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**REPORT**

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## *Synthetic Biology*

### **Association Releases Code of Conduct For Best Practices in Gene Synthesis**

**T**he Heidelberg, Germany-based International Association Synthetic Biology Nov. 3 released a code of conduct for best practices in gene synthesis designed to address dual use concerns.

The IASB is a consortium of companies working in the field of synthetic biology. The code was widely circulated and was formally released at an IASB workshop held in Cambridge, Mass. According to the code's preamble, the code was created "in order to secure the foundations of this fledgling field against abuse and to bring synthetic biology to its full potential. It is aimed at all providers of gene synthesis services."

According to the preamble, the most fundamental tools for the design of synthetic biology applications are synthetic genes and their intrinsic features of freedom of design and artificial biological function. The association says its code of conduct is designed to help companies that provide DNA synthesis services and products and academic and public institutions that practice DNA synthesis to conduct their business in a sensible and responsible way.

Attorney J. Mark Waxman of Foley & Lardner, Boston, told BNA that the need for the code is increasingly important because gene synthesis is not governed by international treaties and will become easier to do as the time required to synthesize genes and the costs go down.

"One of the concerns in gene synthesis is dual use. The synthesis can produce wonderful things, such as sustainable biofuels, new therapeutics, and biodegradable plastics, as well as things on the select agent list," he said, referring to the U.S. government list of highly toxic or infectious agents that could pose a threat to public health or safety. "The problem is, how to promote the good without promoting the bad."

Waxman said the voluntary code is a very good first step, "a recognition of the benefits of reasonable behavior."

**Code Guidance.** In the section titled "General Considerations," the code states, "One important consideration of any regulation for biosafety and biosecurity is the freedom of research. A lot of beneficial developments would be impossible without the freedom to ex-

plore organisms and genes that bear a certain environmental or health risk. It is our conviction that such a risk can be managed and contained in a secure manner, while at the same time ensuring the level of freedom that is necessary for desired scientific advancements. It is our declared intention to raise barriers for malign attackers through a number of measures that will combine to protect Synthetic Biology from abuse."

The signors promise that they will participate or otherwise reasonably contribute for regular scientific dialogue on the further evolution of screening, best practices, and the topic of virulence factors and positive or negative lists of elements against which synthetic genes should be screened. They also agree to develop a compliance plan for adherence to the code of conduct.

The code offers the following guidance:

■ **Risk Assessment and Risk Management.** For biosecurity, risk assessment entails the screening of DNA sequences for genes that can be intentionally abused, for example, in terrorist activities, whereas risk management entails the restriction of access to synthetic DNA to legitimate users.

■ **Record keeping.** Records of suspicious inquiries and positive screening hits as well as statistics on biosecurity- and biosafety-related inquiries and orders will be kept for at least eight years. Information to be retained will include the total number of inquiries and orders for synthetic genes, the number of inquiries and orders with positive screening hits, and the number of orders with positive screening hits that have been respectively filled or rejected.

■ **Cooperation with Authorities.** Gene synthesis providers will take reasonable steps to maintain communications with the government in the nation where they are headquartered and promptly inform authorities each time they encounter evidence, such as attempts to conceal a nonbusiness delivery address, that clearly suggests possible illegal activities.

■ **Sequence Screening.** Gene synthesis companies always should take reasonable steps to determine the relationship of the requested sequences to risk-associated sequences before sending them to customers. The section of the code provides procedure that reflects IASB members' best collective judgment of how to achieve these goals within the framework of existing technology.

■ **Response to Identified Threats.** Whenever any of the procedures described in the previous section produces a "hit" as defined by the then-applicable Technical Expert Group on Biosecurity (TEGB) guidance, the

hit will be assessed by a molecular biologist or similar subject matter expert and, when the hit is deemed authentic, the customer will be notified and made aware of the perceived risk; the order will be accepted only if the customer is a legitimate user and all national regulations that apply to the exporting/producing company have been met.

■ *Customer Screening.* Gene synthesis providers always should take reasonable steps to confirm that their customers are who they say they are. Where customers seek risk-associated sequences, providers should take further reasonable efforts to confirm that the customer seeks the requested sequence for legitimate purposes and has carefully considered any safety or security risks potentially associated with their use of the sequence.

The section provides procedure that reflects IASB members' best collective judgment of how to achieve these goals within the framework of existing technology.

■ *Cooperation on Biosafety and Security.* IASB members pledge to participate in the formation of a TEGB that will review current design and implementation of biosafety and biosecurity measures and propose and initiate improvements. The TEGB will develop an IASB-operated seal of approval program to certify compliance with the code. Providers will be encouraged to apply for seals whether or not they currently are IASB members.

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*The code can be found at <http://op.bna.com/hl.nsf/r?Open=jaqo-7xqpnr>.*