EDITORIAL

Judging synthetic biology risks

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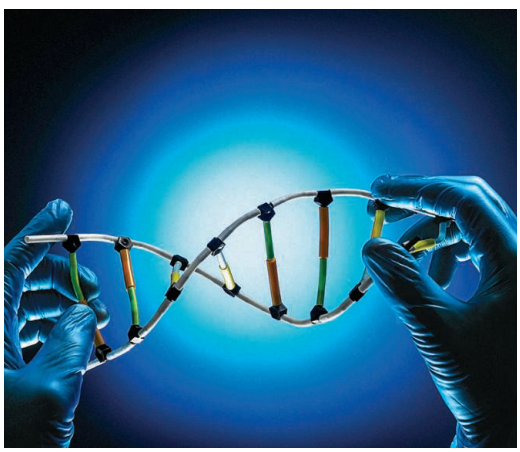
Last month, the European Commission (EC) Scientific Committees issued a draft opinion on whether existing risk assessment methods are adequate for synthetic biology. This opinion, which was written by a Working Group of 20 experts from Europe and the United States,* could have a substantial impact on shaping European and global synthetic biology policy for years to come. It is open for public comment through 3 February 2015.†

Synthetic biology already has delivered transformative products to market, from gene therapies that obliterate leukemia to biodegradable plastics synthesized from sugar. Yet since its beginnings at the turn of the century, synthetic biology has been steeped in controversy regarding its potential for societal benefit or harm. In response, the EC requested a scientific opinion on the definition of synthetic biology, the adequacy of risk assessment methods, and research priorities on risk assessment from a joint panel of its Scientific Committees on Consumer Safety, on Emerging and Newly Identified Health Risks, and on Health and Environmental Risks.



"... this opinion on synthetic biology will have substantial global impact."

Part I was adopted on 25 September 2014 and defined synthetic biology as "the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms." Already, this specification has influenced discussions at the United Nations Convention on Biological Diversity and is making its way into various scientific forums. This definition is important for several reasons. It avoids the traditional focus on conceptual aspects such as "modularity" in favor of a testable definition; it emphasizes that synthetic biology and genetic modification are fundamentally the same and yet continuously evolving fields; and it recognizes that existing regulations and guidelines for biological and genetically modified materials apply to synthetic biology materials. The definition includes the relatively new research areas of genetic parts libraries, designer cell chassis, DNA synthesis, genome editing, and xenobiology (engineering with noncanonical alternatives to DNA and RNA), but excludes research areas (such as bionanoscience and protocell research) that do not presently generate living organisms.

In Part II (draft released on 19 December 2014), the Committees evaluated whether existing methods are adequate to assess the potential risks associated with synthetic biology research and whether "safety locks" can be built into products of synthetic biology. The group wrestled with a broad set of questions. Will the continual acceleration of genetic modification technologies overburden current risk assessment procedures? What are appropriate comparators for synthetic biology organisms if they diverge substantially from the natural organisms? Will current methods ensure safe practices in nontraditional research realms, such as the do-it-yourself biology movements? The Committees balanced a forecast of major technological developments in the next decade, and the long-term scientific ambitions of the field. The resulting recommendations encourage standardization and streamlining of the submission of genetic engineering information to risk assessors, suggest the use of genetically modified organisms with a proven safety record as comparator organisms, and call for research to improve the ability to predict the behavior of complex engineered organisms. Moreover, existing genetic safety locks were considered insufficient as a primary strategy to contain the risks of synthetic biology. The development of additional approaches, including genetic firewalls based on noncanonical genetic material, was recommended.

Given the economic weight and thought leadership of the European Union, this opinion on synthetic biology will have substantial global impact. We encourage the scientific community and general public to comment on the draft opinion before the Committees issue the final opinion in spring 2015.

– **Rainer Breitling, Eriko Takano, Timothy S. Gardner**

*http://ec.europa.eu/health/scientific_committees/emerging/members_wg/index_en.htm#.
†http://ec.europa.eu/health/consultations/index_en.htm.

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