

Settlement Agreement Status Report
January 15, 2011
NRDC v. Johnson,
U.S. District Court, Central District of California
No. CV06-4843 PSG (JTLx)

Pursuant to Paragraph 15 of the Settlement Agreement in the above-referenced matter, the United States Environmental Protection Agency ("EPA" or "the Agency") provides this status report. It includes a description of the actions taken by EPA with respect to its responsibilities under the Settlement Agreement during the preceding six months (July 1, 2010 - December 31, 2010) and a description of the actions EPA intends to take with respect to its responsibilities under the Settlement Agreement during the following six months (January 1, 2011 – June 30, 2011).

Settlement Agreement (SA) ¶ 4(a) Conduct epidemiological studies at POTW-impacted marine beaches in Fairhope, Alabama and Goddard, Rhode Island (P1, P2).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA finished QA/QC and analysis of the epidemiological data (i.e. water quality data and interview responses). EPA submitted a manuscript which was accepted by a peer reviewed publication (online journal) and posted to the journal's website.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA has completed these epidemiological studies and therefore, no further action will be taken with respect to this provision.

SA ¶ 4(b) Provide technical assistance in support of an epidemiological study at a beach in Avalon, CA considered to be impacted by untreated human fecal contamination (P3).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA participated in teleconference calls with SCCWRP and UC Berkeley investigators. EPA provided technical assistance regarding interpretation of qPCR results and discussion of epidemiological data analysis to support consistency between the EPA and SCCWRP epidemiological analyses.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA has fulfilled this responsibility and therefore, no further action will be taken with respect to this provision.

SA ¶ 4(c) Conduct QMRA (based on measurement of pathogenic organisms and indicators) to estimate illness at a freshwater beach impacted by agricultural animal sources of fecal contamination (location to be determined) (clarifying P4).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA conducted a third rain simulation event and analyzed the data. EPA also collected stream water samples during natural rain events. These were taken at streams impacted by runoff. A Quantitative Microbial Risk Assessment (QMRA) was conducted to estimate the human health risks associated with recreational exposure to water containing agricultural animal (cattle, poultry, pigs) fecal contamination. The QMRA report was posted on the agency web site.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA has completed this study and therefore, no further action will be taken with respect to this provision.

SA ¶ 4(d) Study various parameters that affect performance of qPCR signal for enterococci and compare with other methods and pathogens in treated wastewater mixed with ambient waters (enterococci, E. coli, Cryptosporidium, and enterovirus) (P8).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA finished the statistical analyses. EPA prepared a draft final report, which was reviewed by an external peer review panel. EPA finished a final report which responded to peer review comments, and posted it on the agency web site.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA has completed this study and therefore, no further action will be taken with respect to this provision.

SA ¶ 4(e) Design and evaluate a monitoring approach that will characterize the quality of beach waters that takes into account the spatial and temporal variability associated with water sampling (P12).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA completed revisions to the draft report and posted the final document on the agency web site.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA has completed this study and therefore, no further action will be taken with respect to this provision.

SA ¶ 4 (f) Evaluate multiple indicator/method combinations to develop quantifiable relationships (P15).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA completed the statistical analyses to develop quantifiable relationships among indicator/method combinations. EPA prepared a report and posted the final report on the agency web site.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA has completed this study and therefore, no further action will be taken with respect to this provision.

SA ¶4(g) Study the effects of sampling holding time, sample storage, and preservation on sample integrity for future use (P16).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

For the holding time studies, EPA performed laboratory and data analyses of 24-month frozen filter samples for both fresh and marine waters. EPA prepared a draft final report, which was reviewed by an external peer review panel. EPA prepared a final report which responded to peer review comments and posted it on the agency web site.

Actions Planned by EPA from January 1, 2011 to June 30, 2011

EPA has completed this study and therefore, no further action will be taken with respect to this provision.

SA ¶4(h) (1) Develop, refine, validate, and publish one or more new ambient test methods (P17).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA prepared a completion notice for this study.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA has completed this study and therefore, no further actions will be taken with respect to this obligation.

¶4(h) (2) Develop, refine, validate, and publish one or more new wastewater test method(s) provided the results of P8 and P18 indicate that a new wastewater test method is necessary (P17).

Actions Taken By EPA from January 1, 2010 to June 30, 2010

EPA determined not to complete this study and notified the other parties of that determination in EPA's July 2010 status report.

Actions Planned By EPA from July 1, 2010 to December 31, 2010

No further actions will be taken with respect to this obligation.

SA ¶4(i) Evaluate the suitability of individual combinations of indicators and methods for different CWA programs (P18)

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA finalized the study report and posted it on the agency web site.

Actions Planned by EPA from January 1, 2011 to June 30, 2011

EPA completed this study and therefore, no further actions will be taken with respect to this obligation.

SA ¶4(j) Re-analyze archived NEEAR samples using molecular methods for other indicators, including at least *E. coli*, provided the samples have not degraded during storage (depending on the outcome of P16 and the nature of indicator/method) (P22).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA determined not to complete this study and notified the other parties of that determination in EPA's July 2010 status report.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

No further actions will be taken with respect to this obligation.

SA ¶4(k) Pilot test Virtual Beach model for beach notification and advisories/closures (P23).

SA ¶4(l) Refine and validate existing water quality models for freshwater beach notification and advisories/closures (P24).

SA ¶4(m) Refine and validate other existing water quality models for marine beach notification and advisories/closures (P25).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA finished a draft report for these studies. The report was reviewed by an external peer review panel. EPA prepared a final report which responded to peer review comments and posted it on the agency web site.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA completed this study and therefore, no further actions will be taken with respect to this obligation.

SA ¶4(n) Develop technical protocol for site-specific application of predictive models to be used in making beach advisory decisions (P26).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA completed a guide to assist states and localities in developing and using predictive models in their beach management programs and posted the document on the agency web site.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA completed this study and therefore, no further actions will be taken with respect to this obligation.

SA ¶4(o) Compare EPA's 1986 Bacteria Criteria recommendations to NEEAR studies to better understand the relationship between fecal contamination and

illness in these data sets, provided EPA can obtain the raw data used to develop the 1986 Criteria (P27).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA determined not to complete this study and notified the other parties of that determination in EPA's July 2009 status report.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

No further action will be taken with respect to this provision.

SA ¶4(p) Evaluate applicability of NEEAR Great Lakes data to inland waters (P28).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA finalized the summary report and posted it on the agency web site.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA completed this study and therefore, no further actions will be taken with respect to this obligation.

SA ¶4(q) Conduct statistical analysis of children data from epidemiological studies (P29).

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA completed statistical analyses of children's data from studies in the Great Lakes, marine beaches in Biloxi, MS, Fairhope, AL, and Goddard, RI, Surfside, SC, and Boquerón Beach, PR.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA completed this study and therefore, no further actions will be taken with respect to this obligation.

SA ¶ 6 When it completes a study described in Paragraph 4 of this Agreement, EPA will provide written notice to the other Parties, including a summary of the study and findings, and a statement that the study has been completed. This Paragraph does not apply to the study described in Paragraph 4(b), which is not being conducted by EPA.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

On December 15, 2010, EPA provided written notice to the Parties for all of the studies described in Paragraph 4 that EPA completed. EPA did not prepare completion notices for the studies in SA ¶¶ 4(h) (2), 4(j) and 4(o) because they were not completed due to the contingencies identified and, as required by SA ¶ 5, EPA provided notice to the Parties in previous status reports.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

No further actions will be taken with respect to this obligation.

SA ¶ 7 If an epidemiological study proposed by the Southern California Coastal Water Research Project (SCCWRP) for Doheny Beach is initiated by SCCWRP no later than December 2009, EPA will provide technical assistance on study design and analysis.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA participated in teleconference calls with SCCWRP and UC Berkeley investigators. EPA provided technical assistance regarding interpretation of qPCR results and discussion of epidemiological data analysis to support consistency between the EPA and SCCWRP epidemiological analyses.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

No further actions will be taken with respect to this obligation.

SA ¶ 8 For any epidemiological studies to be completed by EPA under Paragraph 4 of this Agreement and Paragraph 5 of the Consent Decree, EPA will use a suite of indicators and methods that EPA determines to be the most promising for the development of new or revised recreational water quality criteria. In making this determination, EPA will consider the indicators and methods that were used in previously conducted epidemiological studies and new indicators and methods that EPA determines to be promising for the development and implementation of new or revised recreational water quality criteria.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

No actions were taken with respect to this obligation.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

No further actions will be taken with respect to this obligation.

SA ¶ 9(a) Continue to conduct research currently underway to identify genetic sequences that could form the basis of chicken and seagull specific fecal source assays

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA continued with the evaluation of selected chicken and gull assays for their potential to uniquely identify specific avian sources of fecal contamination against feces from targeted and non-targeted hosts. EPA generated and analyzed additional molecular data that may prove useful to develop additional gull-specific assays.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA will complete the evaluation of selected chicken and gull assays for their potential to uniquely identify specific avian sources of fecal contamination against feces from targeted and non-targeted hosts. EPA will analyze all molecular data generated previously as a whole to develop additional gull-specific assays.

SA ¶ 9 (b) If EPA determines that it can develop chicken and seagull specific fecal source assays, EPA will evaluate the assays for specificity and sensitivity using a reference collection of fecal samples, as well as environmental water samples with known sources of fecal contamination.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA conducted studies to determine the presence of host markers and sensitivity of avian specific PCR assays in environmental waters. EPA conducted studies to determine the detection limit of avian-specific PCR assays against fecal and water DNA extracts.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA will complete additional studies to determine the presence of waterfowl specific markers used in PCR assays in environmental waters collected in a multi-year study. EPA will complete additional studies to determine the detection limit of avian-specific PCR assays against fecal and water DNA extracts.

SA ¶ 9(c) No later than July 15, 2011, EPA will notify the other Parties in writing whether EPA was able to develop the assays and evaluate the assays as described in subparagraph 9(a). If EPA is able to complete the evaluation by July 15, 2011, the notification will include a brief summary of such evaluation.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA did not take any actions with respect to this obligation during this reporting period.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA will prepare draft materials to notify the other Parties in writing whether EPA was able to develop and evaluate the assays.

SA ¶ 10(a) Subject to any statutory or regulatory limitations restricting the distribution of confidential business information or private information (e.g., names, addresses), EPA will provide access to data from the studies identified in Paragraph 4 of the Settlement Agreement and paragraph 5 of the Consent Decree after EPA has conducted any quality assurance/quality control review and, as deemed necessary by EPA, internal and external peer review, including addressing the comments of such review. EPA may determine to provide access to the data by notifying the Parties in writing that the data are available for their review and its location, or by other method of transmission.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA has provided access to data for the studies identified in Paragraph 4 of the Settlement Agreement and Paragraph 5 of the Consent Decree that EPA completed by notifying the parties in writing that the data are available for review, its location and a point of contact for requesting the data. EPA did not provide access to data for the studies in SA ¶4(h) (2), ¶4(j), and ¶4(o) because those studies were not completed due to the contingencies identified in the Settlement Agreement (See EPA's July 15, 2009 and July 15, 2010 status reports).

Actions Planned By EPA from January 1, 2011 to June 30, 2011

No further actions will be taken with respect to this obligation.

SA ¶ 10(b) Subject to any statutory or regulatory limitations restricting the distribution of confidential business information or private information (e.g., names, addresses), EPA will provide access to data from the epidemiological studies previously conducted by EPA in support of the new or revised recreational water quality criteria no later than June 15, 2009. EPA may determine to provide access to the data by notifying the Parties in writing that the data are available for their review and its location, or by other method of transmission.

Actions Taken By EPA from July 1, 2009 to December 31, 2009

EPA did not take any action with respect to this provision during the reporting period.

Actions Planned By EPA from January 1, 2010 to June 30, 2010

EPA plans no further action for the time period with respect to this provision.

SA ¶ 11 EPA will convene a stakeholder workshop or other mechanism for stakeholder input during 2009, 2010, and 2011. These workshops will provide an opportunity for Plaintiff, Intervenor, and other interested stakeholders to provide input to EPA and/or bring issues to EPA associated with the development of the new or revised criteria to be issued by October 2012. EPA expects these issues to include issues related to implementation of the new or revised water quality criteria EPA will publish in 2012. The focus of the 2009 and 2010 workshops will be for EPA to update stakeholders on the progress EPA has made in completing studies and framing the issues associated with the development of the new or revised criteria and for Plaintiffs, Intervenor, and other interested stakeholders to comment on EPA's update. The focus of the 2011 workshop will be to provide an opportunity for Plaintiff, Intervenor, and other interested stakeholder to comment on EPA's evaluation, synthesis, summarization and statistical analysis of the studies and development of options for the overall structure and content of the recreational water quality criteria that EPA will publish in 2012.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

On October 12, 2010, EPA hosted a webinar event for interested stakeholders on *EPA's Development of New or Revised Recreational Water Quality Criteria*. Webinar topics included an update on recreational water research and information on how EPA is framing issues related to criteria development. Both topics were followed by Q&A sessions. Over 200 people from states, academia, environmental groups and other federal agencies registered for the webinar. EPA began to identify potential locations and facilities with availability and capacity for a stakeholder meeting in the spring/summer of 2011. EPA began the process to identify a facilitator and develop a registration system.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA plans to select a location and dates, prepare and distribute a meeting announcement and agenda, and conduct the meeting.

SA ¶ 12 EPA will validate and publish a rapid test method for the new or revised criteria by October 15, 2012. Validation of a rapid test method will involve conducting an inter-laboratory study, the purpose of which is to characterize method performance (including recovery and precision) for a rapid method in reference matrices and ambient recreational waters (fresh and marine) in multiple laboratories and to develop quantitative quality control acceptance criteria. Publication does not include promulgation of an EPA-approved test method in the Code of Federal Regulations.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA completed the data collection for the multi-lab validation study to characterize method performance and develop quantitative quality control acceptance criteria for Enterococcus qPCR and Bacteroides qPCR in marine waters, and initiated the study for Enterococcus qPCR in freshwater.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA plans to continue the conduct of the multi-lab validation study to characterize method performance and develop quantitative quality control acceptance criteria for Enterococcus qPCR in freshwater.

SA ¶ 13 EPA will review epidemiological studies of swimming-related health risks due to fecal contamination that are completed by entities other than EPA, including, but not limited to, studies of runoff-impacted beaches and beaches impacted by avian sources, if the results are made known by EPA by December 2010. EPA will consider any relevant study findings in developing recreational water quality criteria. EPA will either incorporate the relevant study findings into the recreational water quality criteria or explain, in its notice of proposed new or revised water quality criteria and solicitation of public comment, the reasons why such study findings are not appropriate for incorporation into the recreation water quality criteria.

Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA reviewed final results from epidemiology studies conducted by Marion et al¹, Colford et al², Fleisher et al³, Fleisher et al⁴, Kay et al⁵, and Corbett et al⁶.

¹ Marion, J.W., Lee, J., Lemeshow, S., Buckley, T.J. 2010. Association of illness and recreational water exposure during advisory and non-advisory conditions at an inland U.S. beach. *Water Research* 44(16): 4796-4804.

² Colford JM Jr, Wade TJ, Schiff KC et al. Water quality indicators and the risk of illness at beaches with nonpoint sources of fecal contamination. *Epidemiology* 2007; 18:27-35.

³ Fleisher JM, Fleming L. et al. The BEACHES Study: health effects and exposures from non-point source microbial contaminants in subtropical recreational marine waters

⁴ Fleisher JM, Kay D, Wyer MD, Godfree AF. Estimates of the severity of illnesses associated with bathing in marine recreational waters contaminated with domestic sewage. *Int J Epidemiol* 1998;27:722-26.

⁵ Kay D, Fleisher JM, Salmon RL et al. Predicting likelihood of gastroenteritis from sea bathing: results from randomized exposure. *Lancet* 1994;344:905-9.

⁶ Corbett SJ, Rubin GL, Curry GK, et al. The health effects of swimming at Sydney beaches. The Sydney Beach Users Study Advisory Group. *Am J Public Health*. 1993;83:1701-1706.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA completed this study and therefore, no further actions will be taken with respect to this obligation. EPA may consider the results from other epidemiology studies as time permits.

SA ¶ 14 No later than December 15, 2011, EPA will convene an Experts Scientific Workshop involving both EPA scientists and external scientists for the primary purpose of obtaining input on what future science and research might be conducted to further improve the understanding of potential human health risks from exposure to fecal contamination from avian wildlife and other wildlife in coastal recreational waters. If the experts at the Experts Workshop identify one or more studies that might be conducted to further improve the understanding of the potential health risks from exposure to fecal contamination from avian wildlife or other wildlife, EPA shall evaluate whether the studies should be performed as part of the Agency's review (between 2012 and 2017) of the criteria that EPA will publish in 2012, and EPA shall advise the parties to this Agreement of the results of EPA's evaluation no later than December 15, 2012.

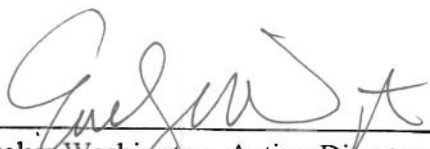
Actions Taken By EPA from July 1, 2010 to December 31, 2010

EPA began work to decide on meeting format and began to develop a draft agenda. Work to decide on location and to begin preparing invitations was delayed because EPA decided to use a contractor for support.

Actions Planned By EPA from January 1, 2011 to June 30, 2011

EPA plans to work with a contractor to decide on meeting format, agenda, and location., and to identify participants and begin to develop meeting materials.

The undersigned, Evelyn Washington and Charles I. Noss are, respectively, the Director, Standards and Health Protection Division, Office of Science and Technology and National Program Director for Water Quality, Office of Research and Development. The Office of Science and Technology in EPA's Office of Water and the Office of Research and Development have primary responsibility for discharging EPA's duties under the Settlement Agreement. This report reflects our best current information concerning the actions taken by EPA with respect to its responsibilities under the Settlement Agreement during the preceding six months (July 1, 2010 – December 31, 2010) and a description of the actions EPA intends to take with respect to its responsibilities under the Settlement Agreement during the following six months (January 1, 2011-June 30, 2011).



Evelyn Washington, Acting Director
Standards and Health Protection Division
Office of Science and Technology
Office of Water
U.S. Environmental Protection Agency

13 Jan 2011
Date



Charles I. Noss, Sc.D.
National Program Director for Water Quality
Office of Research and Development
U.S. Environmental Protection Agency

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Date