

**Biosolids Projects Update
Status of 68 FR 75531 projects**

July 2015

Project No.	Project Title	Status	Comments
1	Biennial Review (BR) Under CWA Section 405(d)(2)(C)	Ongoing	Under the Clean Water Act, EPA is required to collect and analyze available data not less than every two years for the purpose of identifying new pollutants that may need to be regulated. EPA continues to evaluate published data and conduct exposure and hazard evaluations for pollutants when sufficient data are available. The most recent evaluations (i.e., 2005, 2007, 2009, and 2011 Biennial Reviews) identified pollutants for which some data were available (https://www.epa.gov/biosolids/biennial-review). However, the available data were not sufficient at the time to allow the Agency to conduct exposure and hazard assessments or determine what, if any, regulatory action may be needed. EPA will continue to review new peer-reviewed literature and assess availability of relevant data to determine whether additional pollutants should be considered for regulation. Because data are often incomplete and resources to manage chemical releases are finite, EPA is exploring various methods and screening tools that could serve to reduce the number of chemical-pathway combinations OW evaluates in higher-tier assessments, thus saving time and cost of full assessments for all chemical-pathway combinations.
2	Compliance Assistance and Enforcement Actions	Ongoing	EPA and states continue to actively address biosolids violations and require proper land-application of biosolids to prevent risk to human health or the environment. The public can now report possible environmental violations or crimes through EPA's Office of Enforcement and Compliance Assurance website (https://www.epa.gov/biosolids/part-503-compliance-and-annual-reporting-guidance). EPA's Office of Enforcement and Compliance Assurance (OECA) shifted some resources devoted to traditional biosolids enforcement to higher priority enforcement areas and devoted two FTEs to maintain a minimal national presence in biosolids enforcement work. These two FTE are located in a Biosolids Center of Excellence (BCOE), housed in Region 7, which will maintain EPA's biosolids enforcement expertise. Although these FTE will be in EPA Region 7, they are expected to be the national staff leads for all EPA biosolids enforcement activities across the country, coordinating with the other Regions and headquarters as appropriate. OECA also is proposing data standardizations and the corresponding electronic reporting requirements in 40 CFR 3, 122, 123, 127, 403, and 503 that are designed to save the NPDES authorized programs considerable resources, make reporting easier for NPDES-regulated entities, streamline permit renewals (as permit writers typically review previous noncompliance events during permit renewal), ensure full exchange of NPDES general permit data between states and EPA to the public, improve better environmental decision-making, and to protect human health and the environment. The biosolids rules include straight forward performance standards and recordkeeping and reporting requirements that, once EPA's e-reporting rule is fully implemented, will provide more transparency and accountability.
3	Methods Development, Optimization, and Validation for Microbial Pollutants in Sewage Sludge [includes multiple components with different status]		
3a	Optimization of the Methods for Detecting, Enumerating, and Determining the Viability of Helminth / Ascaris Ova in Sewage Sludge	Completed	A Standard Operating Procedure for a helminth ova method that can provide results in as little as a few days for detecting viable helminth ova in sewage sludge is being reviewed and finalized. The method is essentially complete and awaiting multi-lab validation and promulgation to 40 CFR 136, but no schedule or funding is proposed at this time. In the mean time, EPA encourages the helminth ova method available in Appendix I in https://www.epa.gov/biosolids/control-pathogens-and-vector-attraction-sewage-sludge
3b	Improved Methods for Detecting Viruses in Sewage Sludge	Completed	A report was published in September 2007 titled <i>Preliminary Comparative Study of Methods to Extract Virus from Raw and Processed Sewage Sludges</i> , EPA/600/R-07/118. Two simple virus extraction techniques were compared to an EPA standard method for the isolation of human enteric viruses from raw sewage sludge and class A biosolids. The techniques were used to detect both indigenous and seeded virus from a wastewater treatment plant that distributes class A material produced by a heat drying process. The method is essentially complete and awaiting multi-lab validation and promulgation to 40 CFR 136, but no schedule or funding is proposed at this time. In the mean time, EPA encourages the viral method available in Appendix H in https://www.epa.gov/biosolids/control-pathogens-and-vector-attraction-sewage-sludge

3c	Development and Validation of Analytical Methods for Fecal Coliform in Sewage Sludge	Completed	EPA reports EPA-821-R-06-012 (Method 1680) and EPA-821-R-06-013 (Method 1681) were published in September 2005 establishing new and improved methods for detecting and quantifying fecal coliform in sewage sludge: https://www.epa.gov/biosolids/epa-analytical-methods-biological-pollutants-wastewater-and-sewage-sludge
3d	Development and Validation of Analytical Methods for Salmonella in Sewage Sludge	Completed	An EPA report EPA-821-R-06-14 (Method 1682) was published in September 2005 establishing a new and improved method for detecting and quantifying <i>Salmonella</i> in sewage sludge: https://www.epa.gov/biosolids/epa-analytical-methods-biological-pollutants-wastewater-and-sewage-sludge
3e	Microbial organisms	Completed	EPA conducted a new biosolids holding time study to determine appropriate holding times for fecal coliform and <i>Salmonella</i> in biosolids samples. An EPA report (EPA-821-R-07-003) was published and results have been incorporated into analytical methods: https://www.epa.gov/biosolids/epa-analytical-methods-biological-pollutants-wastewater-and-sewage-sludge
4	Field Studies of Application of Treated Sewage Sludge	Completed	In 2005, a collaborative USDA and EPA field-scale evaluation of biosolids application in North Carolina was conducted to assess releases of pollutants (chemicals and microorganisms) to air and soil. Several different sampling and analysis methods were used to assess and optimize the sampling techniques. The final report was posted June 2012: https://www.epa.gov/biosolids/multimedia-sampling-during-application-biosolids-land-test-site
5	Targeted National Sewage Sludge Survey	Survey Completed. Risk Characterization of TNSSS Analytes with Sufficient Data Underway	EPA completed the Targeted National Sewage Sludge Survey (TNSSS) report and posted documents to EPA's Biosolids Web Site in January 2009. Reports are available at https://www.epa.gov/biosolids/sewage-sludge-surveys-0 . Data from the survey will help determine exposure to target pollutants in biosolids and whether target pollutants may need to be evaluated for possible regulation pursuant to 40 CFR 503. Assessment and risk characterization of the 145 pollutants detected and quantified in the survey, where sufficient data exist, is ongoing. A draft-final risk characterization document for Phase I TNSSS pollutants (i.e., barium, beryllium, manganese, molybdenum, silver, 4-Chloroaniline, fluoranthene, pyrene, nitrate and nitrite) was peer reviewed in 2014. EPA will address peer review comments and revise the risk characterization document accordingly in 2015, and then post for public comment. Any regulatory decisions will be made subsequent to risk characterization and risk management decisions. The gathering of information and risk characterization for the 135 Phase II TNSSS pollutants with sufficient information will take place starting in late 2015, subject to available priority and resources.
6	Participate in Incident Tracking Workshop	Completed	EPA attended a Water Environment Research Foundation (WERF) sponsored incident-tracking workshop in 2005. WERF-led follow-up activities from the workshop included developing research that could provide information about the occurrence of reported symptoms near sites where soil amendments, including biosolids, are applied to land. A WERF report <i>Epidemiologic Surveillance and Investigation of Illness Reported by Neighbors of Biosolids Land Application Sites</i> includes a protocol designed to be used by local, state, and federal health and environmental officials. WERF pilot tested and refined the protocol and issued a final report in 2012 titled <i>A Protocol for the Surveillance and Investigation of the Concerns Reported by Neighbors of Land Application (Biosolids and Other Soil Amendments; 08-HHE-5PP-P)</i> : http://www.werf.org/c/KnowledgeAreas/Biosolids/Biosolids_Research_at_a_Glance.aspx .
7	Conduct Exposure Measurement Workshop	Completed	An exposure measurements workshop was held in Cincinnati in March 2006. Attendees of the workshop proposed a list of research projects aimed at addressing exposure following land-applied biosolids. An EPA report was issued September 2007 (EPA/600/R-07/055) that includes presentations by attendees and suggested priority research needs. https://www.epa.gov/biosolids/proceedings-biosolids-exposure-measurement-workshop
8	Assess the Quality and Utility of Data, Tools and Methodologies to Conduct Microbial Risk Assessments on Pathogens	Completed	EPA released the final report, <i>Problem Formulation for Human Health Risk Assessments of Pathogens in Land-Applied Biosolids</i> in March 2011: https://www.epa.gov/biosolids/problem-formulation-human-health-risk-assessments-pathogens-land-applied-biosolids

9	Support Pathogen Equivalency Committee (PEC)	Upgrade of the PEC website is Completed. Evaluation of Equivalency Applications are Ongoing	The PEC developed a more formal approach for evaluating equivalent treatments to current required treatments. The new approach, with its QA requirements, is posted on the Science Advisory Board's webpage. EPA improved the PEC website https://www.epa.gov/biosolids/pathogen-equivalency-committee so applicants can submit requests online using a consistent format that should help expedite reviews. Evaluation criteria are being modified to provide a better understanding of the proposed disinfection process' capabilities. Numerous technologies are in different stages of receiving a recommendation from the PEC of Processes to Further Reduce Pathogens equivalency. With recent and pending retirements of PEC participants, the Agency is evaluating options for managing the PEC moving forward.
10	Development and Application of Analytical Methods for Detecting Pharmaceutical and Personal Care Products in Sewage Sludge	Completed	EPA published a document titled "Research Towards Developing Methods for Selected Pharmaceutical and Personal Care Products (PPCPs) Adapted for Biosolids", EPA/600/X-06/017, September 2006. EPA also developed analytical methods for over 100 pharmaceutical and personal care products for biosolids, water, soil, and sediment. These analytical methods were made publicly available in December 2007 and were used in EPA's Targeted National Sewage Sludge Survey and other applications. Method 1694 for Pharmaceuticals and Personal Care Products in Water, Soil, Sediment, and Biosolids are available on the Clean Water Act Analytical Methods website: https://www.epa.gov/cwa-methods
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	Completed	A special issue of Compost Science, <i>Contemporary Perspectives on Infectious Disease Agents in Sewage Sludge and Manure</i> , was printed and distributed at the Water Environment Federation's Specialty Conference on Biosolids, April 17-21, 2005 in Nashville, TN.
12	Support "Sustainable Land Application Conference"	Completed	The proceedings (many of the papers prepared from the presentations) from the Sustainable Land Application Conference were published in a special issue of Journal of Environmental Quality (JEQ) in February 2005.
13	Review Criteria for Molybdenum in Land-applied Treated Sewage Sludge	Underway	EPA is evaluating molybdenum using additional data developed since 2000, including results from the Targeted National Sewage Sludge Survey released in 2009. EPA expects to complete this assessment in 2015, incorporating any peer review comments received in 2014, and pursuing any regulatory or risk management decisions, as needed.
14	Improve Stakeholder Involvement and Communication	Ongoing	EPA is working to make EPA information on biosolids and other topics more readily available to the public through the web. Also available are a Public Involvement webpage and a website developed by the U.S. Office of Management and Budget and Federal agencies, where Federal programs are assessed and held accountable for improvement.