

## **A Review of a “*Health Survey of Residents Living Near Farm Fields Permitted to Receive Biosolids*”**

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This review was released by the Ohio Water Environment Association to fulfill its mission to “educate our members and the public by sharing information.” The technical review was prepared by Nicholas Basta, Professor of Soil and Environmental Chemistry, School of Environment and Natural Resources, The Ohio State University, Columbus, OH and by members of the Ohio Water Environment Association Residuals Management Committee. The following researchers and scientists were contacted for their review of the paper and provided comments used in the preparation of this document: Timothy Buckley, Rufus Chaney, Paul Chrostowski, Samuel Dorevitch, Charles Gerba, and Ian Pepper

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**Summary:** “Health Survey of Residents Living Near Farm Fields Permitted to Receive Biosolids” (Health Survey) is a research article that has serious flaws that result in unreliable conclusions. A panel of scientists with backgrounds in public and human health—epidemiology, biostatistics, environmental microbiology and environmental science—reviewed the Health Survey and identified three significant errors: 1) incomplete and biased review of scientific literature in forming the study’s hypothesis; 2) flawed design of a research methodology to investigate the authors’ hypothesis; and 3) incomplete and erroneous interpretation of the data derived from the research methodology. While a “Fact Sheet” published subsequent to the article by the authors acknowledged weaknesses of the research design, specifically reporting bias from self-reported incidences of illness, the broader flaws of the study point to more fundamental limitations. Therefore, conclusions drawn from the Health Survey do not have merit.

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**Background:** In 2005, faculty and students from The University of Toledo and Bowling Green State University conducted a survey of self-reported health conditions of residents in Wood County, Ohio (the Health Survey). Health conditions were assessed for residents (1) living on or within one mile of farm fields that were permitted to receive biosolids; and

(2) those residents living greater than one mile from biosolids-permitted farm fields.<sup>(1)</sup>

Faculty and students mailed health surveys to 607 households and received completed surveys from 437 people allegedly exposed to biosolids (living on or within one mile of fields where application was permitted) and from 176 people not exposed to biosolids (living more than one mile from the fields where application was permitted). The authors allowed up to six surveys per household. In summary, the authors reported results that revealed that some reported health-related symptoms were statistically and significantly elevated among the allegedly exposed residents. The authors said, “The findings suggest an increased risk for certain respiratory, gastrointestinal, and other diseases among residents living near farm fields on which the use of biosolids was permitted. However, further studies are needed to address the limitations cited in this study.”

Following publication of the Toledo Health Study in 2007, the authors released a fact sheet (*Health Survey of Residents Living Near Farm Fields Permitted To Receive Biosolids Fact Sheet*). Using a question and answer format, the study authors wrote:

***Do the results and conclusions from your published paper demonstrate that people who reside in close proximity to biosolids land application sites develop a variety of ill-***

*nesses? No. Because these results are based on self-reported symptoms, it is possible that reporting bias and self-selection could have influenced results. Surveys that require self-reporting of data have limitations and should be interpreted with caution. Respondents may have the tendency to under-report behaviors that are socially undesirable, unhealthy, or illegal and over-report desirable behaviors screening. The accuracy of self-reported information also is affected by the ability of respondents to fully recall past behaviors or health screening results. Additionally, the symptoms and diseases were listed for respondents and the questions were not open-ended. This study did not firmly demonstrate that there is a threat to health by living near fields where biosolids are permitted. The study showed statistical associations, which is not the same as causation. Other influences may be at work, including the possibility that individuals living near biosolids-permitted fields relate odors and other biosolid debris to possible health effects and the possibility that the people surveyed may be more prone to report diseases and symptoms. This research is a starting point. Additional studies are needed to further determine any potential for health risk.*

Various agencies in the State of Ohio contacted the Ohio Water Environment Association (OWEA) and The Ohio State University (OSU) for their comments on the “Health Survey of Residents Living Near Farm Fields Permitted to Receive Biosolids.” Dr. Nicholas Basta from Ohio State University solicited external reviews of the manuscript. In 2008, a panel of leading researchers and scientists with backgrounds in public and human health, outside of Ohio reviewed Health Survey of Residents Living Near Farm Fields Permitted to Receive Biosolids. They were asked to assess the competence of the study and concluded it has several critical flaws. Specifically cited in their assessments were:

- Lack of acknowledgement of the substantial body of scientific research on this topic
- Inappropriate citing of supporting documentation

- Inappropriate protocol to support the hypothesis that a hazard exists
- Utilization of a research supposition that self-reporting symptoms is valuable
- Lack of a control for the survey
- Lack of specific and follow-up data associated with farm fields permitted to receive biosolids
- The listing of polio as a chronic disease
- No attempt to determine if biosolids were applied on the permitted fields, nor what other additives may have been applied.

Overall, the researchers and scientists concluded the findings from *Health Survey of Residents Living Near Farm Fields Permitted to Receive Biosolids* do not have merit.

### **Faults of Research Methodology**

The description of the research methods leave important questions unanswered, and these significant methodologic issues preclude drawing conclusions from this study.<sup>(2)</sup> The weak methodology used makes the conclusions of the Health Survey questionable. Major deficiencies of this study include, but are not limited to, the following:

- The Health Survey only focuses on farm fields permitted to receive biosolids. There is no confirmation that the fields actually received biosolids, and no information on application rates and dates of application. It is common for 2 to 5 times more acreage to be permitted than can be amended in one crop year to assure adequate available land. This is done to accommodate changing crop plans by farmers. Therefore, the classification of respondents into those living near and far from biosolids applied fields is very likely in substantial error.
- No control population is used in this study. It is well established that farm operations without land application of biosolids result in the aerosolization of endotoxin and heterotrophic plate count bacteria that can cause respiratory problems.<sup>(3)</sup> The appropriate control for this study should have been farm fields that had not received bio-

solids. Without this control the conclusions of the Health Survey are invalid.

- Exposure was defined as proximity to a permitted farm. This is quite different than exposure to biosolids. Permitted farms may not have received any biosolids, received biosolids years prior to the Health Survey, or may have received biosolids after the health information was collected. This is a major threat to the validity of the exposure classification system (exposed vs. not). While all households on permitted fields were enrolled into the exposed group (as were other households less than one mile from such farms), households in the unexposed group could be miles away. In other words, the “exposed” households were either on or near farms, while the “unexposed” were some distance from farms. Given that Wood County contains large towns (Bowling Green and Perrysburg), unexposed homes may not be located on or near farms at all. Thus, any difference noted between the two groups may reflect differences between residents of farms and residents of towns, rather than any effect of biosolids exposure. A more relevant comparison would have been residents of farms with biosolids application vs. residents of farms without biosolids application. As the authors note, it is also unclear if the one-mile distance is a reasonable data point for exposure difference between the groups, since no exposure measurements were made.<sup>(2)</sup>
- There is no discussion of how the researchers determined what questions would be included in the Health Survey. They indicate that individuals responding to the Health Survey might be polarized by the survey contents. However, without having the opportunity to review the Health Survey questions it is impossible to determine if those responding were polarized, which could result in incorrect conclusions.
- There was no use of established protocols to evaluate the hypothesis that a pathogenic organism causes a disease.<sup>(4)</sup> In fact, the study authors failed to identify a single organism either in biosolids, an exposure pathway, or a receptor that could be respon-

sible for the signs and symptoms reported in the Health Survey. Rather, they inferred that pathogens were present in biosolids, that people were exposed to these pathogens, and that disease resulted from this exposure. Unfortunately, the study authors took this inference a step further. In the Health Survey they did not evaluate fields where biosolids were applied, but fields that were permitted to receive biosolids. Not only does this ignore the fundamental concept of a dose-response relationship in microbial risk assessment,<sup>(5)</sup> but it ignores the possibility that no biosolids were applied prior to the Health Survey. At the very least, the Health Survey should have identified the amount of biosolids applied, type of application, and pathogen (or indicator) density.<sup>(6)</sup>

#### **Omission of Reviews of Existing Literature**

While there have not been any scientifically-documented cases of illnesses caused by biosolids, there have been a number of scientific studies that demonstrate the difficulty of transmitting biosolids-related diseases or illnesses through the air. The study authors did not include critical literature on land application. Research that was not referenced in the article include the following:

Research by Rusin et al.<sup>(7)</sup> in 2003 tested for the presence of *S. aureus* in biosolids and in aerosols. To determine if *S. aureus* is present in biosolids, samples were collected from 15 sites across the United States. Samples analyzed were as follows: 3 raw untreated sewage samples and 2 undigested primary sewage sludge samples; 23 different biosolids samples; and 27 aerosols obtained during biosolids land application. The authors discovered that although *S. aureus* was detected in raw sewage samples, none were found in any of the treated biosolids or in any biosolids aerosol samples. These results suggest that biosolids are not a likely source of *S. aureus* human exposure or infection, and reported no detectable *S. aureus* in biosolids ready for land application.

In 2005, Brooks, J.P. et al. conducted a “*National Study on the Residential Impact of Biological Aerosols from the Land Application of Biosolids.*” The purpose of the study was to

evaluate the community risk of infection from bioaerosols to residents living near biosolids land application sites. Approximately 350 aerosol samples from 10 sites located throughout the United States were collected using bio-samplers. The study evaluated the overall incidence of aerosolized microorganisms from the land application of biosolids and subsequently determined that microbial risks of infection were low for residents close to biosolids application sites.

In 2000, Dowd et al.<sup>(8)</sup> reported that even immunocompromised individuals would be at little risk of infection from aerosolized bacteria and at no risk from aerosolized viruses associated with land application of biosolids. And, Tanner et al.<sup>(9)</sup> in 2005 found that the duration of bioaerosol exposure immediately downwind of spray application of biosolids was brief and that aerosolization of coliphages and coliform bacteria after liquid biosolids have been applied to land does not occur at detectable levels.

While ignoring the substantial body of scientific research, the study authors elected to cite the work of David Lewis *et al.*<sup>(10)</sup> to support their conclusions. Lewis' work cited by the authors was developed solely on anecdotes and contains no specific medical information, risk assessment, pathogen measurements or standard epidemiological techniques.<sup>(2)</sup>

Lastly, a prior study of health risks of biosolids application was conducted in Ohio more than 20 years ago.<sup>(11)</sup> In contrast to the Health Survey, Dorn et al. did not find health risks (to humans or animals) associated with the application of biosolids. Critical differences between the two studies are noted in Table A.

While it is true that one study identified possible health risks and one study did not, it would be a mistake to conclude that the two studies are equivalent. On several critical measures of study quality, the Dorn study was much stronger in design. While the Health Survey had a large sample size (613 vs. 295), the Dorn study utilized randomization and pair matching, which would reduce the need for such a large sample size in order to adjust for potential confounders.

**TABLE A**

Study design factor	Khuder 2007	Dorn 1985
Randomized study	No	Yes
Compared residents of farms without biosolids to residents of farms with biosolids	No	Yes
Determined if, when, and how much biosolids were applied in relation to health measurement	No	Yes
Prospectively followed study participants with person-time at risk calculated	No	Yes
Obtained objective measures of infection	No	Yes
Health information obtained by health professionals in person	No	Yes

**Unreliable Conclusions of Human Health and Disease Symptoms**

Also detracting from the validity of the Health Survey is the analysis relating to the self-diagnosis of the survey's participants. For disease causation to be established, eliminating other etiologic factors is critical. The most prevalent disease characteristics noted by the authors are colds, upper respiratory infections, bronchitis, and gastroenteritis. These are common conditions that have numerous causes. Similarly, the most common symptoms were coughs, sneezing, and headaches. No attempt was made by the authors to rule out other etiologic factors.<sup>(6)</sup>

It is significant that farm families are often exposed to agrochemicals in addition to other potential sources of pathogens, such as manure. Biosolids, however, are required by federal and state regulation to be treated to reduce pathogens, while manures and chemical fertilizers are not subject to similar regulatory controls.

The validity of survey results is undermined by researchers' failure to detect and eliminate im-

plausible self-reported illnesses. One extraordinary example of an implausible illness is the report of an individual contracting polio the previous year. No cases of polio in the United States have been reported since 1973.

In a second example, the researchers single out multiple sclerosis, stating, “the number of multiple sclerosis cases approached statistical significance ( $p=0.065$ ).” This is unfounded, since the data evaluation methods used show no significant difference between exposed and non-exposed populations.

These examples illustrate the unreliability of self-reported health conditions. A failure to censor data that is clearly wrong and failing to use valid statistical tools fundamentally undermines the scientific validity of conclusions drawn from the Health Survey.

In the fact sheet, the study authors acknowledged deficiencies in their article, and indicated that the specific causes of reported symptoms cannot be ascertained because they had not verified reports with medical records. They acknowledged the following: “There are gaps in data that impeded the analysis including lack of objective data on specific environmental exposures, the lack of baseline health assessments among those who returned the surveys, and lack of objective measures of health status before and after the applications of the biosolids.” All of these real data gaps should have been considered and addressed prior to preparing the article.

### **Comments of the Reviewers**

The land application of biosolids has been the focus of hundreds of university research studies that have been conducted over thirty years. The results of this extensive research show that biosolids can be land applied without harm to the environment or to human health. Whereas the Health Survey reaches conclusions that are inconsistent with prior research, a particular scrutiny is warranted of the research methodology, survey design, and analytical procedures of the Health Survey. The scientific panel who conducted this scrutiny are experts in public health, epidemiology, biostatistics, environmental microbiology, and environ-

mental science. They offer the following comments on the article:

Dr. Ian Pepper, Ph.D. Professor of Environmental Microbiology and Director, National Science Foundation Water Quality Center and Director, Environmental Research Laboratory, and Dr. Chuck Gerba, Ph.D., Professor of Environmental Microbiology, The University of Arizona: “This publication has several critical flaws, any one of which should have precluded publication. Specifically, the publication implies that land application of biosolids results in the impaired health of residents close by, but based on the above assessment, none of the (preliminary) conclusions drawn from this study have merit.”

Dr. Samuel Dorevitch, MD, Division of Epidemiology and Biostatistics, University of Illinois at Chicago School of Public Health: “The 2007 study by Khuder et al. addresses a relevant public health question, but important limitations are noted in the design, analysis and interpretation of the research. The results at best suggest a need for further research using the more defensible methods of Dorn, namely, a randomized, prospective investigation with objective measures of exposure and health endpoints.”

Dr. Rufus L. Chaney, Ph.D., Senior Research Agronomist, U.S. Department of Agriculture: “Because of these limitations of the study, I conclude that the findings are invalid and should not be relied upon in consideration of public policy regarding biosolids utilization.”

Dr. Paul C. Chrostowski, Ph.D., Principal, CPF Associates, Inc.: “This article presents results of research that purports to find an “increased risk of respiratory, gastrointestinal and other diseases among residents living near farm fields on which the use of biosolids was permitted. The research is both conceptually and methodologically biased and flawed. In particular, the authors draw conclusions in the absence of supporting evidence, fail to acknowledge the wide body of literature on this topic, and cite supporting documentation inappropriately. This article is so seriously flawed that it should be retracted from publication.”

Dr. Timothy J. Buckley, Ph.D., CIH, Associate Professor and Chair, Division of Environmental Health Sciences, The Ohio State University: “I think that these authors set out to answer an important, but difficult question. There are a number of limitations to this study,

many of which the authors readily admit within their “Comment.” The limitations are quite substantial and in my mind call into question the study conclusions.”

## **References**

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