PO Box 422 ■ Tamworth, NH 03886-0422
www.nebiosolids.org

phone 603-323-7654
fax 603-323-7666
info@nebiosolids.org

nebra
North East Biosolids & Residuals Association

Cooperatively promoting the environmentally sound recycling of biosolids and other residuals

Attn: Docket ID No. FDA-2011-N-0921/RIN 0910-AG35
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted via www.regulations.gov

November 22, 2013

The North East Biosolids and Residuals Association (NEBRA) appreciates the opportunity to comment on the proposed *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (*Federal Register* / Vol. 78, No. 11 / Wednesday, January 16, 2013).

NEBRA is a non-profit professional association advancing the recycling of biosolids and other organic residuals in New England and eastern Canada. NEBRA membership includes the environmental professionals and organizations that produce, treat, test, consult on, and manage most of the region's biosolids and other large volume recyclable organic residuals. NEBRA is funded by membership fees, donations, and project grants. For more information: http://www.nebiosolids.org.

Below we provide some general comments regarding the scientific approach evident in the proposed produce safety rule, which builds on past Food & Drug Administration (FDA) actions and guidance. We then provide brief, specific comments regarding the particular portions of the proposed rule that address biosolids – treated and tested solids from municipal wastewater treatment.

General Comments

We commend FDA and the authors of the Food Safety Modernization Act (FSMA) for the explicit focus on scientific analysis and risk assessment in the creation of the proposed regulations. This careful science was already evident in FDA's discussion of biosolids in the 1998 "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." In that document, FDA formally recognized the significance and effectiveness of the pathogen controls required for biosolids by 40 CFR Part 503, the U. S. Environmental Protection Agency (EPA) regulations for the use and disposal of sewage sludge (biosolids).

This scientific rigor has also been evident in FDA's (and partner agencies') approach, over recent years, in analyzing outbreaks of food-borne illness, using environmental assessment modeling, as discussed in Section II of the proposed produce safety rule. For example, in particular, we commend FDA and the Centers for Disease Control for their diligence in determining the actual risk factors leading

to a *Listeria monocytogenes* outbreak associated with cantaloupe melons from a Colorado farm in 2011 (http://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm276247.htm). At the time, some news reports incorrectly implicated biosolids as a potential cause of the contamination, even though biosolids were not in use on that farm and had not been used in the area for several years. It is critical for public health that such investigations properly determine actual risk factors and rigorously avoid false findings, because false findings a) can lead to doing nothing to address the actual hazard(s), and b) cause disruptions of existing practices (such as use of biosolids) that are being conducted safely and effectively to the benefit of producers and society as a whole.

In addition, we commend FDA for focusing the new proposed produce safety rule on microbiological hazards (pathogens) that have caused documented harm, rather than attempting to also address the low risks associated with potential chemical, physical, or radiological hazards (Section 1, B.). Given limited regulatory resources, and to avoid undue burdens on producers, it is imperative that rules and guidance focus on addressing actual significant risks.

Lastly, we commend FDA for making the proposed rule consistent with other commonly-accepted standards and definitions, such as the science-based international standards expressed in the Codex Code and a generally-agreed-upon technical definition of "composting."

Comments on the Inclusion of Biosolids and Other "Biological Soil Amendments"
We commend FDA for the scientific basis of the definitions and standards in the proposed rule regarding "Biological Soil Amendments" – including biosolids. The proposed rule properly differentiates between "biosolids" and "human waste," which, untreated, is a significant potential source of pathogens.

We appreciate that FDA clearly recognizes the efficacy of the 40 CFR Part 503 biosolids regulations and is "not proposing to implement further restrictions" (*Fed. Reg*., 2013, p. 3578). This is important in avoiding duplicate or conflicting regulations that unnecessarily hamper producers and stymy the recycling of biosolids and other beneficial soil amendments.

We appreciate that FDA recognizes the value of the pathogen reduction treatments required for biosolids by 40 CFR Part 503 and is recommending similar treatments and standards for animal manures, which are applied to soils at a far greater rate than are biosolids. The composting and other treatment standards in Part 503 are based on extensive research and experience and will serve to help ensure produce safety.

Regarding FDA's request for comments on the proposed use of both *Salmonella* and fecal coliforms for validation of new pathogen treatments (*Fed. Reg.,* 2013, p. 3580), we find FDA's rationale reasonable, as long as both tests are required *only in the development and validation of new treatment processes*. We wish to emphasize the importance of the final rule adhering to the statement of intent in the proposed rule: "We intend this provision to provide the standard against which treatment processes must be validated. Farms would be able to use treatment processes that are validated to meet the relevant microbial standard in this section without needing to test the end products of their treatments to confirm that the microbial standard was achieved." We expect this standard to be applicable to biosolids products that have met Part 503 requirements. We would object to biosolids treatments and products that have met the appropriate Part 503 standards being required to meet any additional treatment or testing requirements.

Summary
We commend FDA for including, in the proposed rule, reasonable, science-based standards for biosolids use in the production of produce and recognizing the safety of current biosolids regulations and practices. It is clear from this and past FDA actions that the agency properly recognizes that biosolids are, in reality, just one of several biological soil amendments commonly in use, that biosolids are currently adequately

regulated for safety, and that all such amendments should be managed in similar ways to reduce the risk of human or environmental impacts.

We thank you for this opportunity to provide comments. Should you have any questions or require further information, please do not hesitate to contact the NEBRA office.

Sincerely,

Ned Beecher
Executive Director
ned.beecher@nebiosolids.org
603-323-7654