

Office of Science and Technology Policy (OSTP)
Request for Information (RFI)
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**Response from Spyglass Biosecurity, Inc. and Farragut
Advisory Services LLC:
National Biotechnology Blueprint**

The White House
Office of Science and Technology Policy
Associate Director, Science Division
Assistant Director, Biological Research
Assistant Director, Biotechnology
BIOECONOMY@OSTP.GOV

To Whom It May Concern:

Thank you very much for issuing the above-referenced Request for Information (RFI), in order to solicit input from stakeholders for the development of the Administration's National Biotechnology Blueprint.

Spyglass Biosecurity, Inc. and Farragut Advisory Services LLC are pleased to provide this response to the RFI. Spyglass Biosecurity, Inc. ("Spyglass") is an early-stage California company (a certified service-connected disabled veteran owned business) founded in 2008 by Chris Melançon to serve customers who require timely and precise information to protect and preserve water resources and enable water research. Spyglass delivers portable water laboratories with leading biology-based detection technologies that have been proven in a centralized laboratory setting and that have subsequently been automated for use in a field environment. Farragut Advisory Services LLC is a Washington, D.C.-based consultancy that assists clients in all aspects of doing business with public sector customers ("FAS LLC"). FAS LLC's Principal, Daniel Mazella, has provided thoughtful, cost-effective advice and guidance to clients for more than twenty years.

RFI Question: "Identify one or more grand challenges for the bioeconomy in areas such as health, energy, the environment and agriculture, and suggest steps that would need to be taken [by stakeholders] to achieve this goal."

"Research and development: R&D investments, *particularly in platform technologies*, can support advances in health, energy, the environment, and agriculture, and accelerate the pace of discovery in fundamental life science research."

The health of our water resources is a primary indicator of the health of our planet. Water is necessary for the survival of virtually all life on Earth, but our ability to separate and analyze, identify or quantitate microbial ecosystems and harmful organisms in water has been limited because of barriers to the development and commercialization of biotechnology tools for testing.

We respectfully suggest that an appropriate “Grand Challenge” for consideration is the development and commercialization - and implementation in the field - of biotechnology tools to protect water resources.

Technology exists today that can be further developed and extended in order to effectively respond to the Grand Challenge of protecting our water resources.

Public Health: real-time monitoring of water quality using biotechnology tools and platforms can help prevent illness from water-borne pathogens, toxins and chemical contaminants. For example, emerging pathogens in drinking water can render current treatment methods inadequate; the presence of sewage in beach water (due to aging infrastructure), toxic algal blooms that cause paralytic shellfish poisoning, volatile organic chemicals (VOCs) leaching into water supplies.

Agriculture: real-time monitoring of water quality using biotechnology tools and platforms can help prevent illness from water-borne pathogens, toxins and chemical contaminants that are used for irrigation or processing of agricultural products. For example, during the past year, new strains of *E. coli* were discovered in Germany, and *Salmonella* in food caused illness and resulted in the recall of agricultural products.

Energy: Energy and water are inextricably linked. As new renewable technologies are developed and deployed, a thorough understanding the impact on aquatic ecosystems as well as water supplies is important. We suggest that the use of biotechnology tools and platforms would further scientific research in the nexus between energy and water.

Environment: Seventy five percent of the global population will live within 125 miles of a coastline by 2025. Fifty percent reside there today. We are introducing new stressors and contaminants into our water supplies. We suggest that the best way to manage that impact and respond to it effectively is to have real-time, reliable information on the health and safety of water resources.

Barriers to the Development and Commercialization of Biotechnology Tools for the Protection of Water Resources

The following are, in our view, some of the impediments to the use of biotechnology tools for testing drinking water for man-made and naturally occurring contaminants; monitoring recreational water quality; detecting invasive species; and aquaculture/agriculture pathogen monitoring:

1. Lack of reference standards for pathogen testing of water (seawater and freshwater);
2. Platform technology for the acquisition of samples and for the preparation, collection and isolation of pathogens has not been sufficiently developed and implemented;
3. Funding issues at all levels of government.

In addition, as an early stage company engaged in the development of an information network for testing of water resources, Spyglass can speak from firsthand experience in building a business that develops and commercialize a platform and assays for pathogen testing. Spyglass is faced with the challenge of in-licensing technology, further developing such technology and turning it into a set of products, and selling the products in the marketplace. As such, Spyglass can attest that the so-called “valley of death” that has been described as existing for the development and commercialization of diagnostics and therapeutics also exists for the development and commercialization of biotechnology tools and platforms for the identification of pathogens in water. Obviously, this “valley of death” in funding for the labor and research-intensive time prior to the sale of products is a barrier. Often venture capital seeks returns on investments within three to five years and so the near-term outlook disqualifies many critical technologies from the venture capital funding model.

Concrete Steps to Address the Grand Challenge:

1. Identify state-of-the-art analytical methods as determined by scientifically objective criteria (for example, sensitivity, specificity and limits of detection) and lead the establishment of standards across Federal, state and local governments and authorities for the testing for pathogens in water, the environment, food supplies to protect human health. We suggest that agreement by stakeholders upon the validity of specific analytical methods for pathogen testing and establishment of standards implementing such methods will result in the creation of a market that will be attractive for the commercialization of biotechnology tools and platforms for testing water. We further suggest that a standards-making authority such as the Stakeholders' Panel on Agent Detection Assays (*SPADA*) and AOAC

International as a standards implementation organization be formed to accomplish this step.

2. Invest in the development of new applications based on proven testing methodologies that have demonstrated an impact in existing applications of biotechnology tools and platforms. For example, human clinical diagnostics have proven the effectiveness of genomics in improving health outcomes for humans. That same genomic technology can be applied to protect food supplies, water supplies and the environment.
<http://www.cev.washington.edu/story/Ecogenomic+Sensor>
3. Make protection of our water resources a federal funding priority: Genomic sensors placed within the infrastructure that is part of the Ocean Observatories Initiative (OOI) should be prioritized to provide high-resolution information on the biology of our oceans and extend the program to include testing and analysis of our freshwater resources.
4. *In order to move life sciences breakthroughs from lab to market* (by overcoming the risk, expense, and need for many years of sustained investment), we suggest that the federal government continue to support regional, state and local small business incubation efforts. We also believe the federal government should improve access to federally funded inventions by being more flexible in granting licenses to those inventions.

Thank you very much for providing Spyglass and FAS LLC an opportunity to respond to OSTP's RFI. We hope that our input is helpful in developing the National Bioeconomy Blueprint.



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