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Dear Sirs:

We received the petition dated October 7, 2003, addressed to the United States Environmental Protection Agency (EPA) Administrator Michael O. Leavitt; Assistant Administrator for the Office of Solid Waste and Emergency Response, Marianne Lamont Horinko; and G. Tracy Mehan, III, Assistant Administrator for the Office of Water. The petition is entitled, "Petition Seeking an Emergency Moratorium on the Land Application of Sewage Sludge." We note that the petition was submitted by the Center for Food Safety, Washington, DC on behalf of itself and 72 other organizations. We will refer to all of these organizations as the "petitioners."

Specifically, the petitioners requested that EPA place an immediate moratorium on the land application of sewage sludge by taking the following actions:

- (1) freeze the issuance of new National Pollutant Discharge Elimination System (NPDES) permits authorizing the land application of bulk sewage sludge;
- (2) rewrite and reissue NPDES permits to require a method of sewage sludge disposal other than land application to replace all NPDES permits currently in force that allow the land application of bulk sewage sludge; and
- (3) initiate rulemaking to change the Part 503 Sludge Rule promulgated under the authority of the Clean Water Act (CWA) at 40 CFR 503 to eliminate land application as an acceptable practice for sewage sludge disposal.

This letter constitutes EPA's determination on the issues raised in the petition. EPA has carefully evaluated the information provided in the petition, as well as other sources of information, and has concluded that the facts do not support a moratorium on land application of sewage sludge. Based on the information below, the Agency is denying the petition.

Statutory and Regulatory Background

EPA promulgated Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) under section 405(d) of the CWA, 33 U.S.C. §1345(d), as amended by the Water Quality Act of 1987. As required by section 405(d), the regulations specify the use and disposal options available under the rule and set forth numerical limits and management practices to adequately protect public health and the environment from the reasonably anticipated adverse effects of toxic pollutants in sewage sludge ("biosolids"). Part 503 specifies that sewage sludge may be managed by (1) application to the land, (2) placement in a surface disposal site, such as a sewage sludge-only landfill, (3) combustion in a sewage sludge incinerator, or (4) disposal in a municipal solid waste landfill that complies with the requirements of 40 CFR Part 258. Section 405(e) prohibits any person from disposing of sewage sludge from publicly owned treatment works (POTWs) or other treatment works treating domestic sewage except in compliance with regulations promulgated under section 405.

The petition concerns only the land application of sewage sludge under 40 CFR Part 503. Subparts A (General Provisions), B (Land Application) and D (Pathogens and Vector Attraction Reduction) of Part 503 apply to land application. EPA established numerical limitations for nine metals in sewage sludge, operational standards to reduce or eliminate pathogens in sewage sludge and to reduce vector attraction, and management practices to restrict the application rate and placement of sewage sludge on the land. The rule also requires monitoring, record keeping, and reporting. The requirements apply to any person who prepares sewage sludge that is land-applied, and to any person who applies sewage sludge to the land. "Person who prepares sewage sludge" is defined in 40 CFR. §503.9(r) as either a generator of sewage sludge during treatment of domestic sewage in a treatment works or a person who derives a material from sewage sludge. Sewage sludge that is land applied may be "bulk sewage sludge" or sewage sludge that is sold or given away in a bag or other container (i.e., no more than one metric ton). 40 CFR §503.11(e), (j).

A person who prepares bulk sewage sludge is required to provide written notice of the nitrogen concentration in the sewage sludge to land appliers so that the land appliers can comply with the requirement to apply the sewage sludge at a suitable agronomic rate, as well as "notice and necessary information to comply with the requirements of this part." 40 CFR §503.12(d), (f). Land appliers are required to obtain information as to the concentrations of pollutants for which numerical pollutant limits have been established. 40 CFR §503.12(e). Numeric limits for pollutants in land-applied sewage sludge are expressed as pollutant concentrations in sewage sludge or as cumulative or annual loading rates of pollutants going on receiving soils. 40 CFR §503.13. Land appliers are also subject to management practice requirements, which prescribe

how the sewage sludge is to be placed on the land or otherwise managed in the environment. 40 CFR §503.14. For example, the application of sewage sludge to land closer than 10 meters from waters of the United States is prohibited. Operational standards are technology-based treatment requirements such as process descriptions and performance requirements to reduce or eliminate pathogens from sewage sludge and to reduce vector attraction. Based on the treatment method used, land-applied sewage sludge is classified as either Class A or Class B. Class B sewage sludge is also subject to crop harvesting restrictions and site controls, which together constitute the approach for the control of pathogens in land applied Class B sewage sludge.

Under Part 503, monitoring of chemical and microbial pollutants in sewage sludge and certification of certain actions by the preparer or land applier must be performed at a frequency corresponding to the annual amount of sewage sludge that is land-applied. 40 CFR §503.16. For example, the greater the amount of sewage sludge land-applied annually, the greater the frequency of monitoring and certification that is required. Sewage sludge preparers and land appliers must keep records of these monitoring and certification activities. 40 CFR §503.17. Finally, sewage sludge preparers and land appliers that are Class 1 sludge management facilities (defined in §503.9(c)) must report this information to the permitting authority (EPA or authorized States) at least annually. 40 CFR §503.18.

Issues Identified by the Petition and EPA's Response

The petition for a moratorium on land application of sewage sludge is based on three categories of claims. First, petitioners cite incidences of adverse human and animal health effects, including deaths, which they claim are attributed to exposure to land-applied sewage sludge. Second, they cite the presence of toxic chemical pollutants in sewage sludge that are not regulated in EPA's regulation of sewage sludge. Third, they cite two reports by EPA's Office of Inspector General that document concerns with program oversight, including the level of enforcement activity and resources devoted to biosolids and the need for a health based tracking system. We address each of these issues below.

A. Claims of Adverse Health Effects

The petitioners argue that there "is considerable anecdotal evidence that the land application of sewage sludge—both before and after the EPA began regulating the practice in 1993—has caused specific and measurable harm to people, animals, and the environment." Petition at 14. First, the petitioners cite the Cornell Waste Management Institute (CWMI) collection of over 350 claims of adverse effects from land-applied sewage sludge. Second, petitioners cite to three specific cases of human death where it has been alleged that the deaths were attributable to land-applied sewage sludge. Finally, petitioners point to the case of *Boyceland Dairy v. City of Augusta*, No. 2001-RCCV-126 (Richmond County Super Ct. 2003), in which the death of 300 cattle at a farm in Augusta, Georgia was claimed by the cattle owners to be caused by exposure to land-applied sewage sludge.

EPA does not agree that these claims provide a reasonable basis for banning land application of sewage sludge, because to EPA's knowledge, none of these claimed adverse health effects have been proven or substantiated as having been caused by exposure to land-applied sewage sludge. EPA examined the information provided in the petition, as well as other sources of information, and has found no evidence that exposure to land-applied sewage sludge was the cause of any of the allegations of adverse health effects or of the specific human and animal deaths cited by petitioners.

1. *Anecdotal Claims of Adverse Health Effects*

EPA considered the reported adverse health effects in CWMI's database. An article co-authored by CWMI's director describes the reported incidents in a table and states as follows (Harrison and Oakes, 2002):

Table 1 describes 39 incidents in 15 states affecting more than 328 people. These are complaints the authors were aware of as of July, 2002. The sources of information in Tables 1 and 2 are from newspaper accounts, reports from state agencies, or from the affected individuals. It has not been confirmed by scientific investigation that these persons became ill due to land application of sludges. . . . We attempted to eliminate incidents that may have been associated with practices other than land application of sludges (composting facilities, for example), but were unable to confirm that land application of sewage sludge took place at all the locations in Table 1.

The authors therefore do not claim that this database establishes the cause of these reported incidences of adverse health effects, or even that land application of sewage sludge in fact occurred at all in the vicinity of the reported adverse health effects.

Alleged adverse health effects were also considered by the National Research Council (NRC) of the National Academy of Sciences in its review of EPA's sewage sludge program. The Agency commissioned the NRC to independently review the technical basis of the chemical and pathogen (microbial) reduction requirements in the Part 503 regulations governing land application to help address the human health concerns raised by the public and to fulfill the biennial requirement for periodic reassessment of the Standards for Use or Disposal of Sewage Sludge. In July 2002, the NRC published their report entitled, *Biosolids Applied to Land: Advancing Standards and Practices* in response to EPA's request. EPA will be publishing a final response to the NRC report by January 2004. The NRC report noted that there are anecdotal reports attributing adverse health effects to biosolids exposures, "ranging from relatively mild irritant and allergic reactions to severe and chronic health outcomes" and concluded that "a causal association between biosolids exposures and adverse health outcomes has not been documented."

Based on the lack of evidence substantiating a causal relationship between anecdotal reports of adverse health effects and land applied sewage sludge, EPA does not agree that these reports provide a reasonable basis for banning land application of sewage sludge.

2. *Death of Shayne Conner*

The petitioners cite the November 24, 1995 death of Shayne Conner, a 26 year old male who resided in the town of Greenland, New Hampshire, as a basis for banning land application of sewage sludge. According to the Office of the Chief Medical Examiner in the Department of Justice of the State of New Hampshire, Mr. Conner's family members expressed concern that his death might have been associated with the use of sewage sludge which had been distributed on fields adjacent to Mr. Conner's residence. According to the Acting Chief Medical Examiner, James A. Kaplan, MD, the circumstances of Mr. Conner's death were immediately investigated and an autopsy was performed on the day of his death. On November 27, 1995, the Acting Chief Medical Examiner issued a letter to Dr. Edward J. Schmidt, Director of the Division of Water Supply and Pollution Control in the Department of Environmental Services of the State of New Hampshire, which stated:

It is my opinion after review of the investigation into the circumstances of Mr. Conner's death as well as the initial findings at autopsy that Mr. Conner's death was not the result of possible environmental conditions created by the use of such fertilizer, nor did such materials contribute to his death.

It is important to note that other members of his family who resided with him at the same residence, including his brother and mother, were completely unaffected by environmental conditions on the night of Shayne Conner's death. Investigation revealed that the individual went to bed on the evening of his death without complaints, after passing that day uneventfully; such a history virtually rules out fatal conditions from viral, fungal, or bacterial infection. Additionally, although some autopsy related studies are still pending, initial findings do not support death due to an infectious cause.

After review of pertinent literature, it is my understanding that this type of fertilizer has been tested for a number of hazardous parameters, and found safe to use. There appears to be no scientific basis for connecting this person's sudden and tragic death to any environmental or infectious hazards posed by the use of such material.

Three years later, on November 20, 1998, Joanne Marshall, the mother of Shayne Conner, filed suit against several parties associated with this case, including the land-applier, Synagro. On January 8, 2002, the suit was settled. As part of the settlement, the plaintiffs, Joanne and Thomas Marshall, declared in a statement: "The science developed in this case did not prove that the sewage sludge Synagro's predecessor applied on the Hughes field in Greenland, NH, in

October 1995 caused or contributed to Shayne Conner's death, nor did the science prove that the sewage sludge caused any injuries or illnesses that the other residents of Tuttle Lane allegedly suffered."

3. *Death of Tony Behun*

Petitioners also raised the death of Tony Behun, an 11 year old boy, residing in Clearfield County, Pennsylvania with his parents, as evidence of adverse health effects from land-applied sewage sludge. However, the petitioners submitted no evidence that exposure to land-applied sewage sludge caused his death. EPA obtained the official report of investigation from the Pennsylvania Department of Environmental Protection (DEP or Department) (2000). The following is excerpted from that report.

The Department spoke with Tony's father, Joseph Behun, and with Tony's mother, Brenda Behun Robinson. Ms. Robinson described Tony as an active young boy who spent a lot of time outdoors. She said that Tony had received a motorcycle for his eleventh birthday in June 1994. Ms. Robinson had a 3-wheeler and she would sometimes ride with Tony, otherwise he usually rode alone. She told the DEP that she is certain Tony rode his motorcycle through the Al Hamilton Contracting Mountain Top strip mine area where biosolids had been applied. Two days later, Tony came home from school with a headache. Tony had flu-like symptoms for the next week. After a visit to a family physician, his parents took him to the Clearfield General Hospital. Within a matter of hours on that same day, a decision was made that Tony needed additional treatment and a life-flight helicopter took him to Pittsburgh's Allegheny General Hospital where he died on October 21, 1994.

DEP met with Joel H. Hersh who is the Director of the Bureau of Epidemiology, Pennsylvania Department of Health. Mr. Hersh reviewed the death certificate of Tony Behun and had other medical records reviewed, all of which are confidential and not a matter of public record. This review was performed under the authority of the Department of Health to undertake investigations related to the public's health as contained in the Disease Prevention and Control Act, 35 P.S. §§ 521.1 et seq.

Mr. Hersh reports that the death had as a probable underlying cause a pathogen, which is not known to be found in biosolids, nor is the biosolids environment known to be a suitable media for propagation of this pathogen.

Finally, Mr. Hersh noted that the pathogen is a ubiquitous one, and any number of potential routes of transmission exist through which Tony Behun may have been exposed. This includes the fact that between 20-30 percent of the general population are carriers of the pathogen. Mr. Hersh also said that the coroner of Allegheny County determined that an autopsy was not necessary.

Based on the results of its investigation, the Pennsylvania Department of Environmental Protection has found no medical or scientific evidence that Tony Behun's death was linked to any contact with the biosolids on the Al Hamilton Mountain Top mine site.

4. *Death of Daniel Pennock*

Petitioners also raised the death of 17 year-old Daniel Pennock as evidence of the effects of land-applied sewage sludge, although they provided no specific evidence linking the cause of his death with exposure to sewage sludge. EPA obtained the official interim and final reports of investigation from the Pennsylvania DEP (2001, 2003) and a letter from the Department's Secretary, David E. Hess, to Mr. and Mrs. Pennock (2001). The following is summarized from those documents.

- On April 1, 1995, 17 year old Daniel Pennock of Robesonia, Pennsylvania, died from what a family member described as a staph infection. In February 2001, the Pennsylvania DEP first became aware of the death and the allegations from family members that Daniel Pennock's death was the result of his contact with land-applied sewage sludge at a farm site in the vicinity of his home. As a result, the Pennsylvania DEP began an investigation of Daniel Pennock's death and the circumstances surrounding it.
- The DEP determined that the sewage sludge land application site that Daniel Pennock may have come in contact with was the Gelsinger Farm property which had received sewage sludge as a fertilizer and soil amendment from 1988 to 1995.
- The Final Report states as follows: "In 1987 Richard Lenzi, a partner in Ridge Crest Farms, entered into an agreement with Melvin Gelsinger to have biosolids from the Downingtown Regional Water Pollution Control Center (Downingtown) spread on the Gelsinger Farm. Ridge Crest Farms applied and received a permit (#603014) from the Pennsylvania Department of Environmental Resources (DER) on September 25, 1987." (Pennsylvania DEP, 2003)
- The permit to land apply sewage sludge was reissued by the DER in 1992. The land application of sewage sludge continued on the Gelsinger Farm until the contract between Ridge Crest Farms and Downingtown expired in 1995. "According to Melvin Gelsinger, biosolids have not been applied to the land since 1995." (Pennsylvania DEP, 2003)
- A review of the DEP files found several letters of complaint dated from August 1991 to July 1993 from farm site neighbors regarding odors, alleged groundwater and well contamination, and concerns for the possibility of sewage sludge runoff from the farm site during storm events. Also found in the DEP files were three Notices of Violation dated from March 24, 1988 to March 7, 1990, issued by DEP to the land-applier for this site. These violations consisted of sewage sludge applied to frozen ground, storing sewage sludge at the farm site, sewage sludge not properly stabilized, failure of the applier to

submit a monthly operation report, and sewage sludge not incorporated with the soil within 24 hours of delivery to the farm site. (Pennsylvania DEP 2001)

- DEP also examined the analytical results for metals in the soil at the farm site. For cadmium, copper, chromium, lead, nickel, and zinc, DEP compared the background concentrations for these six metals in the farm soil in 1988, the year that sewage sludge application began, to the concentrations for these six metals in the farm soil in 1996, one year after sewage sludge land application ceased. “The values for the six metal concentrations found in both the 1988 and 1996 soil samples all fell within the range found to exist in typical soils and were all well below the allowable regulatory limits” DEP regulations also establish metal concentration limits in soil for arsenic, mercury, molybdenum, and selenium. Since these parameters in the soil were not required to be analyzed at the time that the original permit was issued in 1987 and sewage sludge land application began at the farm site in 1988, concentrations of these four metals as of 1988 are not available. However, the range of concentrations for these four metals in the 1996 soil samples after sewage sludge land application at the farm site ceased are also well below the allowable DEP regulatory limits.” (Hess, 2001)
- DEP did not analyze the sewage sludge land applied at the Gelsinger Farm site for pathogens. The wastewater treatment plant that produced the sewage sludge treated the sewage sludge before land application by adding lime to raise the pH of the sewage sludge to 12 and holding the sewage sludge at this pH for two hours. This process is called lime stabilization and is an EPA approved Process to Significantly Reduce Pathogens (PSRP) to produce Class B sewage sludge before land application is allowed under the 40 CFR Part 503 Standards for the Use or Disposal of Sewage Sludge. A PSRP is a treatment technology standard under the Part 503 rule. As such, Part 503 does not require that sewage sludge treated by this PSRP technology process be tested for either pathogens, such as salmonella, or pathogen indicator organisms, such as fecal coliform. (Hess, 2001)
- The Pennsylvania DEP, in its final report, discussed soil samples taken on November 26, 2001 from the areas of the Ridge Crest Farms that received sewage sludge, as follows:

The soil was analyzed for *Staphylococcus* bacteria, metals, and PCB content. *Staphylococcus* bacteria were found in all of the samples, however, *Staphylococcus aureus* was not found in any of the samples. Since *Staphylococcus* bacteria are normally found in soil, these results would be consistent with previous soil samples submitted to the Department. No PCBs were found in any of the samples, however a trace of Chlordane was detected at one location. Chlordane was a common pesticide until it was banned in 1983, in part because of its persistence in the environment. The trace of Chlordane found in the sample is probably a holdover from that time period. (Pennsylvania DEP 2003)

- Posting of signs to restrict access by members of the public to a sewage sludge land application site was not required under DEP regulations until 1994. As the DEP permit holder, the sewage sludge land applier was required to mark the boundaries of the land application site. In an inspection by DEP on July 29, 1994, the required signs were found to be in place on the Gelsinger Farm site (Hess, 2001).
- The Pennsylvania DEP “made numerous attempts to secure the medical records of Daniel Pennock from his parents” However, Mr. and Mrs. Pennock did not grant the requests made by DEP. Dr. Richard T. Bell, a pulmonary specialist who treated Daniel Pennock was quoted in a newspaper article on May 31, 2001, as saying that Daniel Pennock “had a viral pneumonia and he got a staph pneumonia on top of it.” Dr. Bell was also quoted as saying, “The infections could have come from anywhere.” (Pennsylvania DEP 2003)
- The final report of investigation by the Pennsylvania DEP contained the following conclusions:
 - There was no evidence to indicate that biosolids were spread outside of the permitted area on the Gelsinger Farm.
 - There was no evidence to indicate that the Biosolids spread on the Gelsinger Farm did not meet all of the treatment requirements for Class B Sewage Sludge.
 - The cause of death for Daniel Pennock was viral pneumonia combined with staph pneumonia. The point of origin of the staph pneumonia could not be determined.
 - This investigation was complicated by the lapse of time from the death of Daniel Pennock to the time the Pennsylvania Department of Environmental Protection became aware of this situation. Also complicating this investigation was the inability to secure all the records that were held or already destroyed by individuals associated with this investigation. It is unknown what value these records may have been to this investigation.

(Pennsylvania DEP 2003)

The information available to EPA from the investigation into Daniel Pennock’s death does not establish a causal connection between land-applied sewage sludge and his death. The source of the viral and staph pneumonia was not established, nor does the report establish that Daniel Pennock had any contact with either sewage sludge or the land to which sewage sludge had been applied.

In summary, there has been no causal connection whatsoever established between the deaths of Shayne Conner, Tony Behun or Daniel Pennock and exposure to land-applied sewage sludge. Therefore, EPA does not agree that any of these cases provide a reasonable basis for banning land application of sewage sludge.

5. *Death of 300 Cattle and Farmland Contamination*

In November 1998, two large dairy farms, McElmurray & Sons, Inc., and Boyceland Dairy Farms, filed lawsuits against the City of Augusta in the United States District Court in the Southern District of Georgia, alleging that sewage sludge from the City of Augusta's Messerly Wastewater Treatment Plant applied to their land caused crop damage and cattle mortalities on the two dairy farms. Specifically, claims of violations of the federal CWA and Resource Conservation and Recovery Act (RCRA), and several state common law claims, were made. The Plaintiffs withdrew four of the claims and the federal judge dismissed the remainder of the case in August 2000. *Boyce v. August-Richmond County*, 111 F. Supp. 1368 (2000).

The case referred to by petitioners was filed in March 2001, by Boyceland Dairy Farms in Richmond County Superior Court, claiming breach of contract against the City of Augusta. Boyceland Dairy claimed that the City of Augusta was obligated to provide a fertilizer product that would be beneficial to the soil, grass crop, and cattle. Boyceland Dairy claimed that the City instead provided a product which poisoned the land and in turn poisoned the cattle herd which led to deaths. Petitioners state that "[o]n June 24, 2003, a court in Georgia ruled that the land application of sewage sludge was the legal cause of the damage to the farmland and the deaths of the farm's prize-winning cattle," citing *Boyceland Dairy v. City of Augusta*, No. 2001-RCCV-126 (Richmond County Super. Ct. 2003). However, EPA understands that the jury awarded \$550,000 of the \$12.5 million in damages sought by the plaintiffs without any findings of fact.

Counsel for the City of Augusta provided the following information with respect to the verdict (Ellison, 2003):

The jury did not make any finding that biosolids damaged the soil or the cattle. Petitioners' representations to the contrary are wrong. The Boyce trial was a breach of contract claim; the tort claims had previously been dismissed by the Court. One of the breaches contended by the Boyces was an alleged failure to keep and maintain good records. Unfortunately and regrettably in the early days of Augusta's land application program, record-keeping was a problem, mostly due to programming problems with the biosolids application software used by Augusta. The verdict may well have represented the jury's dissatisfaction with the records maintained by Augusta.

To conclude, based on that jury verdict that the EPA 503 rules are not protective of the environment, is spurious. The Boyce case is still pending with post-trial motions before the Court on numerous issues including the defendant's contention that there was no evidence to support any causation between the plaintiffs' claims of contaminated land and the death of the cows and the application of biosolids. Augusta has always contended and continues to submit to the Court that there is no evidence that the land has been damaged in any way whatsoever.

EPA was not a party to either of these lawsuits, and was only made aware of the situation in November 1998 by an outside private party who identified an Internet site which contained information and allegations regarding the death of cattle at the two dairy farms. EPA Region 4 investigated the allegations. On December 8-9, 1998, EPA Region 4 conducted a Compliance Evaluation Inspection (CEI) at the Messerly Wastewater Treatment Plant in Augusta, Georgia. The primary purpose of the CEI was to evaluate the City's sewage sludge program, operated pursuant to 40 CFR Part 503. Based on the preliminary findings of the EPA CEI, the Region 4 Enforcement and Investigations Branch conducted a diagnostic evaluation of the City's current sewage sludge treatment processes on February 16-18, 1999. As part of the diagnostic evaluation, EPA collected sewage sludge samples and analyzed the samples to determine whether the City's sewage sludge complied with the federal land application regulatory requirements. In July 1999, EPA mailed the inspection report and sampling analysis results to the City of Augusta. The results of the sample analysis and inspection report of current operations did not find any violations of the Part 503 requirements (e.g., all metals concentrations were found to be below federal regulatory requirements) (USEPA 1998).

In addition to the CEI, in early December 1998, EPA Region 4 asked EPA's Biosolids Incident Response Team (BIRT) to help the Region assess the allegations about the death of dairy cattle. The BIRT, which involves EPA staff from Headquarters and Region 8 with broad experience in sewage sludge management practices, was established by the EPA Biosolids Program to investigate alleged problems associated with the land application of sewage sludge in an effort to develop adequate information to understand what had happened at these sites (and lessons learned) that could be avoided at future land application sites and to develop guidance.

Beginning in December 1998, EPA Region 4 and the BIRT were in contact with the plaintiffs' attorneys (Decker & Hallman) and technical consultants (Newfields, Inc.) to obtain access to soil sampling data, expert reports, and other information related to the livestock deaths at the two dairy farms as well as permission to visit the farms. Minimal information was made available, and EPA was never allowed access to the two dairy farms.

EPA Region 4 staff and the BIRT met with the City of Augusta to review their current and historical operations and request data, expert reports, and other information from the City. EPA also met with the City's current biosolids land application contractor. Region 4 and the BIRT were told that the data and records from both the plaintiffs and the City of Augusta could not be made available due to discovery in the litigation. Discovery ended in July 1999. Region 4 and the BIRT again requested data from both the plaintiffs and the City of Augusta. EPA then began receiving information from both parties that had been filed with the Court, such as expert witness reports, soil sampling results, etc. EPA and the BIRT only received information previously filed with or prepared for the court and open for public record.

The BIRT investigation included compiling and reviewing analytical data covering the quality of sewage sludge (i.e., pollutants, pathogens, vector attraction reduction), soil and forage data, clinical data on the cows, veterinarian records, feed and water quality, and herd

management records. The BIRT sent the available data that met EPA's Quality Assurance/Quality Control (QA/QC) requirements to outside independent reviewers as part of its investigation. Based on these reviews, the BIRT concluded that many of the identified dairy herd health problems are typical of occurrences that can accompany herd expansion. These types of disease problems can insidiously increase if not routinely detected and managed. The data that appear to represent the most focused effort toward problem identification are the mineral analyses, and these provide no definitive evidence of any substantial mineral imbalance. The herds appear to be encountering multiple health problems including infections (e.g., Johne's disease, bovine leukosis virus (BLV) and malignant lymphoma) and metabolic diseases. Improvement or resolution of these problems requires a systematic approach to problem identification that is lacking in the available data. A more systemic approach to clinical record keeping, necropsy examination, serum and tissue sampling and feed analysis would be necessary to more clearly define the basis of the health problems on these farms (CSUILMT, 2001).

EPA's BIRT also reviewed scientifically credible soil information from samples taken from the site and found that the fields were within the range of national, uncontaminated background soil heavy metal levels for the metals in question (e.g., arsenic, cadmium, chromium, copper, lead, mercury, molybdenum, selenium, and zinc) (for background levels see Holmgren *et al*, 1993; Shacklette and Boerngen, 1984; Baxter *et al*, 1983).

On February 2, 1999, Region 4 staff and the BIRT met with University of Georgia veterinarian scientists and soil scientists to discuss the livestock deaths and the University's possible participation in assessing soil and forage characteristics in Burke and Richmond Counties. On August 5, 1999, EPA Headquarters issued a grant to the University of Georgia to assess soil characteristics on biosolids land application sites in Burke County. This effort resulted in the publication of a paper entitled *Long-Term Biosolids Application Effects on Metal Concentrations in Soil and Bermudagrass Forage* (Gaskin *et al*, 2003). The paper presents the University of Georgia's findings of their analyses of trace metals levels in soils and feed that were implicated in the Georgia case. The paper indicates "that toxic levels of metals have not accumulated in the soils due to long-term biosolids application. Overall forage quality from the biosolids-amended fields was similar to that of commercially fertilized fields; however, due to the relatively high sulfur and potential for a low copper to molybdenum ratio, copper supplements should be used to ensure ruminant health" (Gaskin *et al*, 2003).

Thus, EPA's investigation of the site and the sewage sludge did not find any substantiation to the allegations that exposure to sewage sludge applied to the pasture land caused illness or death of the dairy cattle that grazed on the pasture.

The Georgia Department of Natural Resources (DNR), Environmental Protection Division (EPD), also conducted a performance audit in December 1998 and compliance and enforcement activities related to the City of Augusta's wastewater treatment programs, including operation and maintenance, solids management and digestion, process control, administration of the pretreatment program, and wastewater laboratory procedures. Review of EPD's enforcement

history for the past ten years with regard to the City of Augusta indicates a number of enforcement actions had been taken to address areas of noncompliance, primarily focused on meeting NPDES effluent limits and sewer system rehabilitation. The deficiencies documented during the 1998 audit were addressed through a January 2000 Consent Order. Soil sampling of the McElmurray and Boyceland farms conducted in 1999 by EPD documented “that the quality of sewage sludge is in compliance with State Rules and Regulations for Water Quality Control. The results of the values for the metals which were analyzed were below the pollutant concentration limits of the State Rules,” (Georgia DNR, 1999B).

In summary, none of the information that has been brought to EPA’s attention or obtained through its investigations with respect to the Boyceland Dairy matter provides a reasonable basis for a moratorium on the land application of sewage sludge.

B. Toxic Levels of Chemicals in Sewage Sludge

Petitioners describe sewage sludge as “an unpredictable mixture of whatever enters the sewers.” They also characterize sewage sludge as “a toxic mix of heavy metals, synthetic organic compounds, surfactants, pathogens, and radioactive contaminants.” They add, “There are as many as 100,000 chemicals used in American industry, and every year about a thousand new chemicals are put into commercial use.” Petition at 12-13. They conclude that sewage sludge is “inherently unpredictable and inherently hazardous,” and that therefore, EPA is “unable to implement any program or regulatory scheme to protect public health or the environment from the land application of sewage sludge.” Petition at 16. However, the petition cites nothing to support this characterization.

The wastewater that flows to POTWs can show significant variability in its chemical and microbial content when sampled on a one time or daily basis. However, over time, variability decreases to a great extent for several reasons. First, both the wastewater treatment processes and sewage sludge treatment processes and handling practices at POTWs involve extensive amounts of day-to-day mixing. Second, in many cases the amount of sewage sludge generated on a daily basis is mixed and stored for considerable periods of time before final use or disposal. This is particularly true for sewage sludge that is to be land-applied, because it must be treated to meet pathogen and vector attraction reduction requirements. As a result, the longer term variability in chemical content of treated sewage sludges that enter the environment is greatly reduced. Thus, the manner in which wastewater treatment plants are operated and the manner in which sewage sludge is processed and stored prior to land application generally leads to a relatively consistent sewage sludge quality on an annual basis.

The generation of sewage sludge is an integral part of wastewater treatment. Wastewater treatment cleanses wastewater by partitioning both chemical and microbial species into the generated sludge, thereby allowing for a discharge of the treated effluent into the ambient aquatic environment. The sewage sludge matrix has physical and chemical properties such that these species are tightly bound to the matrix. This, in turn, minimizes the transmissions of these

species through the terrestrial environment where the sewage sludge is land-applied and subsequently, significantly reduces exposure to humans, plants, and animals. This is not to imply that refractory materials such as metals do not accumulate in the soil-sewage sludge mixture after long term sewage sludge application to the land. Recognizing this, EPA promulgated risk-based cumulative pollutant loading rates for eight metals in sewage sludge to limit the build-up of these materials in the receiving soils. 40 CFR §503.13(b)(2) (Table 2). *See, e.g.*, concentration data for metals in sludge-amended soils discussed in Sections A.4 and A.5 of this letter.

To demonstrate this principle empirically, extensive testing of sewage sludge samples from across the country using the hazardous waste characterization procedures established under RCRA has clearly demonstrated that sewage sludge samples consistently pass the hazardous waste characteristics tests, including the use of the Toxicity Characteristic Leachate Procedure (TCLP) test for evaluating "toxicity" as a characteristic of a hazardous waste, demonstrating that sewage sludge is not a characteristic hazardous waste under RCRA (USEPA, 1991). The sewage sludge matrix tightly binds the chemical constituents measured by the TCLP preventing sufficient quantities of these constituents from being leached into the leaching medium. This in effect is simulating the extremely low mobility of sewage sludge constituents to the ambient environment.

Both national pretreatment programs administered by either EPA or the States as well as local pretreatment programs administered by local wastewater treatment authorities have resulted in significant reductions in both metals and refractory organic chemicals in the influent to wastewater treatment plants from industrial sources. This has resulted in significant reductions of these substances in wastewaters coming into POTWs for treatment, and most importantly in the generated sewage sludges.

In a study conducted by Pennsylvania State University, College of Agricultural Sciences, (Stehouwer, 1999; Stehouwer *et al.* 2000), the concentrations of several metals were measured in Pennsylvania sewage sludge from 1978 to 1997. The metals measured were arsenic, cadmium, copper, lead, mercury, molybdenum, nickel, selenium, and zinc. Results show that concentrations for most of the elements have decreased by 50 percent or more over the 20 year period. The paper states that "[t]he decreases in these trace metals over the past 20 years represent a major improvement in biosolids quality, much of it due to pretreatment programs requiring industries to remove trace elements and organic chemicals from their wastewater before discharging it to municipal sewerage systems." The study also states that the concentrations of all metals are well below the federal and state standards for metals in sewage sludge. At least with regard to metals, this study further supports the Agency's claim that sewage sludge consistently meets federal regulations and the trend is in the direction of continual improvement.

Finally, the Water Environment Research Foundation (WERF) has funded a project to develop a bioassay toxicity testing procedure applicable to sewage sludge and sewage sludge amended soils (Banks, 2003). The project involved toxicity evaluations of samples of sewage sludges from 20 POTWs using standard tests including earthworm mortality, growth and

reproduction; seedling germination and root elongation; microbial respiration; and nematode mortality/reproduction, in addition to chemical testing. The results of this project were reported in a presentation, *Toxicity Evaluation of Biosolids Amended Soils*, by Paul Schwab at the Water Environment Federation (WEF) Residuals and Biosolids Management Specialty Conference in Baltimore, Maryland on February 22, 2003. Preliminary results from this bioassay demonstrate low residual ecological toxicity from the presence of constituents in sewage sludge.

With regard to particular pollutants, the petition states that in a recently published article (Hale and La Guardia, 2002), polybrominated diphenyl ethers (PBDEs) and nonylphenols have been found at “toxic levels” in sewage sludge. EPA has reviewed this article and believes that the petition mischaracterized the article’s findings and conclusions. The authors of this article did not present any scientific evidence showing that the reported concentrations of these chemicals in sewage sludge are sufficient to cause human health or environmental hazard. Rather, the authors simply report the presence of one or both of these chemicals in sewage sludge and in aquatic sediments, fish, and human tissue samples. However, the authors do not present any data that link the presence of these chemicals in sewage sludge to their presence in environmental media or human tissue.

In the course of its current review of sewage sludge regulations to identify additional toxic pollutants that may warrant regulation under section 405(d)(2)(C) of the CWA, EPA considered PBDEs and nonylphenols among other pollutants (USEPA, 2003B). The PBDE homologues (tetra-, penta-, hexa- and decabromodiphenyl ethers) known to occur in sewage sludge were not included in EPA’s hazard screening assessment because the human health benchmarks (HHBs) in EPA’s Integrated Risk Information System (IRIS) for these PBDE congeners are undergoing a scientific reassessment. However, PBDEs were screened using an estimate of potential hazard, and EPA determined that PBDE’s are not a priority at this time. Nonylphenols were also not included in the hazard screening assessment because HHBs, which are essential for assessing risk, are not available for these chemicals. However, EPA will consider these chemicals for potential identification in future biennial reviews of the sewage sludge regulations when the necessary information is available to enable EPA to determine whether they pose a risk of adverse effects to human health or the environment due to their presence in sewage sludge.

In addition, EPA is pursuing an active research program concerning nonylphenols. Valid analytical methods that are sensitive and reliable are being developed for alkylphenol ethoxylates (APE), including their degradation products nonylphenols. In another research project, the fate and transport of these APEs are being studied in the application of sewage sludge to land. In particular, the amounts of APEs in sewage sludge, degradation following application to land, transport down the soil column, and runoff into surface waters are being studied. The Agency believes that this research program together with the IRIS health assessment of PBDEs will help answer the question whether the presence of these chemicals at the concentrations found in sewage sludge constitute a health or environmental hazard.

In summary, the petition does not support the contention that sewage sludge is inherently unpredictable, toxic or hazardous and therefore incapable of being regulated for purposes of land application. As previously discussed in Section A, the specific allegations of adverse human health effects are not substantiated. Further, the manner in which wastewater is treated and the resulting sewage sludge is handled supports the conclusion that sewage sludge is an inherently consistent material, rather than inherently unpredictable. Nor is there any evidence cited in the petition or known to EPA showing that land application of sewage sludge has resulted in toxic levels of pollutants in the receiving soils. Finally, EPA is in an ongoing process to evaluate additional toxic pollutants for potential regulation under section 405(d) of the CWA. Information in the article cited in the petition concerning two unregulated pollutants does not support the contention that these pollutants are of concern in land-applied sewage sludge.

C. Program Oversight

The petitioners refer to two OIG assessments (USEPA, 2000, 2002) of the EPA sewage sludge program to support their requests. The 2000 report declared that the EPA did not have an “effective program for ensuring compliance with the land application requirements of the Sludge Rule.” The follow-up report in 2002 documented that “EPA cannot assure the public that current land application practices are protective of human health and the environment.” Additional OIG findings cited by the petitioners include:

- EPA performed virtually no inspections of land application sites and few inspections of treatment plants or land applicators.
- There is a lack of resources committed to sewage sludge and there is a low priority placed on the program by EPA.
- There has been almost a 50% reduction in EPA enforcement resources since the earlier assessment.
- There has been a failure to create formal processes for tracking and responding to human health complaints related to the land application of sludge.

EPA has maintained an active presence in biosolids compliance and enforcement activities. EPA’s enforcement and compliance activities are tracked in the Integrated Compliance Information System (ICIS) and Permit Compliance System (PCS) databases. Specifically, the ICIS database documents the following Federal enforcement actions taken to address biosolids: 391 administrative orders for FY 1995 - 2002, 119 administrative penalty orders for FY 1995-2002, and one civil judicial action in FY 1997. The PCS database documents 382 regional and state biosolids inspections for FY 2000 - 2002.

Furthermore, EPA Regions and States have the responsibility to address situations where compliance assistance and enforcement actions to address biosolids are appropriate and necessary. Regional responsibilities for the biosolids program include actively following up on phone calls and complaints received from the public, and, where appropriate as demonstrated by

the data, initiating Agency enforcement actions. EPA has taken enforcement actions and/or appropriate administrative remedies to address biosolids violations of 40 CFR part 503 and will continue to take such actions, including instances where biosolids pose an imminent and substantial endangerment to human health or the environment.

To assist the States and Regions in their oversight of the biosolids program, EPA has, either in place or in development, tools to assist and promote compliance with biosolids regulatory requirements. The NPDES Compliance Inspection Manual, which is used by EPA and State inspectors to perform inspections in the field, includes a “Sludge (Biosolids)” chapter. EPA is currently revising and updating the manual, which is expected to be completed in 2004. The CWA/NPDES Computer Based Inspector Training CD-ROM, including a module specific to biosolids inspections, was finalized in August 2003. EPA plans to make both of these tools available on the EPA website.

Additionally, there are two compliance assistance web sites, which are available for biosolids compliance studies, information and tools, and for links to other sites with pertinent biosolids compliance information. One is the National Environmental Compliance Assistance Clearinghouse at: <http://cfpub.epa.gov/clearinghouse/>. This site is a searchable clearinghouse of compliance assistance materials. The second Web site is the Local Government Environmental Assistance Network (LGEAN) at <http://www.lgean.net>. This on-line compliance assistance center, which focuses on local government environmental requirements, is operated by the International City/County Management Association (ICMA), and has six other partners representing local government.

EPA is also working to improve its data reporting and management system that supports compliance oversight. EPA is continuing to work with States as it modernizes the Permit Compliance System (PCS) to allow for more effective program oversight. As part of the PCS modernization, a separate workgroup (including States and EPA) was devoted to the data needed to manage the biosolids program. Based upon the recommendations of this workgroup, the PCS Executive Council decided to add data elements to PCS to improve tracking and oversight of the biosolids program, and the draft detailed design was distributed for review. The detailed design document was finalized in September 2003, which served as the basis for the software development. The anticipated implementation date for the modernized PCS is December 2005, provided adequate funding is committed to this project.

EPA maintains that the land application of sewage sludge in compliance with EPA’s regulations is an appropriate choice for communities. Furthermore, the NRC (2002) found that “There is no documented scientific evidence that the Part 503 rule has failed to protect human health; however, additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to [sewage sludge].” Thus, EPA has directed its water enforcement and compliance resources to focus on risks posed by wet weather issues and untreated pollutants, including raw sewage and wastes associated with storm water,

sanitary sewer overflows, combined sewer overflows, and concentrated animal feeding operations. Both agriculture and urban runoff/storm sewers are listed in the top four sources of impaired river miles in the 2000 National Water Quality Inventory Report to Congress (section 305(b) report). Given the complexity and magnitude of addressing potential human exposures to pathogens and chemicals from untreated human and animal wastes from wet weather and the present scientific knowledge of the relative risks associated with biosolids and the above-mentioned compliance and enforcement efforts, there is an appropriate level of resources allocated to biosolids compliance and enforcement activities.

Petitioners emphasize that “EPA has no system to track and respond to health complaints related to exposure of sewage sludge.” Petition at 14. As mentioned above, this statement is also supported by findings in the 2002 OIG report. EPA received many public comments urging development of an incident tracking and response process. This was one of the highest research priorities identified by the NRC and participants at the July 2003 WERF Biosolids Research Summit. In response to this priority, WERF has committed to assemble stakeholders in a workshop to be held in 2004. EPA will participate in the workshop, which will begin evaluating the next steps for investigating adverse human health allegations following land application of sewage sludge. The long-term goal of this activity is to determine whether such reported symptoms of illness can be attributed to the land application of sewage sludge.

In order to respond to reported incidences of human illnesses and adverse health effects alleged to have been caused by land application of sewage sludge, and to determine the appropriate next steps in the process, EPA believes that local and State health agencies, in addition to other Federal health agencies, such as the Centers for Disease Control and Prevention (CDC), are positioned best and have the most appropriate expertise to respond to allegations of adverse health effects following use or disposal of sewage sludge. However, EPA plans to participate in the WERF workshop with other stakeholders to develop the research concepts and methods, and interpret and summarize results. This process, starting with a multi-stakeholder workshop, will take place at least through 2005. Additional activities beyond that time frame will depend on the outcome of the workshop and will take into consideration the limitations of such activity and availability of resources. Furthermore, EPA is communicating with CDC with the goal of collaborating in assessing human health incidents reportedly due to sewage sludge exposure.

In addition, EPA will conduct an Exposure Measurement Workshop during 2004 focusing on exposure measurement tools that researchers or health agencies can use to investigate reports of adverse human health effects from land-applied sewage sludge.

Conclusion

EPA has examined the information provided in the petition, as well as other sources of information, and finds no evidence to substantiate the claims they make concerning land-applied

sewage sludge. Petitioners do not present scientifically-based evidence or documentation that links the land application of sewage sludge or chemical pollutants allegedly contained in sewage sludge to human health and environmental impacts that are described in the petition. Consequently, EPA concludes that they do not justify their request for immediate moratorium on the land application of sewage sludge, which they ask to be implemented through a freeze on the issuance of new NPDES permits authorizing the land application of bulk sewage sludge and the reissuance of NPDES permits to require a method of sewage sludge disposal other than land application to replace all NPDES permits currently in force that allow the land application of bulk sewage sludge. In addition, for reasons set forth in this letter and in EPA's Federal Register notice announcing its 2003 biennial review of sewage sludge regulations under section 405(d)(2)(C) of the CWA, EPA concludes that they do not justify their request that EPA should initiate rulemaking to change the Part 503 Sludge Rule promulgated under the authority of the CWA at 40 CFR 503 to eliminate land application as an acceptable practice for sewage sludge disposal. For those foregoing reasons, the petition is denied.

EPA nevertheless recognizes that it is appropriate to continue exploring issues associated with the land application of sewage sludge. The aforementioned Federal Register notice, which we expect to be published by January 2004, will describe EPA's action plan for research and a targeted sewage sludge survey with the goal of reducing the scientific uncertainties associated with the land application of sewage sludge.

We would be happy to meet to discuss issues related to the land application of sewage sludge. Please contact Bob Cantilli in the Office of Water, Office of Science and Technology, at (202) 566-1091.

Sincerely,

G. Tracy Mehan, III
Assistant Administrator

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