

---

their careers in laboratories. For example, the annual iGEM competitions involve college and high school students in synthetic biology experiments (Guan *et al.* 2013).<sup>49</sup>

Some experiments in synthetic biology are carried out by amateur biologists, sometimes referred to as “bio-hackers”, or the do-it-yourself biology (DIYbio) community (Ledford 2010; Schmidt 2009; Guan *et al.* 2013). There is contention over how many people are engaging in modern biotechnology outside of formal laboratories and the sophistication of the research and synthesis they are able to do (Bennett *et al.* 2009). Some civil society groups have expressed concerns that such independent researchers have neither the knowledge nor the tools to properly dispose of wastes or prevent release into the environment and have urged that DIYbio and bio-hackers be individually licensed in addition to their laboratories being licensed (EcoNexus 2011; FOE 2010).

Beyond the matter of laboratory safety practices, there is a broader concern that synthetic biology practitioners lack an understanding of ecosystem and biodiversity science. At the US PCSBI hearings,

the President of the Hastings Center, Tom Murray, stated:

“As the relative participation of biologists, familiar with the complexities and the non-linearities of biological systems diminishes, so may an appreciation of consequences of intentional or unintentional perturbations of, for example, eco systems. It is just not the way they think about it. Biologists are trained or at least particularly whole organism biologists even microbial biologists do think about whole organisms and think about environments and ecosystems. That is less true about some molecular biologists, and probably less true about some of the other people that are now coming into synthetic biology.... Why is this important? We need to make sure the people who are on the leading edge of synthetic biology understand the complexities of the systems they will eventually purport to tinker with” (Murray 2010).

## 8. ADEQUACY OF CURRENT METHODOLOGIES FOR ENVIRONMENTAL RISK ASSESSMENT

---

Perspectives on the adequacy of environmental risk assessments and regulatory structures designed for GMOs/LMOs resulting from classic genetic engineering in addressing organisms resulting from synthetic biology will depend, in part, on the perceived novelty of synthetic biology. Writing for the WWICS Synthetic Biology Project, Michael Rodemeyer noted that near-term products “derived from well-understood bacterial hosts and natural genetic sequences” and intended for contained use are “likely comparable in risk to currently produced genetically engineered organisms” (Rodemeyer 2009). Similarly, national government reports - such as the US Presidential Commission on the Study of Bioethical Issues (PCSBI 2010), the Belgian Biosafety and Biotechnology Unit (Pauwels *et al.* 2012), and the UK Health and Safety Laboratory (Bailey *et al.* 2012) and UK Synthetic Biology Roadmap Coordination Group (UKSBRCG 2012) - express the view that their regulatory regimes and risk assessment methodologies for genetically modified organisms sufficiently apply to the current

and near-term results of synthetic biology techniques. Most of these documents also, however, stress that regulators need to continue to monitor developments in the field, implying that changes may be necessary depending on how synthetic biology develops (Bailey *et al.* 2012; Pauwels *et al.* 2012; UKSBRCG 2012). Rodemeyer (2009), for example, notes that risk assessment will be challenged as the complexity of organisms increases as novel gene sequences are more significantly modified, and as genetic components are assembled from a greater variety of sources. From the perspective of the ICSWGSB (2011), current developments of synthetic biology techniques already demand new risk assessment procedures and regulatory responses. The ICSWGSB (2011) argue that, as current risk assessment methodologies have a strong element of comparison with the risks posed by the recipient or parental organism,<sup>50</sup> they are inadequate for organisms produced using synthetic biology techniques that have no analog in the natural world.

---

49 iGEM notes that the teams work in BSL1 or BSL2 laboratory spaces at high schools, universities, or similar institutions. The teams are required to follow all applicable laws and university biosafety rules.

50 Among the general principles for risk assessment, Annex III of the Cartagena Protocol on Biosafety states that “risks associated with living modified organisms [...] should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.”

---

There is also disagreement over the amount of resources that should be channeled to the research of the risks of organisms resulting from synthetic biology techniques. Some researchers reflect concern for the “unknown unknowns” of synthetic biology in their call for significantly increased funding for dedicated synthetic biology risk research. They argue that no one yet understands the risks that synthetic organisms pose to the environment, what kind of information is needed to support rigorous assessments, or who should collect such data. For example, Dana *et al.* (2012), writing as employees of the Synthetic Biology Project at the Woodrow Wilson International Center for Scholars (WWICS) and Ohio State University, argued for a minimal investment of \$20-30 million in synthetic biology environmental risk research over the next 10 years to address areas such as: the difference in physiology of naturally occurring organisms and organisms resulting from synthetic biology techniques; how microbes could alter habitats, food webs and biodiversity; the rate of evolution of organisms resulting from synthetic biology techniques; and understanding processes of gene transfer. Tait and Castle (2012), writing from the UK ESRC Innovation Centre, responded that the investment proposed by Dana *et al.* was not yet justified. Tait and Castle (2012) also noted that “the questions raised by Dana *et al.* should be considered as part of any risk-governance system for synthetic biology”. Their disagreement thus seems to be around the scale of dedicated risk research, and not the content. Synthetic biologist de Lorenzo (2010b) argues that the results of current synthetic biology research, as well as organisms and commercial products resulting from current synthetic biology applications (i.e., not yet orthogonal systems such as xenobiology) are sufficiently familiar, and that the risk assessments conducted on a case-by-case basis for GMOs/LMOs produced through classic genetic engineering are still appropriate.

Social scientists Zhang *et al.* (2011) recommend recognition of the full range of scientific uncertainties relating to synthetic biology. Drawing on the work of Brian Wynne (1992) and Andy Stirling (2008; 2010), Zhang *et al.* (2011) note that risks describe situations in which possible kinds of damage and their probabilities can be known. Other kinds of limited scientific certainty can be described as uncertainty (when the types of harm can be identified,

but not their probabilities), ambiguity (where the measurement or meanings of the kinds of harm are contested), and ignorance (where neither the outcomes nor probabilities can be characterized) (Wynne 1992; Stirling 2010). Zhang *et al.* (2011) warn that, as with other emerging technologies, there has been a tendency among governments to respond to synthetic biology as if it represents only identifiable and measurable risks.

Most existing biosafety regulations, including the Cartagena Protocol on Biosafety, rely on case-by-case assessments of environmental risks which take into account any environment which may be exposed to the organism, the characteristics of the organism and its intended uses. Current and near-term commercial applications of synthetic biology build on techniques of modern biotechnology to create organisms with novel combinations of genetic material. As such, the general risk assessment methodology for living modified organisms is expected to be applicable to organisms produced through synthetic biology, albeit specific considerations will likely be needed to identify any gaps that may exist in the methodologies that are currently in place to assess the environmental risks of living modified organisms and propose guidance on how to fill such gaps. The need for developing risk assessment guidance that focuses specifically on organisms developed using synthetic biology techniques was already foreseen by a group of experts representing the Parties to the Cartagena Protocol on Biosafety (CBD 2014).

A revised risk assessment methodology may not necessarily demand the set-up of regulatory regimes distinct from existing biosafety regimes covering GMOs/LMOs. If and when future commercial applications of synthetic biology evolve to use techniques that do not rely on the *in vitro* manipulation of nucleic acids to cause inheritable changes in an organism, current methodologies for environmental risk assessment may no longer be suitable as these organisms would no longer fall within the scope of many biosafety instruments.

For a more in-depth analysis of the gaps and overlaps with the applicable provisions of the Convention on Biological Diversity, its Protocols, and other applicable international instruments see document UNEP/CBD/COP/12/INF/12.<sup>51</sup>

---

51 Available at <http://www.cbd.int/doc/?meeting=COP-12>.