Executive summary

The potential of synthetic biology

As a platform technology, synthetic biology addresses a wide range of industry sectors and types of applications. It has the potential to offer significant economic benefits and bring greater efficiency to manufacturing (e.g. low production volume, high-value medicines and high volume, relatively low-cost transport fuels). It may also help meet bioeconomy objectives: reduction of greenhouse gas (GHG) emissions, food and energy security.

The future of synthetic biology depends on reliable, low-error, accurate and inexpensive DNA synthesis. Since 2003, the cost of DNA sequencing has dropped a million-fold and is now negligible. For DNA synthesis, i.e. writing the genetic code, costs need to tumble by similar orders of magnitude.

Meeting the technical difficulties

The technical difficulties involved in reaching parity with sequencing (the "tipping point" of DNA synthesis cost) are considerable and create high financial risks for the typically small, high-technology companies working to develop synthetic biology. These companies are always vulnerable in their formative years.

Governments can support them through grant schemes, loan guarantees, R&D tax credits, advanced manufacturing tax credits and public procurement. Governments might also examine ways to overcome barriers to venture capital investment raised by the lengthy innovation cycle in the life sciences. Innovative tools for decreasing private investment risk could reap rewards, and public-private partnerships may help reduce risk for vulnerable small companies. Eventually, synthetic biology might reduce innovation cycle times.

Major hurdles must also be overcome in bioinformatics and software infrastructure. The relevant software will become accessible to a mass audience long before DNA synthesis. This can be good for synthetic biology (e.g. by creating interest among school pupils) but it increases the need for biosecurity vigilance, as sequence designs could be sent to other countries for manufacture without appropriate controls.

Developing the research infrastructure

Some countries are now actively developing infrastructure and creating roadmaps to advance these goals, with the United States, China and the United Kingdom in the lead. Europe has a growing number of research groups, and some countries have strategies for developing synthetic biology (e.g. the UK roadmap). The potential duplication and fragmentation of European efforts is an issue the EU is seeking to address, possibly through the development of an EU roadmap.

Synthetic biology is developing in strong research institutions and close to other important facilities, such as sequencing centres. To reach its fullest potential it will have to move into the mainstream, probably when the required lowering of costs has been achieved. Governments can set up centres of excellence based around key researchers and create dedicated calls for research proposals. They can also implement simple measures such as funding mechanisms for physical and virtual networking, e.g. knowledge transfer networks and international exchanges.

Education and skills

Education in synthetic biology is particularly challenging owing to its multidisciplinarity and the need for business and entrepreneurial skills, such as change management. The route from the laboratory to the market is complex and any country engaging in synthetic biology beyond the research stage will need a strong cadre of suitably trained individuals. Synthetic biology companies engaged in manufacture of advanced biofuels are finding the transition to full-scale production challenging. There has long been a shortage of biochemical engineers, and the role of the chemical engineer could be enhanced. Education and training policy will have to evolve to meet these challenges.

Intellectual property

Much has been learned over the last 30 years about patenting life science inventions. The challenges specifically raised by synthetic biology should be recognised but should not be insurmountable and are generally manageable within the current intellectual property system. Potential solutions include open innovation and patent clearinghouses. The biotechnology industry has always had technically complex patents, and intellectual property is a big draw for investors. Synthetic biology may also learn from the semiconductor industry. Indeed, synthetic biology patents may eventually resemble a semiconductor patent more than a typical life sciences patent.

Regulation

Most practitioners believe that regulation applicable to GMOs is sufficient for synthetic biology, except for DNA synthesis. DNA synthesis creates unique biosecurity issues, which the nascent research community and industry are addressing. Although synthesised DNA does not present a security risk as such, its translation into products may. Risk-based assessment could be used to deal with this.

If regulation is too heavy, countries/regions that undertake synthetic biology R&D may lose out, as commercial deployment and capacity building may take place elsewhere.

Public opinion and engagement

Use of synthetic biology to develop the bioeconomy can help address the grand challenges of our times. However, public resistance to GM technology can hinder the application of synthetic biology and inhibit bioeconomy capacity building. Stakeholders must engage with the public. Continuing discussion among scientists, policy makers and the public at large can help clarify misunderstandings. Governments can also support competitions (such as MIT's iGEM) to captivate young people's interest. They can encourage knowledge transfer networks and social media open to the public as well as the scientific community to facilitate exchange of ideas.

Key messages

Synthetic biology holds the promise of bringing biotechnology products to mass markets as a result of rational design. Many policy gaps and hurdles must be navigated. A long-term effort is required. It will require policy flexibility and recognition both of the potential societal benefits and the need for public acceptance for it to achieve its full capability. A high degree of international exchange and co-operation will be needed. The OECD can play a pivotal role in providing appropriate mechanisms for discussion and assisting countries to address the policy issues of synthetic biology in a constructive manner.