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Do You Have a Biosecurity Strategy?

By bioscentric | Biology

The pace of technological evolution in the biological sciences in the last two decades, or even the last several years, has been astonishing. Advances have enabled us to sequence a full human genome for several thousand dollars, accurately synthesize thousands of base pairs of DNA at a time, develop new generations of drugs that are safer and more effective than their predecessors, and engineer genomes with more precision than ever before.

Rapid progress has evoked a new sense of curiosity in scientists dreaming of new possibilities for biology-based products and processes, but has also jump started conversations that easier-to-use biological tools could be intentionally abused. While a sound biosecurity strategy is required at the national level, individual companies will play a pivotal role in holding intelligent and balanced discourse with the general public and developing reality-based safeguards with regulatory bodies. As this technology is progressing rapidly, and as the capacity for governmental bodies to keep pace is limited, industry will likely play an outsize role in defining rational and actually feasible

approaches. If biosecurity isn't already on your company's radar, then you should consider its importance.

Trending higher

In November 2016 the President's Council of Advisors on Science and Technology submitted a proposal (link opens PDF) to the Obama White House outlining ways to modernize existing biodefense preparedness and response procedures. The recommendations were intended to allow the federal government to continue existing efforts to surveil, respond, and recover disease agents; while also acknowledging that new biological tools have fundamentally changed the source of potential risks.

But biosecurity's popularity has been rising for several years. In 2012 the Emerging Leaders in Biosecurity Fellowship was created to bring together a multidisciplinary group of young professionals and established leaders to generate and execute public policy ideas related to the topic.

In 2015 the Pentagon noted that "gene drives," tools that push genetic traits through a species in a few generations, posed a potential bioterrorism threat. The beneficial uses are various: some have proposed using the tools to make wild mosquitoes resistant to malaria or other diseases transmitted to humans, although even the scientists at the forefront of advances in the lab are starting to ponder the difficult questions gene drives may pose. That's because nearly anyone with a modern biology lab, whether a giant healthcare company or a skilled undergraduate, can access the technology.

The International Genetically Engineered Machine Foundation, better known as iGEM, grappled with the ease-of-use issue this past year when a team from University of Minnesota attempted to build a gene drive after downloading a foundational paper authored by Dr. George Church that outlined how to construct one. There were two parts: a gene drive that knocked out the ADE2 gene in yeast (causing a pigment to accumulate and turning the colonies pink), and a "recovery" gene drive that would reverse the knockout by adding a functional but altered copy of the AED2 gene. The team took precautions by expecting to include three of the four necessary genetic components in the yeast, while separating a crucial fourth, and used a yeast strain that could only survive if fed unique amino acids available in a lab setting.

The team ultimately fell short of its goals. However, the project's undertaking forced iGEM leaders to implement new rules weeks after the competition regarding future pursuits of gene drives. It's not so much that members are worried a team will intentionally misuse the technology, but rather to reduce the risks of an accidental release.

While the move may appear minor, it could be regarded as an instance of policy experimentalism, one that may have a useful impact as national agencies enter this domain. The new policy doesn't ban gene drives outright, instead allowing participants the freedom to investigate and advance such tools responsibly (we would footnote to the policy but it's not posted publicly yet). No national government has attempted to regulate gene drives just yet, which means the competition's self-policing could set a precedent. Moreover, several individuals on iGEM's safety committee are regulators in Canada and the Netherlands.

Biosecurity blueprint

iGEM, which has listed the FBI among its sponsors for several years now, can be looked to as an example of how to respond to emerging issues in biosecurity. The competition immediately reacted to a scenario that had never before been encountered before — students working with a potentially high-risk project — without overreacting. As Pier Millett, iGEM's Director of Safety and Security, told STAT, "I know some government regulators will be watching very closely about how this is dealt with inside of iGEM." The fact that iGEM has a director of safety and security and related committees made a swift response possible. And there are several examples from within the biotech industry that iGEM could draw from where individual companies have worked together to self-police or generate an experimental policy long before an issue even lands on agency radar. For instance, DNA synthesis companies have worked together to screen all orders against a shared library of harmful agents to ensure that customers aren't building a dangerous bioproduct, whether intentionally or accidentally. As with the student competition, there was no national standard in place for dealing with potential biosecurity issues related to synthetic DNA purchases when the industry implemented its policy, only guidance issued by the U.S. Department of Health and Human Services.

The fast pace of innovation in biotech promises to usher in new technologies and industries capable of improving the health and welfare of the planet, but it also increases the risks that bad actors intentionally misuse biological tools to disrupt ecosystems and societies. What this means for multinationals and non biotech companies that are partnering in the space is that even if it seems that you are or your brand are insulated from biosecurity issues today, awareness of the landscape is invaluable.

Don't know where to start? Send representatives to iGEM to take a closer look. Adopt best-practices in responsible innovation laid out by the competition or the Engineering Biology Research Consortium. Consider the regulatory gaps facing your industry and use existing public sector infrastructure that may exist to shape intelligent policy. Biosecurity is an important emerging topic for the field — don't get left behind.