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## **WORLD'S TOP GENE SYNTHESIS COMPANIES ESTABLISH TOUGH BIOSECURITY SCREENING PROTOCOL**

*Form International Gene Synthesis Consortium (IGSC)  
to Coordinate Best Practices in Risk Reduction*

*Five Member Companies Represent 80 Percent of Worldwide Gene Synthesis Capacity*

**Washington D. C., November 19, 2009**—Five of the world's leading gene synthesis companies today announced agreement that they will apply a common screening protocol to promote biosecurity in the gene synthesis industry. By screening the sequences of synthetic gene orders and the customers who place them, the companies aim to support government efforts to prevent the misuse of gene synthesis technology. Blue Heron Biotechnology, DNA2.0, GENEART, GenScript and Integrated DNA Technologies together represent approximately 80 percent of the global gene synthesis capacity. They have formed the International Gene Synthesis Consortium (IGSC) to coordinate ongoing best practices development and to work together with governments and others concerned to promote the beneficial application of gene synthesis technology and to safeguard biosecurity.

"We are proud to announce the formation of the International Gene Synthesis Consortium and equally proud of the commitment to the secure and safe synthesis of DNA it demonstrates," said John Mulligan, Founder and CSO of Blue Heron Biotechnology. "The depth and breadth of expertise in gene synthesis represented by the participating companies, in concert with our dedication to policy based on sound science and thoughtful leadership, will enable us to shape the growth of a safe gene synthesis industry poised to help address the technological needs of the 21<sup>st</sup> century."

“Safety and security are a chief priority for all of the IGSC companies, as the growth of the gene synthesis industry depends on an impeccable safety record. Each of the five founding companies has demonstrated a strong commitment to the safe delivery of synthetic DNA by implementing strong internal biosecurity practices,” said Dr. Ralf Wagner, CEO and CSO of GENEART. “We hope that the IGSC will help to encourage effective collaboration with government and policy organizations and promote internationally consistent approaches to safety and security in gene synthesis.”

“Each of the IGSC companies have worked over the past several years to implement internal sequence and customer screening processes, while contributing to the larger conversation amongst government agencies, policy organizations and the broader scientific community about developing an internationally coordinated approach to biosecurity,” said Nick Yan, Vice President, Marketing of GenScript USA. “Recognizing that achieving real gains in biosecurity requires harmonization of screening and other practices, we have drafted a harmonized screening protocol and decided to form the IGSC in an effort to coordinate ongoing work toward shared best practices in the gene synthesis industry.”

The IGSC’s “Harmonized Screening Protocol for Gene Sequence & Customer Screening to Promote Biosecurity” establishes the five core components that each IGSC company will apply to promote the safe use of synthetic genes:

**Gene Sequence Screening:** The complete DNA sequence of every synthetic gene order is to be screened against a Regulated Pathogen Database developed by the consortium and one or more of the internationally coordinated sequence reference databanks (i.e., NCBI/GenBank, EBI/EMBL or DDBJ). Amino acid sequences of possible translation products for each synthetic gene ordered will also be screened.

**Gene Customer Screening:** A complete and thorough screening of each potential gene synthesis customer will be conducted to establish identity and clearance for delivery of genes ordered, in accordance with national guidelines. The screening protocol assigns special considerations to the ordering of Select Agent genes.

**Record Keeping:** The IGSC companies will keep all screening, customer and order records for at least eight years.

**Order Refusal & Reporting:** IGSC companies reserve the right to refuse to fill any order and to notify authorities upon identifying potentially problematic orders, coordinating efforts with local and national law enforcement and intelligence agencies.

**Regulatory Compliance:** IGSC companies comply with all applicable laws and regulations governing the synthesis, possession, transport, export and import of gene synthesis and other products.

“Gene synthesis is the technology driver that will enable research institutions, companies and even individuals or small teams of scientists to develop solutions to the great challenges of our age, such as climate change, world hunger and pandemic disease. Gene synthesis itself provides us with powerful new opportunities to combat the threat of bioterrorism,” said Jeremy Minshull, president of DNA2.0. “We won’t

tolerate attempts to misuse gene synthesis technology to threaten the safety of any community. We scrutinize our orders to ensure that our customers are using our products for their potential benefits.”

“The founding companies of the IGSC have been working hand-in-hand with government and with the greater community of scientists and policy advocates to share our expertise in gene synthesis and to help us all devise the most effective biosecurity practices,” said Damon Terrill, Senior Vice President & General Counsel for International Legal and Regulatory Affairs for Integrated DNA Technologies. “For over three years, that collaboration has included close consultation with the Federal Bureau of Investigation and the Departments of Homeland Security and State, as well as with governments in Europe, especially. We encourage all companies who conduct gene synthesis to adopt the IGSC’s approach to sequence and customer screening, and we invite any company with significant business in gene synthesis to join us in the effort.”

### **About the IGSC**

The International Gene Synthesis Consortium (IGSC) represents the gene synthesis industry. For more information please visit [www.genesynthesisconsortium.org](http://www.genesynthesisconsortium.org) .