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November 15, 2013

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
Via www.regulations.gov

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the proposed *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (78 Fed. Reg. 3504; January 16, 2013) (*Proposed Standards*) and applauds the Food and Drug Administration (FDA) for its sound approach to addressing the land application of biosolids. NACWA represents more than 280 publicly owned wastewater treatment utilities across the country. NACWA's members collectively serve the majority of the sewered population in the United States, and generate over ten thousand dry tons of biosolids (sewage sludge) every day. Maintaining a range of options for safely and effectively managing biosolids is a top priority for the Association, and FDA's *Proposed Standards* will ensure the safe and continued use of biosolids on fields used for growing produce for human consumption.

More than half of the biosolids generated in this country are beneficially reused through land application on farm fields. Biosolids provide primary nutrients (nitrogen and phosphorus) and secondary nutrients such as calcium, iron, magnesium and zinc that plants need to grow and thrive. The use of biosolids increases crop yields and maintains nutrients in the root zone and, unlike chemical fertilizers, biosolids provide nitrogen that is released slowly over the growing season as the nutrient is mineralized and made available for plant uptake. Biosolids offer a sound and sustainable alternative to chemical and manure-based fertilizers.

Hundreds of successful land application programs operate around the country in accordance with the risk-based regulations established by the U.S. Environmental Protection Agency (EPA) at 40 CFR Part 503 in 1993. In developing its Part 503 rules, EPA undertook a broad study of the potential impacts of land application and other biosolids management practices. Based on the results of a comprehensive risk assessment, EPA identified and set numeric limits for nine trace elements (heavy

metals), and mandated that wastewater treatment facilities use at least one of several alternative technologies to significantly decrease or eliminate levels of pathogens in biosolids before being beneficially reused. These numeric limits and treatment standards, together with a set of site management restrictions (e.g., waiting periods between application and harvest), ensure that biosolids can be used safely and effectively as a soil amendment.

Recognizing the comprehensive nature of the Part 503 rules, the FDA in its *Proposed Standards* has carefully crafted a regulatory framework that prohibits the use of human waste in the growing of produce with the exception of “sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements” (Proposed Section 112.53). As FDA states in the preamble, the “standards [40 CFR Part 503, Subpart D] are appropriate for protecting public health and, therefore, we [FDA] are not proposing to implement further restrictions.” NACWA strongly supports this regulatory construction that acknowledges and defers to EPA’s existing comprehensive rules. The Part 503 regulations and implementation of the land application provisions have been and continue to be carefully scrutinized by a range of stakeholders, and, as mandated by Congress, EPA regularly conducts reviews of its regulations to determine if the pollutant levels and other requirements remain protective. Year after year for the past two decades, the protectiveness of the Part 503 regulations has been consistently confirmed.

Since the implementation of Part 503 rule, two reports of the National Research Council (NRC) of the National Academy of Sciences have considered whether land application of biosolids is safe and beneficial. In 1996, the NRC published *Use of Reclaimed Water and Sewage Sludge in Food Crop Production*, which concluded that the application of biosolids to farmland—when practiced in accordance with existing federal guidelines and regulations—presents negligible risk to the consumer, to crop production, and to the environment. The report concluded that current technology to remove pollutants from wastewater, coupled with existing regulations and guidelines governing the use of reclaimed wastewater and sludge in crop production, are adequate to protect human health and the environment.

In 2000, EPA asked the NRC to review the science and methods supporting Part 503 to address concerns regarding human health impacts of land application of biosolids. As a result of its “search for evidence on human health effects related to biosolids,” the NRC’s 2002 report concluded that “there is no documented scientific evidence that the Part 503 rule has failed to protect public health”; “[a] causal association between biosolids exposures and adverse health outcomes has not been documented”; and “there are no scientifically documented outbreaks or excess illnesses that have occurred from microorganisms in treated biosolids.” The NRC also observed that “persistent uncertainties” regarding the safety of land application necessitate more scientific research, but it did not call for any specific changes to Part 503. That scientific work continues today, led by the clean water community and by EPA itself, but to date there has been no identified need for establishing more stringent requirements or regulating additional pollutants.

The past twenty years of implementation demonstrate that the federal framework under 40 CFR Part 503 is sound and protective of human health and the environment. Beyond the federal level, many states and local governments have developed additional regulations to further guide the management of biosolids. The thoughtful regulatory structure crafted by the FDA will ensure that this carefully crafted, comprehensive framework of federal, state and local regulations that has worked effectively for the past twenty years will continue to guide the use of biosolids in the growing of produce covered by the *Proposed Standards* and beyond.

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Again, NACWA appreciates the opportunity to comment on the *Proposed Standards*. Please contact me at 202/833-9106 or chornback@nacwa.org should you have any questions or would like to discuss our comments further.

Sincerely,

A handwritten signature in black ink, appearing to read "Chris Hornback", with a stylized flourish at the end.

Chris Hornback
Senior Director, Regulatory Affairs