assessment (NCEA).1999. Exposure Factors Handbook (EFH). EPA/600/C-99/001. CD ROM.

US EPA Office of Research and Development. National Center for Environmental Assessment (NCEA).1999. Exposure Factors Handbook (EFH). EPA/600/C-99/001. CD ROM.

US EPA Office of Solid Waste. 1998. Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities. Peer Review Draft. EPA 530-D-98-001A.

US EPA Office of Solid Waste. 1998. Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities. Peer Review Draft. EPA 530-D-98-001A.

US EPA Office of Research and Development, National Center for Environmental Assessment (NCEA). 1997a. Policy for Use of Probabilistic Analysis in Risk Assessment at the US Environmental Protection Agency. Available at: http://www.epa.gov/ncea/mcpolicy.htm. 4pp.

US EPA Office of Research and Development, National Center for Environmental Assessment (NCEA). 1997. Policy for Use of Probabilistic Analysis in Risk Assessment at the US Environmental Protection Agency. Available at: http://www.epa.gov/ncea/mcpolicy.htm. 4pp.

US EPA Risk Assessment Forum. 1997. Guiding Principles for Monte Carlo Analysis. EPA/630/R-97/001. http://www.epa.gov/oppefed1/ecorisk/backgrn.htm. 35pp.

US EPA Risk Assessment Forum. 1997b. Guiding Principles for Monte Carlo Analysis. EPA/630/R-97/001. http://www.epa.gov/oppefed1/ecorisk/backgrn.htm. 35pp.

US EPA Office of Health and Environmental Assessment. 1994. Estimating Exposure to Dioxin-Like Compounds. EPA/600/6-88/005Ca.

US EPA. 1990. National Sewage Sludge Survey; Availability of Information and Data, and Anticipated Impacts on Proposed Regulations; Proposed Rule. Part III. Federal Register 55(21B): 47210 – 47283

US EPA. 1983. An Overview of the Contaminants of Concern in the Disposal and Utilization of Municipal Sewage Sludge. Booz Allen & Hamilton, Inc.

Van den Berg, M., L. Birnbaum, A. T. C. Bosveld, B. Brunstrom, P. Cook, M. Feeley, J. P. Giesy, A. Hanberg, R. Hasegawa, S. W. Kennedy, T. Kubiak, J. C. Larsen, F. X. R. van Leeuwen, A. K. D. Liem, C. Nolt, R. E. Peterson, L. Poellinger, S. Save, D. Schrenk, D. Tillitt, M. Tysklind, M. Younes, F. Waern and T. Zacharewski. 1998. Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and Wildlife. Environmental Health Perspectives. 106:12.

Vikelsoe, J., M. Thomsen, and L. Carlsen. 2002. Phthalates and Nonylphenols in Profiles of Differently Dressed Soils. The Science of the Total Environment. 296: 105-116

Wang, M-J., S.P. McGrath, and K.C. Jones. 1995. Chlorobenzenes in Field Soil with a History of Multiple Sewage Sludge Applications. Environ. Sci. and Technol. 29 (2).

Webber, M.D. and J.A. Nichols. 1995. Organic and Metal Cotaminants in Canadian Municipal Sludges and A Sludge Compost. Wastewater Technology Centre.

Weber L. W. D. and H. Greim. 1997. The toxicity of brominated and mixed-halogenated dibenzo-p-dioxins and dibenzofurans: An overview. Journal of Toxicology and Environmental Health. 50(3):195-215.

Welsch-Pausch K. and M. S. McLachlan. 1998. Fate of airborne polychlorinated dibenzo p-dioxins and dibenzofurans in an agricultural ecosystem. Environmental Pollution. 102(1):129-137.

Wild, S. R., J. Stuart, H. and K. C. Jones. 1994. The Influence of Sewage Sludge Applications to Agricultural Land on Human Exposure to Polychlorinated Dibenzo-p-Dioxins (PCDDs) and -Furans (PCDFs). Environmental Pollution. 83(3):357-369.

Wild, S.R. and K.C. Jones. 1992. Organic chemicals entering agricultural soils in sewage sludges: screening for their potential to transfer to crop plants and livestock. The Science of the Total Envrionment. 119: 85-119

Wilson, S. C., R. E. Alcock, A. P. Sewart and K. C. Jones. 1997. Persistence of Organic Contaminants in Sewage Sludge-Amended Soil: A Field Experiment. J. Environ. Qual. 26:1467-1477.

Wilson, S.C., R.E. Alcock, A.P. Sewart, and K.C. Jones. 1997. Organic Chemicals in the Environment: Persistence of Organic Contaminants in Sewage Sludge-Amended Soil: A Field Experiment. J. Envrion. Qual. 26: 1467-1477.

World Health Organization. 1998. Assessment of the health risk of dioxins: re-evaluation of the Tolerable Daily Intake (TDI), Executive Summary. WHO Consultation. Geneva, Switzerland. May 25-29, 1998. (http://www.who.int/pcs/pubs/dioxin-exec-sum/exe-sum-final.html)

Appendix A

Pennsylvania/EPA/USDA Research
Harrison's Comments on the draft QAPP
June 16, 2002

Major remaining points

Limitations section:
This section should refer to the small areal extent and short duration of application as a limitation.
As discussed below, the very limited pathogen monitoring (particularly viruses) needs to be in the limitations. Language I suggested previously was not included and the current document does not address limitations adequately. (see below)

Bioaerosol/pathogens:
The section on pathogens has improved, but I remain VERY CONCERNED about it, particularly in regard to enteric viruses.

The tables do no seem to have been updated to reflect the discussion and decisions from the Harrisburg meeting. For example on p 23 and 24 the tables do no mention MPN analysis and the footnotes say that Adeno, hepatitis, Norwalk-like, Rota will be detected, conversation today with Susan Butryos today, she reiterated that in doing MPN and PFU on BGM, you can detect the following viruses only:
Reo – but not Rota. Can detect the 3 common serotypes
Echo – good detection of most sero types, but not all echos
Cox Bs are picked up, not A in most cases
Polio

The text goes in to what might have been but is not being tested (p. 43) which is helpful and better reflects what Envir. Assoc. can detect. The text, however, needs to also say what IS being tested for in re viruses. Very clearly and specifically what the tests done are capable of detecting and what they can quantify. What is means to "enumerate" but not to count the various viruses needs to be described.

In the section starting on p 40 on bioaerosol sampling, it says ."…culturable enteric viruses [64 non-polio serotypes]". As stated, this is would seem to be leading the reader to believe that a

wide array of viruses will be tested for. This does not seem to be the case. I assume the 64 are various subtypes of the several viruses that are capable of being detected. What the 64 refers to needs to be described. The text states that "a broad spectrum of culturable enteric viruses" (p 42) will be assayed. I don't think that is accurate. The limited number of viruses being tested for needs to be clear both here (p 40) AND IN THE LIMITATION discussion. My suggested insertion from previous comments (p 55, Part 3) was not included. It is CRITICAL to me that a better description of the limitations in regard not only to collection methods (which a paragraph describes well) but also as to detection and quantification of viruses be included in limitations. As written, I think this document is misleading and will encourage misuse and misinterpretation of the pathogen data.

The text also makes a blanket statement that "enteric viruses, those ones measured, as limited as they may be, are considered the hardiest and as such they represent how well all enteric viruses are treated." First I believe that this is an overstatement. Second, since this study is not about treatment efficiency, this is not particularly relevant and is potentially misleading.

The Testing and measurement protolcols section (p69, sec 7.2) also seems to be contradictory to what Envir Assoc can do in re enteric viruses. It lists many viruses that they cannot detect.

The discussion of particular organisms (bacteria and others) around p 40-43 deals with issues of their use and detection in water. A couple of places dealing with air or soil samples are mentioned – but in many these media are not discussed. Since this project is not measure water, but soil, sludge and air, the capability and significance of measuring these microbes in those media needs to be addressed. I don't know what the last sentence on p 41 paragraph 3 (" The use of indicator…) means. It needs to be rewritten more clearly. Really, we probably don't know the significance so no wonder it is vague.

Mention of heterotrophic bacteria as a positive control could be slightly expanded to explain why they are useful for that purpose.

The second paragraph on p 44 (These alternative…) seems to be misplaced. I don't know which "these" refers to. Perhaps it belongs after the bacterial discussion?

Air Sampling
I did not see a response to my question concerning what, if anything, is being done to validate air sampling methods (p 49, Part 3, critical measures section). The field sample collection aspects seem a significant hurdle for the particulates and bioaerosols and I wonder what kind of control can be done for quality assurance). I did see protocol on p 58 regarding recovery experiment for 2 of the 3 samplers, but it appears to me that this will test survival through sampling equipment but not collection efficiency. It was also not clear that the samples in this recovery experiment will follow the same transportation and storage protocols as the "real" samples. Similarly for the impinger test with polio. Will all the sample handling procedures also follow the "real" sample protocols?

Land Sampling

The other section and component of research I remain concerned about is the land sampling and ecotox testing. I reiterate my concern that using composite samples from 0-15 cm depth given the application and timing procedures is going to be such a dilute sample as to be meaningless. I appreciate that that depth may be related to worm activity (though I believe they go much deeper) – but since this whole experimental procedure is not a good mimic of real world applications (which tend to be repeated applications to the same lands and thus result in higher loadings and long-term exposures), I believe that at the very least there should be separate ecotox studies of the 3 different depths of soil.

I am glad that FAME testing on the sludge itself has been added. I remain concerned that the FAME testing will be confounded by the fact that results are likely to reflect changes over time that may not be in response to sludge application but to environmental changes including plant growth over the intervening month. The QAPP cites a reference (Nazih, 2001) which I have not had time to find, but the sentence in the text says "This study will be looking at whole soil FAME profiles and not specific subsoil profiles; THEREFORE it has been shown that there are no differences of FAME profiles based on moderate temperature differences and matric water potentials over 15 days (Nazih, 2001)." This reference presumably showed that under one site growing soy beans, FAME did not change over 15 days. Several things make this sludge experiment different. First, the time frame is longer (day -7 to day 30), second the crops will not be soy beans most likely, third, site history is likely to play a significant role. I remain convinced that there needs to be non-sludged control plots for comparison.

The specific language in paragraph 5 p 64 section 6.2.6 has been modified to try and address some of my previous comments. As written, it seems to me to claim too much. I suggest deleting sentence 2 which says "In general, assays were selected to cover a range of species, exposure periods and assay endpoints." Germination and growth of two plants and mortality of one animal species at a few points in time (none longer than a month) is hardly a range in my mind. The last sentence of that paragraph might be more specific. The assays selected include plant growth (not animal).

What is the meaning of the last sentence on p 64 paragraph 6 which says that the "current assay list provides a toxicological evaluation"? That seems a very broad and misleading statement. I don't consider the short duration, high dilution, non-developmental, etc. etc testing that will be done to provide what I consider a toxicological evaluation. As written, if you find no impact, you are saying what? That it is non-toxic? That is my interpretation of this sentence.

The last paragraph on p 64 does not make it clear that the eco tox texting will be done on a composite sample from 0-15 cm (which I hope you will change).

Table 6-1 is confusing. Under sampling for pathogens it has 3 samples on Day-1, on biosolids, on day 1 and 15 on day 15 – and NS for the particular pathogens listed. I am unclear – are 3 samples being taken and tested for all the listed pathogens? In which case I'd just leave off the NS.

Odor

The section on odors mentions previous research which shows that odors are strongest in the first hour and goes on to say that is why the VOC measures in that time are warranted. What is the citation for that research? Do we know that all VOCs would follow odors?

The odor measure to be reported is the geometric mean of the panels results. As we know, this biases results grossly towards the data of those who can't smell low concentrations. The data from those persons showing greater sensitivity should be reported and discussed.