

BIO Statement for the BWC Review Conference CNS Conference July 7, 2016

The Biotechnology Innovation Organization (BIO) is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the U.S. and more than 30 countries. Our members harness modern biotechnology to provide breakthrough therapeutics, vaccines and diagnostics to treat, prevent and diagnose life-threatening chronic and infectious diseases. Recent advances in biotechnology are helping us prepare for and meet society's most pressing challenges.

BIO has actively supported efforts to ensure that benefits derived from biotechnology research and development are accomplished safely and securely. To this end, BIO and its member companies have actively participated in many of the recent Biological Weapons Convention (BWC) meetings to ensure that our industry is working with the global community to achieve our shared objectives.

Industry is specifically focused on two key areas within the BWC pillars.

One of our first areas of interest is the review of science and technology. While we recognize that biotechnology offers many benefits, we also know there is the potential for rogue states and actors to use that power to cause harm and endanger many lives. There is a need to maintain the balance between the many benefits and potential harms. This means that it is critical that the BWC continue to track, assess and evaluate the role and applicability of new developments in the life sciences. BIO has and will continue to offer expertise to the ISU and States Parties as they seek to understand the nuances of the current technical environment. Experts in our industry are able to provide insights into how modern tools can be leveraged for beneficial uses in health, agriculture and industrial application. BIO can help identify developments and advances that might help further the aims of the BWC, such as national assistance and preparedness activities.

BIO supports the creation of a process or mechanism within the BWC to more systematically advise the BWC States Parties on the potential impact of new technological advances in the life sciences. BIO believes that it is vital that industry and academia play an active and transparent role in this process given their part in the discovery, development and use of novel science and technology. This could be done in several ways: 1) a select number of advisors could be chosen with either current or past industry or academic experience; 2) industry and academic experts could be added to technical working groups on specific topics (for example, the application of gene sequencing technology) such that they can provide input to a set of advisors from the various States Parties. As an example, The World Health Organization (WHO) Pandemic Influenza Preparedness (PIP) Framework has established an Advisory Group as part of its governance and review structure. The Advisory Group is comprised of a diverse group of members, primarily from governments, who represent all regions of the world. When the AG has to develop proposals on more complex issues they form technical working groups and include experts from industry and academia to ensure they include



all perspectives but also capture the latest scientific information. A similar, transparent process within the BWC would provide for a regular forum to collect stakeholder input and disseminate expert recommendations and reports to States Parties.

Our second area of interest is the preparedness and response activities undertaken by the States Parties. The world currently faces biological threats that come in different forms. These include emerging infectious diseases (i.e. Zika), pandemics (i.e. influenza), and deliberate acts of biological terrorism. Collectively, we must strengthen our public health preparedness efforts so that we are able to detect when an event has occurred, accurately diagnose the infectious agent, respond to and treat those who are ill, limit the spread of disease through prevention, and effectively recover. In previous BWC meetings, BIO has provided innovative examples of how the biotechnology industry can help mitigate the risks of these threats. BIO supports the efforts of States Parties to strengthen biodefense capabilities, including through further national work under Article VII. BIO would urge States Parties to consider incorporating public health preparedness activities and partnerships with the global biopharmaceutical industry as a part of their overall public health mission.

Advances in biotechnology research and development within industry have provided us with the ability to respond to biological events faster than ever. BIO and its member companies have made significant progress and investments in flexible platform technologies that allow companies to adapt quickly to real-world needs to develop necessary medical countermeasures. The advent of such capabilities offers new opportunities for cooperation to build infrastructure and capacity to protect against these threats. We hope that there is a role for BIO and its member companies as States Parties consider how best to enhance their efforts to review such developments. One potential mechanism for better sharing best practices and ideas for national and regional preparedness could be the Global Health Security Agenda. The GHSA could add an Action Package that encourages Countries to develop plans to work with global and local industry partners to better prepare and respond to natural and man-made threats, especially biologic ones.

Lastly, BIO believes the Implementation Support Unit (ISU) must be provided with the necessary resources in order for the BWC to effectively achieve its mission. The complexity of the subject matter coupled with the pace of advancement in biotechnology requires a robust ISU workforce that has the ability to comprehend information quickly and distill it for a broader audience.

BIO will be working to ensure a productive meeting and are planning a dedicated side event at the August Preparatory Committee to explore ways in which industry can contribute.