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REQUEST FOR TECHNOLOGIES

Title: Demonstration of Algal Toxin Detection Field Sensors and Kits

Date: September 7, 2017

Program: The Alliance for Coastal Technologies (ACT)

Application Deadline: Application (form with signed cover letter) must be received by 5:00 p.m. Eastern Time on October 20, 2017.

The Alliance for Coastal Technologies (ACT) is currently accepting preliminary applications from developers and manufacturers of sensors and test kits for the detection of harmful algal toxins to participate in independent performance testing. This demonstration is complementary to an ongoing ACT Technology Evaluation conducted on fluorescence-based instruments designed to characterize phytoplankton abundance and taxonomic composition and aligns with our current theme on technologies for the detection of harmful algae and their toxins. Over the last decade, a large number of new test approaches have been developed, including but not limited to immunoassay and molecular methods. However, an independent evaluation of assay types, relative to standard methods, is currently a barrier to use for many stakeholders. Sensors and field-portable/-deployable assays quantifying toxins of interest (including but not limited to domoic acid, saxitoxins, and microcystins) will be prioritized. Testing will be conducted under controlled laboratory conditions, as well as under diverse field conditions. Like all ACT Technology Evaluations, participation in this effort will be voluntary and free of charge for qualifying applicants, and results will be made available to the public in individual summary reports for each sensor/assay tested.

ACT is a component of US IOOS, funded by NOAA and EPA, and a partnership of research institutions, agencies, state and regional resource managers, and private sector companies interested in developing, improving, and applying sensor technologies for studying and monitoring aquatic environments. ACT was established on the understanding that instrument validation is necessary so that effective existing technologies are recognized and promising new technologies can be made available to support both successful coastal science and resource management, and the long-term success of Integrated Ocean Observing Systems (IOOS). The specific functions of ACT are to serve as: (1) an unbiased, third-party testbed for evaluating existing, new, and developing coastal sensors and sensor platforms, (2) a comprehensive data and information clearinghouse on coastal technologies, and (3) a forum for capacity and consensus building.

Please visit our web site at www.act-us.info for additional information on ACT, to download application forms, and for detailed information on the ACT Algal Toxin Detection Field Sensors and Kits Demonstration (including deadlines). More information can also be obtained by contacting Dr. Mario Tamburri (tamburri@umces.edu) and Dr. Tom Johengen (johengen@umich.edu).

Synopsis of Program

The Alliance for Coastal Technologies (ACT) provides an unbiased, third party testbed for evaluating existing, new and developing sensors, and related technologies, for studying and monitoring freshwater, coastal and ocean environments. ACT has launched a series of activities focused on technologies for detecting harmful algal blooms (HABs) and their toxins. The first, a Performance Verification for fluorescence-based instruments designed to characterize abundance/biomass of phytoplankton and community composition, is testing commercially available sensors in summer-fall 2017. The current call is the second in the series, and focuses on sensors, test kits, and assays for HAB toxin detection in marine and freshwater environments. In general, three criteria are considered in the selection of a technology evaluation theme. First, there was a consensus of the stakeholders that there is a legitimate coastal management and research need for the technology. Second, there are a number of assays and test kits designed for the detection of HAB toxins available for testing. Third, testing of these technologies is feasible within a reasonable timeframe with existing ACT capabilities and funding.

The occurrence of HABs in fresh, estuarine and coastal water is increasing in both frequency and extent worldwide, with large negative impacts on the environment, economy and human health. A critical component to understanding, predicting, and addressing this significant problem lies in the ability to quantify toxins produced by these organisms with a high degree of specificity and accuracy and with reasonable constraints on time, cost, and effort. These approaches are essential to both basic research questions on HAB ecology and to management efforts to protect human, animal, and ecosystem health.

It is important to note that ACT does not certify technologies or guarantee that a technology will always, or under circumstances other than those used in testing, operate at the levels verified. ACT does not seek to determine regulatory compliance; does not rank technologies or directly compare their performance; does not label or list technologies as acceptable or unacceptable; and does not seek to determine “best available technology” in any form. ACT will avoid all potential pathways to picking “winners and losers”. Therefore, although demonstration of performance will apply to all sensors/assays evaluated under common testing protocols, no direct comparisons will be made between technologies from different manufacturers and sensor/assay-specific Demonstration Statements will be released to the public for each sensor/assay type as a final report.

Focus of Demonstration

Accurately and efficiently detecting and measuring HAB toxins in freshwater and marine systems requires specific, accurate, and time/cost-efficient technologies. Standard methods for detecting and quantifying toxins (e.g. LC-MS/MS, HPLC, mouse bioassay, receptor-binding assay) are highly accurate but tend to be time-, cost-, and labor-intensive. The time, cost and effort required to generate data from samples often means that few samples are analyzed and that there are significant time lags in generating those data. There are several field-portable/-deployable assays, test kits, and sensor-based approaches that detect HAB toxins via immunological (i.e. antibody) and/or molecular methods. **As these approaches and instruments are incorporated into harmful algal bloom monitoring and management efforts, it is important to understand their performance.**

This ACT Performance Demonstration will therefore focus on the suite of instruments and/or assays with the specific application of detecting HAB toxins in marine and freshwater systems, particularly those sensors that are field-portable or field-deployable. Technologies may be either autonomous or require a human operator. Sensors and assays quantifying toxins of interest (including but not limited to domoic acid, saxitoxins, and microcystins) will be prioritized. The evaluation will quantify instrument/assay accuracy, precision, range/detection limits, and reliability against standard methods. Protocols and a detailed test plan will be developed with the aid of applicants and a Technical Advisory Committee to evaluate these specific parameters under both controlled laboratory and diverse field conditions. Initial laboratory tests will focus on quantifying accuracy, precision, dynamic range, and detection limit under controlled environments and taking into account matrix effects. Limited field tests will follow that focus on instrument reliability and ability to detect and quantify toxins against a complex natural background.

Eligible Technologies Must Be:

- Commercially available technologies.
- New, near-commercial technologies that are ready for the market with available quality testing data to support performance claims. Preference will be given to technologies that fall above a NASA technology readiness level of 7 or higher (https://www.nasa.gov/pdf/458490main_TRL_Definitions.pdf)
- Designed to detect and/or semi- or fully quantify HAB toxins (in situ or portable). Preference will be given to field-portable or field-deployable sensors and assays quantifying toxins of interest (including but not limited to domoic acid, saxitoxins, and microcystins). Sensors/assays quantifying other algal toxins may be tested according to availability of reference methods for detection, availability of certified reference standards and ACT personnel and budget.

One-to-three sensors or test kits may be requested from participants, depending on the specific evaluation protocols developed and timing of test deployments. ACT will take responsibility for the sensors during the demonstration testing and will return all non-expendable materials and units when the evaluation is complete. Qualifying applicants will also be asked to participate in the design of evaluation protocols. The results and summaries from all demonstrations will be provided to qualifying applicants and made public after evaluations are completed. Because of limited resources, ACT may select to evaluate only one sensor model or kit/assay type per individual developer, manufacturer, or vendor depending on the number of qualifying applicants. We will, however, consult with applicants if this selection process is necessary.

Benefits of Technology Demonstration:

ACT will provide technology developers with an independent, scientifically objective process for testing their instruments in a diverse range of coastal marine and freshwater environments and under actual situations for which their products were designed. Moreover, ACT results will provide potential investors and users of innovative approaches with information on how technologies perform in comparison to reference methods. Through this process of demonstration, ACT will ultimately aid in the implementation of accurate and reliable technologies that will enable the effective monitoring and an increased understanding of coastal resources and processes.

Specific benefits for technology developers, manufacturers, and vendors:

- Access to expertise in demonstrating, verifying, and applying coastal monitoring technologies.
- An opportunity to test a technology on a nation-wide basis under different environmental conditions where appropriate for the technology.
- An unbiased, reputable evaluation of technology performance.
- Increased credibility from having independent performance data. Valuable, independent ACT data in support of application for regulatory acceptance. Increased product recognition nationally and internationally through ACT outreach.
- A potential market advantage that customers and users may consider in their technology purchasing decisions.
- Increased confidence for investors.

Specific benefits for technology users:

- Timely information on the performance of sensor required to address an environmental emergency and recovery.
- Easily accessible information on sensor technologies for application in coastal environments.

- Credible technology performance verifications and demonstrations independent of developer, manufacturer, or vendor claims.
- Performance-based verification and demonstration testing addressing realistic data quality objectives under varying environmental conditions.
- ACT, NOAA and EPA review of verification and demonstration results.

Application Process and Acceptance for Rapid Response Evaluation:

The application and acceptance process consists of four steps: a preliminary application, conditional acceptance, a full application, and agreement on a test plan. The tentative schedule and deadlines for each step are provided below.

Step 1. Preliminary Application - Applicants (developers, manufacturers, and vendors are requested to provide summary information about the technology proposed for testing and about their organization by submitting a signed cover letter (no longer than two pages) and by completing the ACT Application for Evaluation form (available at www.act-us.info/evaluation/rft.php). The purpose of the preliminary application is to determine if the technology meets the criteria/requirements set forth in this Request for Technology, if ACT facilities are capable of conducting an appropriate and safe evaluation, and if a conflict of interest exists between the applicant and ACT. Preliminary applications are screened and categorized by ACT Headquarters staff based on at least the following criteria:

- Does the technology fit the stated theme?
- Does the technology address the stated priorities?
- Is the technology applicable to in situ, portable and/or field deployable monitoring/studying of aquatic systems?
- Is the technology based on sound scientific and technical principles?
- Is the technology sufficiently commercially-ready for demonstration testing?
- Can the applicant demonstrate ownership of the technology?

Step 2. Conditional Acceptance - All applicants that meet the requirements for an ACT Technology Evaluation will be identified and accepted contingent upon the successful completion of Steps 3 and 4. Acceptance notification will be delivered to the applicant within one week of the receipt of the initial application.

Step 3. Full Application - The Full Application for testing requests additional information about the technology to ensure a clear understanding of the proposed technology, including the scientific and engineering principles of operation, previous performance data (if applicable), and potential users/customers. The application should include appropriate peer-reviewed literature, technical articles, reports, process flow diagrams, equipment specification sheets, operating instructions, and other related materials to enable the reviewer to fully understand the technology and any data and information that are available to support the application.

Full Applications must also include proposed protocols for conducting the evaluation. The draft protocols should be based on standard scientific testing practices and must include:

- Requirements for qualifications of test personnel.
- Requirements for health and safety of test personnel, the public, and the environment.
- Proposed methods and procedures for demonstration including: a) set-up, b) period of operation, c) operation parameters, d) experimental design with number of replicates and controls, e) demobilization, and f) QA/QC.
- A standard measure or existing, accepted standard reference material to be calibrated by.
- A standard measure or existing, accepted method to be tested against for performance comparison.
- Proposed methods and procedures for storing, retrieving, analyzing, and reporting data.

Step 4. Agreement on Test Plan - ACT Headquarters staff, Technology Advisory Committee, Technical Coordinators for each Partner Institution, QA/QC Coordinator, and representatives for each qualifying applicant will gather for a workshop tentatively scheduled for XXX, to discuss and draft a Test Plan based on the recommendations for each qualifying applicant and an appropriate QA/QC strategy. The draft will be externally reviewed by a panel consisting of Federal, academic and appropriate industry professionals for appropriateness of experimental design and statistical analyses before a Final Test Plan is submitted to the qualifying applicants. Although ACT does not conduct direct comparisons of instruments being evaluated, the standardization of methods in Test Plans will allow simultaneous assessment of the various technologies and permit end-users to draw their own conclusions regarding the sensor and/or kit that best meets their needs.

Deadlines and Dates:

- Preliminary Application (form with signed cover letter) must be received by 5:00 p.m. Eastern Time – October 20, 2017
- Notification of Conditional Acceptance – November 3, 2017
- Full Application packages due – December 8, 2017
- Protocol Workshop, Bowling Green, OH – February 2017
- Final demonstration protocols and Test Plan – April 2017
- Laboratory and field demonstration tentatively scheduled to begin in May 2017

Demonstration Agreement:

A legal agreement (the Agreement) between ACT and individual qualifying applicants will be drafted to state that all parties agree to conduct the evaluation in accordance with the final Test Plan and that the results will be released to the public. The Agreement will also state that there will be no modifications to final Test Plan, regardless of unforeseen circumstance encountered during testing, without written consent from all parties. Furthermore, the Agreement will clearly state that although the developers, manufacturers, or vendors will be allowed to view the Demonstration Statements before they are released to the public, they will not be allowed to make changes to the final report. Under special circumstances ACT will consider inclusion of comments (in the form of a one-page letter) from the developers, manufacturers, or vendors as an appendix to Demonstration Statements. Finally, it will be noted that all data collected during demonstrations by the instruments tested are the property of the proponent and cannot be used by any other party without consent. The Agreement will be signed by the ACT Director and the appropriate representative from the qualifying applicant's organization.

Additional Information and Forms:

Please visit our web site at www.act-us.info for additional information on the ACT program, details on the ACT Evaluation Process, and to download required application forms. More information can also be obtained by contacting Dr. Mario Tamburri (tamburri@umces.edu) and Dr. Tom Johengen (johengen@umich.edu).

Initial Technical Advisory Committee:

(proposed waiting for confirmation)

- Dr. Joel Allen, EPA
- Dr. Greg Doucette, NOAA
- Dr. Dianne Greenfield, USC
- Dr. Meredith Howard, SCCWRP
- Dr. Keith Loftin, USGS