The Challenges of Deploying Synthetic Biology Technologies in Developing Countries**

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Summary

The planet faces a "perfect storm," caused in large part by a growing population and environmental degradation. This will require producing more biomass for food, feed, bioenergy, fabric, and materials with less land, water, and oil, and in the face of climate change and rapid loss of biodiversity. Maintaining the status quo, especially in developing countries, is *not an option;* we must act now. These formidable challenges are also incredible opportunities for change. Humanity is embarking on a new powerful genomic revolution, coupled with the digital and nanotechnology revolutions. The field of synthetic biology (SB) offers the promise of revolutionary new products to enhance health and create wealth. Like biotechnology, SB will likely be regulated under the guidelines of the Cartagena Protocol on Biosafety to the Convention of Biological Diversity (CP) for signatory countries.

Policy makers must acknowledge both the potential of SB and the public's deep mistrust of new, untested technologies they feel are outside their control. The future success of SB depends to a large extent on whether public policy is well-crafted. To build public confidence in the governance of SB, transparency, together with adherence to high safety and environmental standards and ethical principles, is essential. However, the all-important safety aspects of policy must be guided by scientifically defensible, risk-based approaches rather than public opinion, especially when the latter is driven by activist groups and political agendas. To promote sustainable development and global harmony, industrialized countries also have a moral imperative not to influence policies that limit development of other less advanced countries and learn from the missteps of regulating genetic engineering that illustrate that choosing a flawed paradigm has critical implications for a technology.

Current realities

In 2009, Sir John Beddington, United Kingdom Chief Scientific Advisor, warned that the world of the 21st century faces a "perfect storm" of problems that include food shortages, scarce water, environmental degradation, and insufficient energy resources. These challenges threaten to unleash public unrest, cross-border conflicts, and mass migration as people flee from the worst-affected regions. Rising standards of living in developing countries will trigger a surge in demand for food, water, and energy over the next two decades, at a time when governments must also make major progress in combating climate change. These formidable problems are all intimately connected. In the same way, countries and regions are interconnected, the actions, decisions, and policies applied in one region can have profound social, economic, and environmental impacts in other regions. An example of this is the excessive oversight of agricultural biotechnology, especially in the European Union. This oversight has deeply influenced and could be potentially devastating to agricultural development and food production in the poorest nations of the world.

The formidable challenges need to be addressed with approaches that include adhering to ethical behavior and deploying new technologies. The field of SB offers the promise of revolutionary new products that could greatly benefit society, both in industrialized and developing countries, by enhancing health, contributing to care for the environment, and creating wealth. Building public confidence in the governance of SB by following ethical principles and high standards of safety for human health and the environment is critical. A key ethical principle is the sharing of benefits from those technologies beyond the industrialized nations that are pioneering the technology.

Many argue that care is needed to involve the public in discussions and decisions relating to the development and use of new technologies (Sunstein, 2002) — especially those who invoke a strong version of the precautionary principle in regulating new technologies like biotechnology, nanotechnology, and SB. Building confidence in the governance of SB is necessary in assuring the acceptability of the products of SB, along with ensuring that SB products meet the necessary safety requirements and environmental standards. However, policy makers should also learn from the example of genetic engineering, which illustrates that choosing a flawed paradigm and "democratic decision-making" that involves many segments of civil society who may not fully understand the complexities of the technology, can also have critical implications for successfully deploying that technology. Sometimes, especially in developing countries, the general public, with a low level of education, may not fully appreciate the technical complexities related to the oversight of new technologies and the complex dimensions of risk science that must form the basis of decision-making.

Scientific opportunities and challenges

Great challenges offer great opportunities for change. Technologies as powerful as those offered by nanotechnology, the digital revolution, and the genomics revolution, can significantly contribute to solving global problems. The risks posed by these technologies must be carefully weighed against the benefits and the *risk of inaction* and *maintaining the status quo.* This especially applies to developing countries with the greatest increases in population, which arguably have the greatest challenges. It may least apply to industrialized regions where population is shrinking, food is plentiful, and health care and sanitation are adequate. There, the main concern is not poverty, but continued economic growth and environmental conservation. Environmental activist groups and self-styled "intellectual elites" who purport to represent the public interest have negatively influenced the adoption of agricultural biotechnology and demonized genetically modified organisms (e.g., pest-resistant crops or sterile mosquito vectors to manage diseases in developing countries). Many of these groups originate in regions, such as the E.U., with challenges other than food security and widespread tropical diseases (e.g., dengue).

SB is a logical extension of genetic engineering and will probably be regulated, for signatory countries, under the auspices of the CP. Countries that have signed and ratified the CP include the E.U. and most developing countries in the world, although not the United States. The debate around the oversight of SB has been initiated by NGOs active in the CP debate. These NGOs have asked the member countries to adopt a *de facto* moratorium on synthetic biology, and to apply the precautionary approach to field releases of synthetic life into the environment, acknowledging states parties' rights to suspend such releases.

Policy issues

Given the global challenges that need to be urgently addressed, regulation and oversight should avoid unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers. As with the oversight of modern biotechnology/genetic engineering, a case-by-case approach is necessary for SB. We must not assume that all products or organisms derived from SB will be safe or that all will be dangerous, and the U.S. approach of *regulating the product and not the process* seems sensible. An identification of key "categories of risk" that includes intellectual property (IP), biosecurity, biosafety, and ethics, and a categorization of SB products and applications as proposed by Kuzma & Tanji (2010) offers an obvious first step to develop appropriate international regulation. Further recommendations include:

- To adhere to ethical principles of benefit sharing and to contribute to solving global problems under the principle of "shared but differentiated responsibilities" (Rio +20), develop guidance frameworks that take into account global interests, not only domestic.

- What is an acceptable risk in a developing country will be different in a developed country, particularly given the scale of the challenges faced in the former. As such, the risk of testing new, unproven technologies versus the risk of maintaining the status quo must be considered.

- Take into account lessons learned from the oversight of other technologies, such as agricultural biotechnology, and use informed risk assessment for decision-making and not solely public opinion and political agendas.

- Most of the training for the regulation of agricultural biotechnology has been undertaken by UN agencies and NGOs involved in environmental, and not agricultural, activities, which has distorted and slowed the rate of adoption of this technology. National governments and the scientific community, especially those in developing countries, should pay close attention to capacity-building in risk science and biosafety regulation by experts in relevant areas.

- Carefully consider the balance of "democratizing" decision-making by involving the public in an effort to build confidence in the governance of SB and assuring acceptability of products versus adding great complexity and different agendas to the decision-making process that could result in inaction. Different regions have different agendas for public involvement (e.g., environmental conservation in Europe and California versus access to clean water in Central America). Discussions of certain issues should involve wider society, but in developing countries, highly technical issues, such as the regulation of genetically modified or SB products, are beyond the general understanding of the public, who will not see past the demonizing publicity of activist groups. Unfortunately, regulators in developing countries will carefully watch what regulators in more-advanced countries decide, especially when they don't understand a technology, such as genetic modification.

- Expand the capacity for solving global problems by the global scientific community by having open access to information, without excessive restrictions from intellectual property issues or excessive and costly regulation

- Heavily regulating a technology to limit bioterrorism also limits its potential to contribute to solutions. The excessive regulation and thus high cost of agricultural biotechnology has resulted in the almost exclusive dominance of this technology by big industry and the exclusion of public-sector institutions (universities) and small companies. This fact should outweigh the threat of bioterrorism and should influence the regulation of SB

- Allow the initial technical or biosafety problems from the first-generation products of SB to be solved by approaches developed in second-generation products, without unjustifiably inhibiting innovation by excessive oversight.

References

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