UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 30 2019

OFFICE OF WATER

MEMORANDUM

SUBJECT: Response to November 15, 2018, Office of Inspector General's Final Report, "EPA Unable to Assess the impact of Hundreds of Unregulated Pollutants in the Land-Applied Biosolids on Human Health and the Environment"

FROM: David P. Ross, Assistant Administrator
Office of Water

TO: Charles Sheehan, Acting Assistant Inspector General
Office of Audit and Evaluation

The Environmental Protection Agency (EPA) appreciates the revisions that the Office of Inspector General (OIG) made to recommendations 10, 11, and 13 following the dispute resolution meeting with the EPA Chief Financial Officer on April 30, 2019. Based on the productive discussions during that meeting and subsequent discussions between the EPA and OIG staff, the Agency has revised the corrective actions corresponding to recommendations 9, 10, 11, and 13, and understands that with these revisions, resolution has been reached between the EPA and OIG.

Biosolids are an important resource for this country and the EPA takes very seriously its statutory obligations to evaluate and regulate, where appropriate, contaminants in biosolids that may pose a risk to human health and the environment through discharges to waters subject to Clean Water Act (CWA) jurisdiction. The EPA continues to make significant progress in building capacity to assess pollutants identified in biosolids by developing the necessary tools and data needed to evaluate risk so that the Agency can fulfill its statutory mandates. The Agency appreciates the OIG's interest and engagement on this important issue.

As you may be aware, both the EPA and the OIG have heard from multiple national and regional associations identifying concerns with certain aspects of the OIG's November 2018 final report. These are associations that represent hundreds of public clean water utilities, local utilities, and businesses throughout the United States that take seriously their responsibilities to treat wastewater and manage residuals so not to harm human health and the environment. All the organizations offered continued support for the EPA's Biosolids Program and assistance in moving the science forward to ensure the best possible biosolids management practices. In that same spirit, the EPA would be happy to provide additional information to relevant OIG staff regarding the use of risk assessment in the EPA's biosolids and other programs, and the current state of science underlying the use and management of biosolids in the wastewater sector.

Again, we appreciate the engagement of the OIG on this important issue and look forward to working together to implement many of the recommendations in the November 2018 report. I would ask, however, that the OIG consider updating some of its materials related to the report to ensure that the

public is not misinformed regarding the law as applied to biosolids management. For example, the "At a Glance" section of the report inaccurately characterizes the CWA as follows: "The Clean Water Act requires the EPA to review biosolids regulations at least every 2 years to identify additional toxic pollutants *and promulgate regulations for such pollutants*" (emphasis added). The "and promulgate" language omits the fact that this statutory requirement is contingent on the EPA having sufficient scientific evidence that the pollutants may harm (i.e., there is risk to) human health or the environment. As written, the report seems to imply that the EPA promulgate regulations for all identified pollutants.

It can be challenging to communicate information about risks to human health and the environment. Risk assessment is a scientific process that, according to longstanding EPA policies, considers three primary factors: 1) how much of a chemical is present in an environmental medium (e.g., biosolids); 2) how much contact a person or ecological receptor has with the contaminated environmental medium; and 3) the inherent toxicity of the chemical. The presence of a pollutant in biosolids alone does not equate to scientific risk, but the EPA's Biosolids Program is working hard to prioritize its risk assessment work for known but not yet regulated pollutants.

Please let me know if you have any remaining questions related to the Biosolids Program, or your staff may contact Elizabeth Resek in the Office of Water at resek.elizabeth@epa.gov or 202-566-1228.

OIG Final Report: "EPA Unable to Assess the impact of Hundreds of Unregulated Pollutants in the Land-Applied Biosolids on Human Health and the Environment"

Revised Corrective Action Plan (CAP) for Final Report Recommendations 7, 9, 10, 11, and 13

Final Report Recommendation (page 58-59)	Revised Recommendation	Revised Corrective Action
7. Issue guidance on what new technologies are allowable options or alternatives for biosolids pathogens reduction.	None	The OW is updating the biosolids website to clarify existing information on the Pathogen Equivalency Committee's determinations on alternative technologies for pathogen reduction. EPA does not agree with the characterization of this recommendation as necessary to correct a program deficiency but does agree with the intent of the recommendation to improve the Biosolids Program. (May 31, 2019)
9. Change the website response to the question "Are biosolids safe?" to include that the EPA cannot make a determination on the safety of biosolids because there are unregulated pollutants found in the biosolids that still need to have risk assessments completed. This change should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.	None	The EPA is in the process of revising the entire EPA biosolids website in order to update and clarify information and ensure transparency. This will include deleting the question "Are biosolids safe?" Instead, the EPA will use appropriate risk communication language that will ensure that potential risk from unregulated pollutants found in biosolids is adequately communicated. (September 30, 2019)
10. Modify the EPA's website responding to public questions on the safety of biosolids to: (a) identify unregulated pollutants found in biosolids, (b) disclose biosolids data gaps, and (c) include descriptions of areas where more research is needed. Make similar revisions in other EPA-published documents that include a response to the question "Are biosolids safe?" These changes should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.	10. Modify the EPA's website on biosolids to: (a) identify unregulated pollutants found in biosolids, (b) disclose biosolids data gaps, and (c) include descriptions of areas where more research is needed. These changes should stay in place until the EPA can assess the risk of all unregulated pollutants found in biosolids.	The EPA is in the process of revising the entire EPA biosolids website in order to update and clarify information and ensure transparency. This includes identifying pollutants found in biosolids, disclosing biosolids data gaps and addressing research areas. The EPA is consolidating the information so that it is more easily obtained. (September 30, 2019)

Final Report Recommendation (page 58-59)	Revised Recommendation	Revised Corrective Action
11. Determine whether the impact on the safety and protection of human health justifies a requirement to include a general disclaimer message on the biosolids labels and information sheets regarding unregulated pollutants and a referral to the website for additional information. Publish the rationale for the determination on the EPA biosolids website.	11. Determine whether the impact on the safety and protection of human health justifies a requirement to include a general disclaimer message on the biosolids labels and information sheets regarding unregulated pollutants and a referral to the website for additional information.	The EPA will determine whether a general disclaimer and a referral to the Agency's biosolids website on potential risk to human health from unregulated pollutants found in biosolids is needed on biosolids labels and information sheets. (September 30, 2019)
13. In addition to EPA technical biosolids trainings or conferences, start and maintain a website repository of technical and procedural as well as general questions and answers the regions and states have dealt with regarding biosolids to improve EPA knowledge transfer to regional and state biosolids program managers as well as wastewater treatment plant operators.	13. In addition to EPA technical biosolids trainings or conferences, include on the biosolids website general questions and answers the regions and states have dealt with regarding biosolids to improve EPA knowledge transfer to regional and state biosolids program managers as well as wastewater treatment plant operators.	In addition to conducting technical biosolids training or conferences, the EPA is in the process of revising the entire EPA biosolids website in order to update and clarify information and ensure transparency. This includes updating frequently asked questions and answers regions and states have communicated to EPA on biosolids management. The technical, programmatic and policy-related information can be used to assist EPA regions, states and biosolids stakeholders. (September 30, 2019)