AMERICAN SOCIETY FOR MICROBIOLOGY

American Society for Microbiology Response to

White House OSTP Request for Information (RFI) on the Bioeconomy

84 Fed. Reg. 175: 47561-2, September 10, 2019

October 22, 2019

The American Society for Microbiology (ASM) is one of the oldest and largest life sciences societies, with more than 30,000 members. Our mission is to promote and advance the microbial sciences through conferences, publications, certifications, educational opportunities and advocacy. We enhance laboratory capacity around the globe through training and resources, and we provide a network for scientists in academia, industry and clinical settings. Additionally, ASM promotes a deeper understanding of the microbial sciences to diverse audiences. Our members bring the basic, translational and clinical research expertise that plays an instrumental role in developing the bio-based economy of the 21st century.

ASM thanks the White House Office of Science and Technology Policy (OSTP) for providing this opportunity to weigh in on the steps needed to advance the bioeconomy.

Background

The central importance of the microbial sciences to understanding the world around us and solving major problems of our time cannot be overstated. Thanks to past investments in basic research, we now understand that microbial communities exist on, in, and around people, plants, animals, soil, oceans, and the atmosphere. Thus making microbiology and concepts like the microbiome relevant to almost everything, including the grand societal challenge of growing the emerging U.S. bioeconomy. There are myriad reasons for this. Microbes serve as the ultimate organisms for molecular and cellular biology research that has generated breakthrough technologies, from recombinant DNA technology to improved crop yields to CRISPR-Cas gene editing technology. Microbes are the source of industrial catalysts, and they drive the production of everything from food, to chemicals, pharmaceuticals and antimicrobials. Microbes form the basis of next generation bio-based fuels and chemicals, and as innovative inhabitants of every corner of the planet, they are adaptable to changing environments and the climate, and central to the earth's geochemical cycle and environmental change. The interdisciplinary nature of the microbial sciences positions the field to play a pivotal role in further developing a robust bioeconomy that provides jobs, economic benefits, the production of food, drugs, and new uses for renewable materials from agriculture, food and manufacturing activities.

Microbes have a legacy of providing products for society, especially when one considers their impact on the food, beverage, pharmaceutical, biotechnology, wastewater treatment, chemical, and other industries. Research on microbes routinely benefits science and technology well beyond the initial areas of study, and the federal government plays an instrumental role in funding that research. Continued advances made by microbial scientists focused on next generation pharmaceuticals, foods, as well as the conversion of renewable resources into fuel and chemicals, could propel work by private sector entities to produce products that are not based on fossil fuels, plus those that cannot currently be produced at industrial scale. Basic research on microbial physiology and ecology could translate into revolutionary applied research in multiple economically-important fields, including synthetic biology. The National Microbiome Initiative[1], outlined in the Interagency Strategic Plan for Microbiome Research, outlines the potential of this effort and notes that, with appropriate support, we can continue to catalyze this area of study.

Another critical and unique component of the national bioeconomy is that which deals with biodefense. National health and security is at risk from especially dangerous emerging infectious diseases caused by pathogens such as Ebola virus and antibiotic resistant microbes. The national network of biocontainment laboratories is an essential element in our critical national infrastructure required to safely and securely address these dangerous threats.

A grand challenge to build a new bioeconomy has the potential to create new sources of income for families and communities, possibly tens of millions of jobs nationwide, yield not only new and unique products, but also sustainable replacements for high value products from resources that are often considered wastes. The creation of this new bioeconomy has the potential to have a profound and everlasting positive impact on human and animal health, air, soil and water quality, food production and safety, national security, and environments across the United States and around the world.

ASM's specific responses to questions posed in the published Request for Information are below.

Q1: What specific actions could the U.S. Government (USG) take to reinforce a values-based ecosystem that will guide the transformation and expansion of the U.S. bioeconomy, in both short and long term?

[1] None, None. *Interagency Strategic Plan for Microbiome Research, FY 2018-2022*. United States: N. p., 2018. Web. doi:10.2172/1471707.

Addressing the varied aspects of the bioeconomy will require the federal government to launch a long-term, large scale, multi-disciplinary effort to ensure that the U.S. is **the** leader in this field in the next decade. Such an endeavor should include a robust federal investment in fundamental microbial research and its applications across multiple agencies to develop and refine the use of microbes to support a 21st century bioeconomy. If we are to capitalize on this investment, fundamental advances are needed, but these must also be translated to industrial scales. Thus achieving a strong bioeconomy will require continued refinement of inventions, collaboration with economists, social and political scientists, as well as policies that support the commercialization and global protection of these technologies. Perhaps most importantly, it will require a sustained financial investment from the federal government now and in the years to come.

The potential benefits of this investment are enormous. They range from training of blue collar, white collar and technical experts who will form the workforce for this new bioeconomy, to development of knowledge that forms the technologies that support existing industries or create whole new economic sectors. Benefits also include the underpinnings of integrated supply chains that will generate revenue and jobs for rural sectors that have not traditionally benefitted from the 20th century industrial revolution.

As a global society with a presence in 112 countries, ASM is particularly attuned to the need for international collaboration to grow the bioeconomy. As countries around the world face grand challenges like climate change, antimicrobial resistance, food and water shortages and renewable energy, ensuring that the scientific knowledge and new technologies reach areas most in need is essential. As part of its leadership role in building this bioeconomy, the U.S. federal government must ensure that experts both inside and outside government entities are consulted about the scientific underpinnings, and that all available evidence is used to guide decisions.

Likewise, to protect the bioeconomy from threats associated with infectious disease and pathogens, vaccine development and deployment and clinical laboratory infrastructure have important roles to play. The network of academic biocontainment laboratories has a global role to play in advancing our understanding of the most dangerous pathogens, and the development of products needed for their prevention and control.

Challenges to implementing change

The traditional organizational structures of academia, industry, and the government often make cross-collaboration difficult. However, federal leadership of and investment in grand challenges such as sending a man to the moon, sequencing the human genome, and creating the internet illustrate how a major endeavor can transform the daily life of citizens and position

the U.S. to be the global leader in paradigm-shifting technologies. By analogy to these examples, ASM proposes that transcending these structural challenges to build a sustainable bioeconomy will require a set of coordinated activities, including:

- The integration of expertise across disciplines;
- A reduction in the existing barriers that discourage these sectors from working together to achieve common goals;
- Initiatives to train leaders for a technology sector that does not currently exist; and,
- Systems to promote the kind of transformational breakthroughs that often best occur when experts and expertise from different domains come together to solve a problem.

While microbes and microbiologists will be key players in development of this new bioeconomy, ASM knows that its success will require collaborations with scientists from other disciplines (including social scientists), engineers and economists.

With respect to the microbial sciences, enormous investments are required for purchase, maintenance, and staffing of advanced equipment for new techniques including cryo-electron microscopy, super resolution microscopy, multimodal imaging, and deep sequencing of genomes. The rising costs of doing this research, particularly keeping up with major advances in technology and equipment, present a significant barrier to progress. These expenses make it increasingly difficult for institutions, most of which are nonprofit, to cover these expenses through conventional grants or facilities and administration costs. Similarly, the buildings that house this equipment are aging, and universities have limited resources for renovation and replacement.

Likewise, the biocontainment laboratory network is threatened due to high operating costs, and an increasing regulatory burden associated with the demands for a highly trained workforce and the Federal Select Agent Program regulations. These costs cannot be met through traditional facilities and administration costs associated with extramural grants and contracts. Regulations should be at the appropriate level to ensure entities handling dangerous pathogens are doing so responsibly and in accordance with guidelines, while not wasting the time and effort with compliance tasks that do not benefit the laboratories or protect the public.

Q2: In what ways can the USG partner with the private sector, industry, professional organizations and academia to ensure the training and continued development of a skilled workforce to support the growth of the Bioeconomy?

For more than a decade, federal government research grant pay-lines have been so low that young scientists have been turning away from academic research as a career goal. The problem has been compounded by the targeting of funds to more translationally-focused initiatives. This has the effect of discouraging people from pursuing research in basic science, which is the foundation for most of the advances in clinical-translational research. Agency priorities should include training of the next generation of scientists. We must ensure that sufficient funding is appropriated so agencies can allocate resources toward trainees and early career scientists to encourage their development as independent scientists in academic settings, especially for those who are dedicated to basic research.

To fully realize the potential of the bioeconomy, it is also essential that this robust support focus on building an inclusive and diverse scientific workforce. Moreover, federal support is needed for the development of infrastructural resources, such as training programs at the undergraduate and graduate levels for new leaders in this growing field. With strong public support, multidisciplinary teams can be assembled at the institutional level that include scientists, engineers, economists and policy experts to develop the learning systems needed to grow a beneficial bioeconomy.

With respect to biodefense, successful operation of biocontainment laboratories requires skilled building engineers and safety officers who are adept at managing the unique requirements of these complex facilities. Collectively, the workforce associated with biocontainment laboratories is highly trained and represents a major investment by universities that are home to this critical national infrastructure.

Societies like ASM can serve as strong partners to the federal government by convening scientists across multiple disciplines to come together to share research, data and to solve complex problems. In addition to our annual scientific meeting called Microbe, ASM is proud to administer the Annual Biomedical Research Conference for Minority Students (ABRCMS). This conference exemplifies the value of bringing diverse students from multiple disciplines together to share ideas and science, and continue to inspire them to pursue a career in research. Federal support from the National Institute of General Medical Sciences makes this unique conference possible.

Q4: Across the spectrum, from basic discovery to practical application, what data policies, information-sharing mechanisms, and safeguards will be necessary for a prosperous U.S. Bioeconomy?

With respect to biodefense and its role in the bioeconomy, we must ensure that biocontainment laboratories are safe and secure, particularly as these entities proliferate around the globe. For example, today there are more than 50 BSL4 laboratories in operation or under construction around the world.

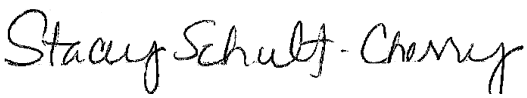
The U.S. should re-establish a program to support international engagement with foreign biocontainment laboratories to ensure safety and security of these facilities by providing training in best practices and conducting collaborative research activities to enhance transparency and reduce the risk of intentional misuse of dangerous pathogens.

Funding is no longer available to ensure that the U.S., which has always been a global leader in research and development involving especially dangerous pathogens, can assist new facilities in foreign countries with the establishment of best practices for safe and secure operations of their facilities. This leaves a massive gap in global security because without safeguards and training in place, the risk of accidental release of dangerous pathogens and misuse by nefarious actors greatly increases. Funding is needed to resume these critical educational activities.

Conclusion

Advancing the bioeconomy is dependent upon the advancement of the microbial sciences and their application in the world. The American Society for Microbiology thanks the White House Office of Science and Technology for its attention to this important and rapidly growing dimension to the U.S. economy, and for making research and development a key priority. ASM and its members look forward to next steps in this endeavor and stand ready to assist you. For more information, please contact Allen Segal, ASM Director of Public Policy and Advocacy, at asegal@asmusa.org or 202-942-9294.

Sincerely,



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