REPORT OF THE
VIRGINIA DEPARTMENT OF HEALTH ON

THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S RESPONSE TO THE NATIONAL RESEARCH COUNCIL'S REPORT PERTAINING TO THE LAND APPLICATION OF BIOSOLIDS

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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Report of the Virginia Department of Health on the U.S. Environmental Protection Agency's Response to the National Research Council's Report Pertaining to the Land Application of Biosolids (Pursuant to SB 1088 of the 2003 General Assembly Session)

Introduction

In accordance with § 32.1-164.7(2) of the Code of Virginia, the Virginia Department of Health (VDH) has prepared a report to the State Board of Health and the Virginia General Assembly concerning the response of the United States Environmental Protection Agency (EPA) to the National Research Council's (NRC) July 2002 Report entitled "Biosolids Applied to Land: Advancing Standards and Practices." This study was mandated by SB 1088 of the 2003 General Assembly Session (see Appendix). In developing its findings and recommendations, VDH requested comments from other state agencies, local governments, and organizations and persons having an interest in the land application of sewage sludge through a general notice published in the April 5, 2004 issue of the Virginia Register. The VDH Report includes recommendations for revisions to current state laws and regulations governing the land application of sewage sludge as biosolids that VDH deems necessary to ensure protection of public health and safety, the environment and natural resources, agricultural land and state waters. Comments from Virginia Agencies received in response to the general notice are summarized in this report. No comments in response to the general notice were received from individual citizens or groups within the time period advertised in the general notice. Any subsequent public comments received will be carefully reviewed and considered by VDH.

In the April 9, 2003, Federal Register notice (68 FR 17384), EPA presented its preliminary strategy for responding to the NRC recommendations. In response to the NRC Report EPA identified three main objectives for attaining a better understanding of biosolids and reducing the potential for, or reducing the uncertainty related to, human health impact:

1. update the scientific basis of Part 503 by conducting research in priority areas,

2. strengthen the biosolids program by evaluating results of completed, ongoing, or planned studies both within and outside EPA, and

3. continue ongoing activities for enhancing communication with outside associations and with the public.

EPA's planned approach included promoting policy and procedural guidance for ensuring and maximizing the quality of the information disseminated. Completed studies and ongoing research, once compiled, would be reviewed and evaluated for their contribution to EPA's biosolids program in accordance with Information Quality Guidelines (expressed in "Guidelines for Ensuring and Maximizing the Quality,

Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency" USEPA 2002b). These guidelines stress that information disseminated by EPA should adhere to a basic standard of quality, including objectivity, utility, and integrity.

Over the next two years, subject to available resources, the Agency proposed to pursue biosolids activities in the following priority areas:

- Continue program implementation (regulatory, compliance, and enforcement).
- Evaluate the state-of-the-science and revise risk assessment methodologies, as appropriate.
- Review available data, track ongoing studies by researchers outside of EPA, and identify information gaps. Initiate further field studies as needed.
- Continue ongoing/planned activities relative to exposure, risk assessment, biosolids management, and analytical methods development.
- Determine what pollutants, if any, warrant further regulation under the CWA.
- Design and begin conducting a targeted survey that uses information obtained from published pollutant occurrence and effects data, State occurrence data bases, and input received during the public comment period.
- Conduct a dialogue with other health-based federal agencies, such as CDC, on the possibility of cooperatively tracking incident reports and investigating whether adverse human health outcomes can be associated with biosolids exposure. The results could help the Agency identify research gaps and, if appropriate, the need for a more comprehensive research plan.

These activities would be aimed at implementing NRC recommendations for reducing the potential for public health impact and updating the scientific basis of Part 503.

EPA Action Plan

The Agency's proposed long-term biosolids activities would depend on results of activities conducted in FY03/FY04 and available resources. The following priority areas were aimed at implementing recommendations for reducing the potential for public health impact:

- Continue program implementation (regulatory, compliance, and enforcement).
- Update the scientific basis of Part 503 by using FY03/04 research or by conducting research in priority areas.

- Strengthen the biosolids program by incorporating results of completed, ongoing, or planned research activities both within and outside EPA to possibly include: quantitative microbial risk assessment; improved understanding of exposure pathways/scenarios, molecular tracking study, etc.

- Continue activities to establish partnerships and communicate more effectively with other public health-based agencies, outside associations and the public.

EPA published a final action plan in response to the NRC Report in the December 31, 2003 ***Federal Register*** (Volume 68, Number 250) in which 14 projects were identified as priority areas of study (http://www.epa.gov/fedrgstr/EPA-WATER/2003/December/Day-31/w32217.htm). The 14 specific projects EPA identified in Section VII of the Federal Register notice are to be initiated over the next 2-3 years. They include:

- Project 1: Biennial Review Under CWA Section 405(d)(2)(C),
- Project 2: Compliance Assistance and Enforcement Actions,
- Project 3a: Optimization of the Method for Detecting, Enumerating, and Determining the Viability of Ascaris Ova in Biosolids,
- Project 3b: Improved Methods for Detecting Viruses in Biosolids,
- Project 3c: Development and Validation of Analytical Methods for Fecal Coliform in Biosolids,
- Project 3d: Development and Validation of Analytical Methods for Salmonella in Biosolids,
- Project 4: Field Studies of Application of Treated Biosolids,
- Project 5: Targeted National Survey of Pollutants in Biosolids,
- Project 6: Participate in an Incident Tracking Workshop,
- Project 7: Conduct Exposure Measurement Workshop,
- Project 8: Assess the Quality and Utility of Data, Tools and Methodologies to Conduct Microbial Risk Assessments on Pathogens,
- Project 9: Support Pathogen Equivalency Committee,
- Project 10: Development and Application of Analytical Methods for Detecting Pharmaceutical and Personal Care Products in Biosolids,
- Project 11: Publish the Proceedings of USEPA-USDA Workshop on Emerging Infectious Disease Agents and Issues Associated with Animal Manures, Biosolids, and Other Similar By-Products,
- Project 12: Support Sustainable Land Application Conference,
- Project 13: Review Criteria for Molybdenum in Land-applied Treated Biosolids, and
- Project 14: Improve Stakeholder Involvement and Risk Communication.

EPA stated that these 14 projects and associated activities will strengthen the biosolids program by improving the Agency's ability to:

- Measure pollutants of interest;
- Determine the risks posed by contaminants identified as potentially hazardous;
- Bring various stakeholder groups together via a workshop to begin development of a national incidence tracking system to ultimately determine health effects following land application of biosolids;
- Better understand and characterize the odors, volatile chemicals, and bioaerosols that may be emitted from land application sites;
- Better understand the effectiveness of biosolids processes and management practices to control pathogens;
- Improve the Agency's inspection and compliance initiatives; and
- Improve stakeholders' involvement in EPA's biosolids program.

There are two projects in the Agency's preliminary strategy (68 FR 17379):

1. re-evaluation of the risk assessment used for pollutants regulated or evaluated in Round One and
2. a molecular pathogen tracking exposure study, that EPA has decided not to do given all ongoing studies presented in the action plan, changing priorities, and limited resources.

The molecular pathogen tracking exposure study was intended to focus on individuals who have received medical attention and who suspect that they have been affected by sewage sludge application practices to potentially isolate causative agents. The Agency believes that such a study may still have merit, but in order to respond to reported incidents of human illnesses and adverse health effects alleged to have been caused by land application of sewage sludge, EPA believes that it should include various stakeholders who have had experiences with incidences related to sewage sludge, stakeholders who may be interested in participating, and those who have the expertise and should take part in helping to develop such a program. For this reason, EPA will participate in an incident tracking workshop to bring these stakeholders together and determine the next steps.

Section 405(d)(2)(C) of the Clean Water Act requires that EPA review the biosolids regulations for the purpose of identifying additional pollutants and promulgating regulations for such pollutants consistent with the requirements of section 405(d). As part of its biennial review, EPA also identified 15 pollutants for further review. They include: acetone, anthracene, barium, beryllium, carbon disulfide, 4-chloroaniline, diazinon, fluoranthene, manganese, methyl ethyl ketone, nitrate, nitrite, phenol, pyrene, and silver. These identified 15 pollutants do not mean that EPA has concluded that these pollutants in biosolids adversely affect human health or the environment. Some, or perhaps even all, of these pollutants may not be present in concentrations that warrant regulation; or a refined risk assessment may indicate that there is insufficient risk to human health or the environment to warrant regulation.

EPA stated that it does not have sufficient resources to implement all of the NRC recommendations, but does agree that certain projects can help reduce the persistent

uncertainty related to exposure to sewage sludge. EPA plans to review and evaluate completed research projects, both inside and outside EPA, as well as complete or begin other projects, to improve the basis for conducting risk assessments and upgrading the basis for the Part 503 regulations or improving management practices. Therefore, EPA has developed the final action plan in response to the NRC recommendations with consideration of public comments on the April 9, 2003, preliminary strategy, information gathered from broad stakeholder input received through the WERF Research Summit, and Agency priorities and resource availability. The final action plan is based on fiscal year (FY) 2004 estimated resources. For planning purposes, the Agency has assumed the same level of funding (i.e., at the estimated FY 2004 level) for future years; however, EPA recognizes that funding for FY 2005 and thereafter is subject to final appropriations.

Response From Other States

Comments concerning the action plan were sent to EPA on behalf of state biosolids coordinators, with concurrence from at least 40 states (some states were unable to respond in time for the submittal). The state biosolids coordinators requested EPA to weigh the comments as a collective representation from state officials who must implement and ensure regulatory compliance separately or in parallel with EPA. The submittal noted that several key areas should be given special consideration by EPA as the evaluation of the biosolids program continues and future policy decisions are made. These key issues are of national importance and include:

1. The viability of a national biosolids program, which includes responsible biosolids recycling, will be in question without a firm commitment of resources. Those resources need to be in both staffing levels and dollars. EPA should: provide access to expert technical support to states and maintain a national technical support program to include the Pathogen Equivalency Committee (PEC), provide general program oversight, coordinate and implement research and a research plan, and provide permitting activities in non-delegated states. The Agency should encourage and facilitate state delegation by seeking the appropriation of necessary funds from Congress.

2. Program priority should not be based on risk alone, but rather on the necessary level of program support and research to maintain its viability. Local restrictive bans on land application are often in response to a real or perceived lack of oversight in a particular locale and result from a lack of public confidence in program integrity. Public confidence in program oversight, regulatory adequacy, and long-term viability of Agency objectives should be considered when assessing priority.

The issuance of permits to sludge generators/biosolids recyclers is critical to demonstrate effective oversight and ensure compliance. A commitment is mandatory to achieve this either through the National Pollutant Discharge Elimination System program, Resource Conservation and Recovery Act, the Safe Drinking Water Act, or the

Clean Air Act. The permit issuance serves as the link between the regulator and the regulated entity. Once permits are issued, a standard protocol for compliance assistance and enforcement can and should be developed and implemented.

The State of Washington biosolids coordinator additionally commented as follows:

"Properly managed and with proper oversight, biosolids do not pose a significant risk to public health and the environment. It is more than evident, however, that many members of the public and even some agency staff at both federal and state levels do not share this belief. Concerns are only exacerbated by the common knowledge that EPA is not adequately implementing this program. In the business of risk management EPA should remember that *perception = reality*. Further, the capital and operating costs associated with the production, treatment and management of biosolids from treatment works are a significant portion of total costs, ranging to 30-40% by some accounts. While I do not question that clean water should be a higher priority for national and state environmental programs, EPA's attention to the second major effluent stream produced by treatment work*s* has been disproportionate as compared to the resources invested by treatment works and overall has simply been inadequate. Assumptions that public concerns are somehow mollified by assurances of low risk do not hold up under even the most casual scrutiny where there are conflicts around alleged impacts to public health. Further assumptions that the national program can remain viable on a diet of assurances are ill-advised at the very best. Not to diminish at all the hard work of many operators, consulting professionals, scholars, and trade organizations across the country, it is a simple fact that the viability of the national biosolids program has been largely sustained for several years by a relative handful of extraordinarily dedicated staff at the federal and state levels. I do not believe EPA as an institution has fully appreciated the level of effort and sacrifice that has been required of some of these people. Recognizing that some prioritization will occur and expecting that perhaps not all resources necessary can be allocated toward meeting the NRC recommendations, EPA must cease the caveats, pull-back from ideas borne of program disinvestment philosophy, and look within itself to reprioritize the funds necessary to adequately address the majority of the critical issues identified in the NRC report."

The following additional comments were provided to EPA by the State of Florida biosolids coordinator:

1. Regulatory Activities - Site Restrictions: While it may be more appropriate for state and local entities to adopt more stringent site management restrictions as indicated in the EPA response, Part 503 is expected to contain adequate, minimum standards for site restrictions. EPA made site management restrictions an integral part of the strategy in Part 503 to ensure the safety of Class B land application. Thus, after ten years of implementation experience with Part 503, it is recommended that EPA review the adequacy of current site restrictions as well as consider the recommendations by the NRC to evaluate potential new restrictions for various site-related factors such as site slope and depth to ground

water. Furthermore, existing site restrictions and any potential future ones should be reviewed by EPA with regard to the ability to reasonably enforce the restrictions, especially given the limited resources of the EPA and state biosolids staffs.

2. Regulatory Activities – Other Countries Regulations: In addition to the NRC's recommendation to review other countries' regulations, it is recommended that EPA review various state regulations as well as other federal agency regulations and programs for different viewpoints, perspectives, and regulatory strategies.

3. Biosolids Management – Regional Office Resources: The subject of resources for oversight by the EPA Regional offices, particularly field staff, are not adequately addressed by the EPA response. The current levels of staffing and enforcement by both EPA and states were known by the NRC panel during their study. Also, past EPA reports and documents that were available to the NRC panel would have indicated to the panel the general EPA position of basing funding for the biosolids program on the assessment of relative risks. However, it was after reviewing this information that the NRC panel came to the conclusion that increased resources were needed and thus, made the recommendation that EPA increase oversight resources. We recommend EPA consider increasing regional office resources as recommended by the NRC report.

4. Biosolids Management – State Funding: As mentioned above, despite knowing the current extent of state programs, the NRC panel recommended the EPA provide funding to state programs to help them provide additional, sufficient levels of oversight. While it is recognized that many of the EPA sponsored activities such as the annual EPA-funded state regulators meeting, the National Biosolids Partnership, the Biosolids Data Management System, and other activities are very beneficial to states and are vital to continue, additional funding would help states maintain and increase biosolids staffing levels. Since statements in other parts of the EPA draft response indicate that EPA is relying on states for enforcement of biosolids activities, it is recommended that the EPA reconsider the NRC recommendation of providing funding to states to support the biosolids program.

5. Biosolids Management – PEC: The NRC called for the Pathogen Equivalency Committee (PEC) to be formally funded, supported, and officially sanctioned as an integral part of the federal biosolids program. However, it appears that the EPA response only commits to continuing to operate the PEC as it does now, without formally allocating staff time, funding, or providing recognition in agency mission statements. We support the NRC recommendations regarding the PEC and it is recommended the EPA response be revised to commit to this recommendation.

WERF Research Summit

In July 2003, the Water Environment Research Foundation (WERF) organized the Biosolids Research Summit in response to the 2002 NRC report, Biosolids Applied to Land: Advancing Standards and Practices. Participants identified 31 potential highest-priority research projects in six categories needed to address concerns regarding land application of Class A and/or Class B treated sewage sludge/biosolids. The categories are: human health; pathogens; fate and transport of organic and inorganic chemicals; risk assessment; treatment, odor, and management; and social and economic issues. The WERF report describes these research priorities along with full summary of the event.

The Biosolids Research Summit Participants represented a range of views as to the appropriateness and safety of land applied biosolids/ treated sewage sludge and included a number of nontraditional stakeholders from the public arena in addition to traditional stakeholders. All Summit participants formed breakout groups to discuss the four sessions of work: 1) brainstorming what it takes to have credible and legitimate research, 2) brainstorming research areas that participants felt should make up the future research agenda, 3) agreeing on principles and strategies for credible and legitimate research, and 4) developing research concepts and templates for prioritization by the whole group. Summit participants identified 31 priority research projects. The WERF report (www.werf.org/pdf/03HHE1.pdf) documents the Summit proceedings. The transcripts from the summit are also available at: www.werf.org/pdf/MasterBiosolidsTranscript.pdf.

In the time since the NRC issued its report in 2002, EPA has taken steps to enhance its research program to improve the sewage sludge program and to begin implementing recommendations by the NRC. Much of EPA's research complements work being done by others outside the Agency, such as the research projects and the research issues identified at the July 2003 WERF Biosolids Research Summit. EPA plans to participate in and/or use, as appropriate, outside research, in conjunction with EPA-specific research, in order to make the most of the Agency's limited resources and to enhance the Part 503 program. EPA's research program includes projects that will be initiated or completed in the near term (i.e., through 2005).

Virginia Agency Comments

In accordance with § 32.1-164.7(2) of the *Code of Virginia*, VDH announced in the April 5, 2004 publication of the *Virginia Register* that it was preparing a report to the State Board of Health and the Virginia General Assembly concerning the EPA response to the NRC July 2002 Report. To assist in developing its findings and recommendations, VDH requested comments from other state agencies, local governments, and organizations and persons having an interest in the land application of sewage sludge. It was noted that the VDH Report is to include any recommendations for revisions to current state laws and regulations governing the land application of sewage sludge as

biosolids that VDH deems necessary to ensure protection of public health and safety, the environment and natural resources, agricultural land and state waters.

In response to the April 5, 2004 notice, the Hampton Roads Sanitation District (HRSD) commented as follows:

Based on NRC's conclusion that there is no scientific evidence to indicate failure of the EPA regulations to protect human health, the extensive research EPA has already initiated, and the proposed near future studies, HRSD recommends that no action be taken to revise current Virginia state laws concerning biosolids reuse at this time. The Virginia *Biosolids Use Regulations* (BUR) are more comprehensive than the Federal regulations and address site specific conditions beyond the EPA Part 503 requirements therefore providing an even greater level of protection to human health and the environment.

HRSD strongly recommends that VDH and the BUR Advisory Committee (BURAC) continue to monitor the results of the projects that EPA has outlined in the December 31, 2003 Federal Register Notice. If additional scientific information gathered from these projects indicates a modification to the BUR is necessary in order to protect human health and the environment, then the BURAC should develop recommendations for such changes to be brought to the Virginia Board of Health. In the interim, VDH should proceed with the proposed BUR modifications already in process.

The Virginia Department of Environmental Quality (DEQ) Division of Water staff concluded that based on their review of the EPA response, they would not recommend any immediate changes to the Virginia *Biosolids Use Regulations.*

However, DEQ stated that in light of the concerns raised by local governments and concerned citizens regarding biosolids impact on public health and the environment, a number of projects proposed in EPA's final action plan could be pursued at the state level to help allay these concerns. Specifically, DEQ offered the following comments for consideration by VDH:

1. Although no immediate changes should be made to state laws or the regulations in response to EPA's final action plan, VDH should closely monitor the results of the EPA biennial review under the Clean Water Act Section 405 (d)(2)(C) and the upcoming review of molybdenum criteria. The pollutant and pathogen criteria in the BUR should be revised if and when the federal standards are changed as a result of EPA's further review.

2. We recognize that VDH has begun the work to enhance compliance assistance and enforcement actions by providing guidance and training to the staff of Local Health Districts and local monitors. SB 1088 stipulates that the Board of Health shall promulgate regulations and standards for training, testing and certification of land applicators. We urge VDH to initiate the rulemaking process for the regulations of the land applicator certification program as soon as possible. The

training program developed under these regulations could also benefit the staff of Local Health Districts, local monitors, and other state agency staff.

3. One of the overarching recommendations made by the NRC report was to establish a framework for an approach to implement human health investigations. It suggested that the framework should include a means for tracking allegations and sentinel events (compliance, management, or health based), investigations and conclusions. We encourage VDH to participate in the Incident Tracking Workshop proposed by the Water Environment Research Foundation and work with other stakeholders to establish such a framework in the long term. In the short term and perhaps in a smaller scale, a complaint tracking system that contains incident responses and resolutions should be developed to replace the complaint report that is currently available on the VDH web site. The development and maintenance of the searchable electronic database will also fulfill the provision of SB 1088 (2003) regarding procedures for prompt investigation and disposition of complaints.

The staff of the Virginia Department of Conservation and Recreation (DCR) Nutrient Management Program offered the following:

1. The NRC Report recommended, "Exemptions from nutrient management and site restrictions for land application of bulk EQ biosolids should be eliminated." The current Biosolids Use Regulations 12 VAC 5-585 provides guidelines on marketing and distribution and a loading rate of approximately one pound dry weight of biosolids per square foot. We would recommend that the Biosolids Use Regulations include nutrient management practices for the land application of bulk exceptional quality (EQ) biosolids including site restrictions to protect state waters from the loss of nitrogen and phosphorus to the environment. Since §32.1-164.5 of the Code of Virginia requires site-specific nutrient management plans to be developed prior to land application for all sites where sewage sludge is land applied, the Biosolids Use Regulation should be revised to be conform with this Virginia statute and should include all applications of bulk EQ biosolids. An exception to this could be considered for exceptional quality biosolids that also have a final carbon to nitrogen ratio of greater than 25 to 1.

2. The NRC Report indicated that EPA should include more site-specific controls on winter applications of biosolids. The Biosolids Use Regulations allows biosolids applications on high-risk sites during late fall and winter. In considering the NRC Report and research conducted in Virginia that indicated losses of nitrogen from late fall and winter applications are likely greater than once believed, additional controls are needed during this time period. We recommend that the rates, timing, and management practices of the late fall and winter applications of biosolids in the current Biosolids Use Regulations be revised to ensure protection of the water quality, particularly the leaching of nitrate to groundwater.

3. The NRC Report indicated that Part 503 does not address phosphorus, while phosphorus concentration in sewage sludge is increasing due to wastewater treatment plants ncreasingly being forced to limit phosphorus in their discharge. The NRC (1996) Report recommended: "Where excess phosphorus is of concern, soil phosphorus levels should be monitored and biosolids application rates should be adjusted to correspond to crop phosphorus rather than nitrogen." We recommend that the Biosolids Use Regulations be revised to more clearly address phosphorus concerns. DCR has begun a regulatory revision process for our Nutrient Management Training and Certification Regulations. Since future biosolids application sites will require nutrient management plans developed by a certified individual, VDH could simply adopt whatever phosphorus criteria results from the DCR regulatory revision.

4. The report recommends that "a process should be established to track allegations and sentinel events (compliance, management, or health based), investigations, and conclusions." If such a system does not already exist within VDH, we suggest that an appropriate tracking system be devised and implemented.

Land Applier Comments

In response to the VDH notice, Synagro Technolgies, Inc. commented as follows:

The NAS/NRC report recommended updating exposure assessment concepts for the reasonable maximum exposure individual, refined fate and transport models, and conducting exposure studies for preplanned population groups. EPA proposes to continue some existing studies, use literature to focus new studies, and develop a plan for a molecular pathogen tracking study. The proposed molecular tracking study has potential pitfalls—self-identification is problematic, because there needs to be physician verification for credibility and accountability. Additionally, there are no existing standardized protocols for these studies. Furthermore, all sources of pathogens need to be identified—not only biosolids. However, the real focus needs to be on the on-going studies being conducted by WERF, the NSF-WQC, and USDA.

Synagro noted that EPA should consider the following factors in regard to pathogen risk assessment efforts.

- EPA should not undertake quantitative microbiological risk assessments unless it has developed and published a peer-reviewed guidance document that has the approval of the Science Advisory Board. Anything less would not comply with the Information Quality Guidelines.
- Quantitative microbial risk assessment (QMRA) is a relatively new tool that has neither a history of use in rule making nor the degree of validation necessary to ensure its reliability. The elements of a QMRA are similar to those of a chemical risk assessment. QMRA requires problem formulation, exposure analysis, pathogen occurrence analysis, evaluation of potential health effects and the dose-

response relationship and the combination of this information in a risk characterization.

Synagro added that the NAS/NRC report called for response incident investigations, targeted exposure surveillance, and well-designed epidemiological studies. EPA has proposed developing a tracking mechanism with CDC and collaborative exposure assessment work with USDA, State of PA, and the NSF-WQC at the University of Arizona. Synagro listed the following issues as problematic for investigating claims of illness:

- No documented cases of human illness to date directly related to transmission of biosolids constituents.
- Meaningful epidemiological studies probably can't be done because of confounding factors, lack of exposure methods, small population near land application sites, etc.
- Physicians and local health departments should be first point of contact and screen out unjustified complaints and work with state environmental agencies.
- CDC could keep national database of justified complaints, documented illnesses.
- Any health studies should be conducted using good practice and standard protocols.
- Epidemiological definitions of causation should be standard for linking complaints to biosolids exposure.

Synagro concluded that until there is evidence that biosolids recycling has caused health problems, EPA should not consider any studies that would waste valuable taxpayer's dollars. EPA should not waste taxpayers' money on frivolous studies suggested by a small vocal minority of self-interested researchers. These are actions that make Congressional Oversight hearings so difficult for EPA.

Synagro also stated that, the burden of proof should be on those making allegations of deaths and serious illnesses (the so called "sludge victims"). All that is available is anecdotal information that documents nothing. The only epidemiological study done with biosolids was the Ohio Farm Study in 1985 that showed no problems with families living near sites where biosolids were land applied compared to families living on farms where no biosolids were used. If EPA wants to spend any money in this area, it should be to fully investigate some of the claims of the so called "sludge victims" with an independent and credible third party, such as the CDC.

VDH Biosolids Work Group

To ensure ongoing review of the public health aspects of the land application of biosolids, a VDH Biosolids Workgroup comprised of eight District Health Directors (physicians) who are preventive medicine specialists, an epidemiologist and a toxicologist, has been established by the State Health Commissioner. The workgroup conducted a review of the 2002 National Academy of Sciences study report and attended

a seminar presentation on bioaerosols studies given by University of Arizona researchers in order to advise the State Health Commissioner and the State Board of Health on public health aspects of the program. The Biosolids Workgroup also had a very informative presentation by Bob Jacobs from Eastern Virginia Medical School on current research on health risks of biosolids aerosols. A summary of the Biosolids Workgroup findings was presented to the Board of Health at their July 25, 2003 meeting. The workgroup concluded that a moratorium on the land application of biosolids was not necessary. The VDH Biosolids Workgroup will also serve to establish a system for local health department review of health issues involved with biosolids applications.

The VDH Biosolids Workgroup concluded that the public should identify potential scientific data that addresses their concerns. Public interest reflects genuine concern. It also reflects the growing knowledge that processes such as these are not static but changing. It suggests we need a mechanism in the Commonwealth to address these ongoing concerns, similar to NRC type periodic review of the latest evidence and/or materials, done for the EPA. However, it is imperative to solicit recommendations from all sides of these issues, to allow all sides to be recognized and heard. The Biosolids Workgroup also concluded that the current regulations should be routinely re-examined as well as the assumptions/studies used to develop the past governing policy recommendations. Any new materials that could challenge the conclusions of the past should be closely evaluated. Most if not all members of the VDH Biosolids Workgroup agree that any consideration of the health effects of biosolids cannot be done in a vacuum. Rather the consideration of the health effects of all available waste management techniques must be examined to put concerns about health effects of biosolids in an appropriate context/reference.

Amendments to the Biosolids Use Regulations

The Biosolids Use Regulations (12 VAC 5-585) were adopted by the Board of Health in 1995 pursuant to Section 32.1-164.5 of the *Code of Virginia.* The Biosolids Use Regulations were subsequently revised, effective on October 15, 1997, in accordance with the Virginia Administrative Process Act (APA). The State Board of Health adopted amendments to the Biosolids Use Regulations providing for the collection of land application fees and the reimbursement of local monitoring expenses at its January 31, 2003 meeting. Those amendments became final in March 2003.

A Petition for Rulemaking was submitted by Synagro WWT, Inc., Recyc Systems, Inc., and Nutri-Blend Inc., corporations that have been issued permits for land application of biosolids in various Virginia counties, through the Biosolids Use Regulations. The APA (Section 2.2-4007.A of the *Code of Virginia*) provides that any person may petition an Agency to amend an existing regulation. The Petition for Rulemaking requested that the Biosolids Use Regulations be amended with respect to the following requirements:

1. Posting of informational signs at permitted sites prior to and during land application of biosolids. Specifying sign dimensions, informational content and location.

2. Evidence of financial responsibility (such as liability insurance or other financial resources) in a determined amount, provided by permit applicants and maintained by permitted entities, established for the purpose of compensating third parties for personal injury or property damage, and removing, or remedy of, any established environmental contamination, resulting from the land application of biosolids.

3. Notification of Local Governments prior to the land application of biosolids at specific sites. The contents and timing of such notices is to be specified.

4. Development and implementation of spill prevention and response plans by permitted entities. Such plans are to also address the tracking of residues on State Roads by biosolids transport vehicles.

5. Methods for communicating information on complaints and reported incidents related to or arising from the land application of biosolids.

The requested amendments to the Biosolids Use Regulations will involve the following specific sections of the regulations:

1. 12 VAC 5-585-310
2. 12 VAC 5-585-460
3. 12 VAC 5-585-480
4. 12 VAC 5-585-490

A Regulations Advisory Committee (BURAC) has assisted the VDH in developing amendments to the Biosolids Use Regulations that were approved by the Board of Health as proposed amendments in accordance with the APA. The amendments reflect the recommendations from a majority of committee members. The amendments as requested by the petition from the land appliers will be noticed in the Virginia Register establishing a 60 day public comment period and a date, time and location for a public hearing. The proposed amendments with any revisions necessary to address public comment will then be presented to the Board of Health for consideration as final amendments to begin the process of promulgation in accordance with the APA.

Section 12 VAC 5-585-500 of the Biosolids Use Regulations is to be revised to provide for field storage as an alternative to routine storage. The use of smaller temporary storage sites located near land application operations has provided an alternative that minimizes the operational problems associated with larger routine storage facilities. However, the approval of temporary storage for biosolids, in excess of that transported to a site during a single day operation and not land applied on that site that day, has required the issuance of variances to the Regulations (12 VAC 5-585-90). The issuance of such variances is time consuming and costly. Variances are a case-by-case

response to a situation that could be more effectively and efficiently addressed by a consistent statewide requirement and policy.

The Field Storage Amendment was presented to the State Board of Health at its October 24, 2003 meeting for its approval as a proposed amendment. The State Board of Health recommended that several revisions be made to the draft amendment, including providing a standard 500 foot buffer zone around the field storage site. Other recommendations included revisions to the draft seasonal storage requirements. The State Board of Health recommendations have been included in the proposed amendment. The proposed amendment will now be processed through administrative review in accordance with the APA.

The legislation passed by the General Assembly in 2003 (SB 1088) also provides for amendments to the Biosolids Use Regulations. The adopted legislation requires nutrient management plans (NMPs) prepared by persons certified by the Virginia Department of Conservation and Recreation (DCR) for all land application sites, regardless of the frequency of application. Under the current regulations, only sites where biosolids are applied more than once every three years are required to prepare NMPs prior to permit issuance. The bill also requires DCR approval of all NMPs for sites where the permit authorizes land application more than once every three years at greater than 50 percent of agronomic rates, and certain sites operated by the owner or lessee of a Confined Animal Feeding Operation or Confined Poultry Feeding Operation. The legislation allows VDH to incorporate into the permit reasonable site-specific special conditions to protect the environment or the health, safety and welfare of persons residing in the vicinity of the proposed application site. VDH must also include in its notice of special conditions such site-specific conditions recommended by the locality. The permit applicant will have at least 14 days to respond to the proposed conditions and any objections shall be heard by the State Health Commissioner. The legislation requires permit holders to provide VDH with evidence of financial responsibility, to be established by regulation, which shall be available to pay claims for cleanup costs, personal injury and property damage. The legislation creates a land application certification program to be established by VDH pursuant to which all future land application sites must have a certified land applicator on location at all times during the application process. The legislation grants localities that have adopted a biosolids testing and monitoring ordinance the authority to order the abatement of land application activity for violations of relevant laws and regulations. In addition, VDH is to establish a standard complaint and investigation procedure, including the maintenance of a searchable electronic database of complaints.

The BURAC has developed draft amendments concerning land application site management practices. The amendments would revise current requirements in the Biosolids Use Regulations as follows:

1. 12 VAC 5-585-70. Specify the procedures for resolving disputes involving local ordinances and alleged permit violations.

2. 12 VAC 5-585-510A. Require Best Management Practices or prohibit application to sites with soils identified as having a high potential for erosion. Require timely planting of a cover crop for seasonal applications to sites with certain soil characteristics.

3. 12 VAC 5-585-610. Include specific restrictions on applications to soils with high phosphorus levels.

4. 12 VAC 5-585-630A. Require a nutrient management plan approved by the Virginia Department of Conservation and Recreation to be submitted for all sites prior to permit issuance where the permit authorizes land application more frequently than once every three years at greater than 50 percent of the annual agronomic rate. A nutrient management plan approved by the Virginia Department of Conservation and Recreation shall also be submitted prior to permit issuance for proposed application sites owned or operated in conjunction with animal waste operations.

Draft amendments for these will be prepared by VDH staff for presentation to the Board of Health to be considered for approval as proposed amendments that would be processed through administrative review in accordance with the APA.

VDH Recommendations

The NRC report encouraged the Environmental Protection Agency (EPA) to initiate appropriate risk assessment studies to determine the impact of biosolids exposure on workers and local populations. The Final Action Plan developed by EPA outlines the programmatic steps necessary for evaluating human health outcomes as a result of biosolids exposure. As the results of the proposed studies become available, it may be possible to better assess the necessary management practices requirements for sites where biosolids are to be applied. However, in spite of the current projections of low risk levels an appropriate level of resources must be maintained to support a credible regulatory program. The Commonwealth should routinely re-examine the assumptions/studies used to develop the past governing policy recommendations as well as any new materials that could challenge the conclusions of the past. This report as required under SB 1088 (2003) is a vehicle for accomplishing this objective.

If additional scientific information gathered from the initiatives and projects described in EPA's Final Action Plan indicates that modifications to state laws and regulations are necessary in order to protect human health and the environment, then amendments to the regulations will be developed and brought to the State Board of Health for adoption. Also, the state regulations will be revised as appropriate to reflect any changes to the federal regulations and standards. In the interim, VDH will proceed with the proposed amendments already in process including the requirements specified in SB 1088 (2003).

Additional recommendations for VDH actions include the following:

1. Develop standard procedures for incident response and investigation of complaints of illness due to exposure to biosolids.

2. Encourage local governments to both adopt appropriate ordinances and to establish local monitoring and testing capabilities in cooperation with Local Health Departments.

3. Continue to train local biosolids monitors.

4. Initiate the rulemaking process establishing regulations for the land applicator certification program as soon as possible.

5. Develop databases for permit information and complaint resolution tracking.

6. Develop standard permit compliance and enforcement protocols.

APPENDIX

VIRGINIA ACTS OF ASSEMBLY -- 2003 SESSION

CHAPTER 681

An Act to amend and reenact § 32.1-164.5 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 32.1-164.6 and 32.1-164.7, relating to land application of sewage sludge; study; report.

[S 1088]

Approved March 19, 2003

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-164.5 of the Code of Virginia is amended and reenacted, and that the Code of Virginia is amended by adding sections numbered 32.1-164.6 and 32.1-164.7 as follows:

§ 32.1-164.5. Land application, marketing and distribution of sewage sludge; regulations.

A. No person shall contract or propose to contract, with the owner of a sewage treatment works, to land apply, market or distribute sewage sludge in the Commonwealth, nor shall any person land apply, market or distribute sewage sludge in the Commonwealth without a current Virginia Pollution Abatement Permit from the State Water Control Board or a current permit from the State Health Commissioner authorizing land application, marketing or distribution of sewage sludge and specifying the location or locations, and the terms and conditions of such land application, marketing or distribution.

B. The Board of Health, with the assistance of the Departments of Environmental Quality and Conservation and Recreation, shall promulgate regulations to ensure that (i) sewage sludge permitted for land application, marketing or distribution is properly treated or stabilized, (ii) land application, marketing and distribution of sewage sludge is performed in a manner that will protect public health and the environment, and (iii) the escape, flow or discharge of sewage sludge into state waters, in a manner that would cause pollution of state waters, as those terms are defined in § 62.1-44.3, will be prevented.

C. Regulations promulgated by the Board of Health, with the assistance of the Departments of Environmental Quality and Conservation and Recreation pursuant to subsection B of this section, shall include:

1. Requirements and procedures for the issuance and amendment of permits as required by this section;

2. Procedures for amending land application permits to include additional application sites and sewage sludge types;

3. Standards for treatment or stabilization of sewage sludge prior to land application, marketing or distribution;

4. Requirements for determining the suitability of land application sites and facilities used in land application, marketing or distribution of sewage sludge;

5. Required procedures for land application, marketing and distribution of sewage sludge;

6. Requirements for sampling, analysis, record keeping and reporting in connection with land application, marketing and distribution of sewage sludge;

7. Provisions for notification of local governing bodies to ensure compliance with §§ 32.1-164.2 and 62.1-44.15:3;

8. ~~Conditions where a~~ *Requirements for site-specific* nutrient management ~~plan approved by the Department of Conservation and Recreation may be required.~~ *plans, which shall be developed by persons certified in accordance with § 10.1-104.2 prior to land application for all sites where sewage sludge is land applied, and requirements for approval of nutrient management plans by the Department of Conservation and Recreation prior to permit issuance under specific conditions, including but not limited to sites operated by an owner or lessee of a Confined Animal Feeding Operation, as defined in subsection A of § 62.1-44.17:1, or Confined Poultry Feeding Operation, and sites where the permit authorizes land application more frequently than once every three years at greater than 50 percent of the annual agronomic rate; and*

9. Procedures for the prompt investigation and disposition of complaints concerning land application of sewage sludge, including the requirements that (i) holders of permits issued under this section shall report all complaints received by them to the State Department of Health and to the local governing body of the jurisdiction in which the complaint originates, and (ii) localities receiving complaints concerning land application of sewage sludge shall notify the Department and the permit holder. The Department shall maintain a searchable electronic database of complaints received during the current and preceding calendar year, which shall include information detailing each complaint and how it was resolved.

D. ~~The Board of Health shall adopt regulations in accordance with this section not later than October 1, 1994. The Board of Health may adopt, as final, proposed regulations that were the subject of public notice and for which one or more public hearings or informational meetings were held in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) after July 1, 1993, and prior to September 30, 1994.~~ *Where, because of site-specific conditions identified during the permit application review process, the Department determines that special requirements are necessary to protect the environment or the health, safety or welfare of persons residing in the vicinity of a proposed land application site, the Department may incorporate in the permit at the time it is issued reasonable special conditions regarding buffering, transportation routes, slope, material source, methods of handling and application and time of day restrictions exceeding those required by the regulations promulgated under this section. Before incorporating any such conditions into the permit, the Department shall provide written notice to the permit applicant, specifying the reasons therefor and identifying the site-specific conditions justifying the additional requirements. The Department shall incorporate into the notice any written requests or recommendations concerning such site-specific conditions submitted by the local governing body where the land application is to take place. The permit applicant shall have at least 14 days in which to review and respond to the proposed conditions. Should the permit applicant object to the inclusion of any such condition, the approval of the Commissioner shall be required before the condition objected to may be included in the permit.*

E. The Board may adopt regulations prescribing a reasonable fee not to exceed $2,500 to be charged for the direct and indirect costs associated with the processing of an application to issue, reissue, amend or modify any permit to land apply, distribute or market sewage sludge pursuant to this section.

F. There is hereby established in the treasury a special fund to be known as the Sludge Management Permit Fee Fund, hereinafter referred to as the fund. The fees required by this section shall be transmitted to the Comptroller to be deposited into the fund. The income and principal of the fund shall be used only and exclusively for the direct and indirect costs associated with the processing of an application to issue, reissue, amend or modify any permit to land apply, distribute or market sewage sludge. The State Treasurer shall be the custodian of the moneys deposited in the fund. No part of the fund, either principal or interest earned thereon, shall revert to the general fund of the state treasury.

G. ~~Any permit, certificate or authorization for the land application, marketing or distribution of sewage sludge issued prior to October 1, 1994, shall remain in effect for the remainder of the term specified in such permit, certificate or authorization. Such permits, certificates and authorizations may be amended in accordance with the Administrative Process Act (2.2-4000 et seq.). Any amendment after the adoption of the regulations specified in this section shall be in accordance with such regulations.~~ *All persons holding or applying for a permit authorizing the land application of sewage sludge shall provide to the Department written evidence of financial responsibility, which shall be available to pay claims for cleanup costs, personal injury and property damages resulting from the transportation, storage or land application of sewage sludge. The Board of Health shall, by regulation, establish and prescribe mechanisms for meeting the financial responsibility requirements of this section.*

§ 32.1-164.6. Certification of Sewage Sludge Land Applicators.

A. The Board, with the assistance of the State Department of Health, Department of Environmental Quality and Department of Professional and Occupational Regulation shall promulgate regulations and standards for training, testing and certification of persons land applying Class B sewage sludge in the Commonwealth, and for revoking, suspending or denying such certification from any person for cause. The regulations shall include standards and criteria for the approval of programs of instruction taught by governmental entities and by the private sector for the purpose of certifying sewage sludge land applicators. The Board shall promulgate the regulations and standards required by this subsection by no later than July 1, 2004.

B. No person shall land apply Class B sewage sludge pursuant to a permit under § 32.1-164.5 or § 62.1-44.19:3 unless a certified sewage sludge land applicator is onsite at all times during such land application, as of 180 days following the effective date of regulations required by this section.

§ 32.1-164.7. Local enforcement of sewage sludge regulations.

Any locality that has adopted an ordinance for the testing and monitoring of the land application of sewage sludge pursuant to § 62.1-44.19:3 shall have the authority to order the abatement of any violation of §§ 32.1-164.5, 32.1-164.6 or § 62.1-44.19:3 or of any violation of any regulation promulgated under those sections. Such abatement order shall identify the activity constituting the violation, specify the Code provision or regulation violated by the activity and order that the activity cease immediately.

In the event of any dispute concerning the existence of a violation, the activity alleged to be in violation shall be halted pending a determination by the Department, whose decision shall be final and binding unless reversed on judicial appeal pursuant to § 2.2-4026. Any person who fails or refuses to halt such activity may be compelled to do so by injunction issued by a court having competent jurisdiction. Upon determination by the Department that there has been a violation §§ 32.1-164.5, 32.1-164.6 or § 62.1-44.19:3 or of any regulation promulgated under those sections and that such violation poses an imminent threat to public health, safety or welfare, the Commissioner shall commence appropriate action to abate the violation and immediately notify the chief administrative officer of any locality potentially affected by the violation. Neither the Commissioner, the Commonwealth, nor any employee of the Commonwealth shall be liable for failing to provide the notification required by this section.

2. That the State Department of Health shall review the July 2002 Report of the National Research Council titled "Biosolids Applied to Land: Advancing Standards and Practices," the June 2003 comment and response document prepared by the U.S. Environmental Protection Agency and the December 2003 recommendation by the U.S. Environmental Protection Agency for revisions to the federal regulations governing the land application of sewage sludge, as well as plans and recommendations developed by the U.S. Environmental Protection Agency in response to such report, and shall submit an executive summary and report its findings and recommendations to the Virginia State Board of Health and the General Assembly no later than June 30, 2004, as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports. The executive summary and the report shall be posted on the General Assembly's website. In developing its findings and recommendations, the Department shall request comments from other state agencies, local governments, and organizations and persons having an interest in the land application of sewage sludge. The report shall include any recommendations for revisions to current state laws and regulations governing the land application of sewage sludge that the Department deems necessary to ensure protection of public health and safety, the environment and natural resources, agricultural land and state waters. The Virginia State Board of Health shall initiate rulemaking proceedings pursuant to § 2.2-4007 no later than September 1, 2004, should the Board determine such proceedings are necessary to implement any such recommendations.