Many thanks to Ms. María Andrea Orjuela for monitoring this discussion. This response is submitted on behalf of the UK Synthetic Biology Leadership Council (SBLC) and its Governance Subgroup (GSG). (<https://www.gov.uk/government/groups/synthetic-biology-leadership-council>). It is relevant to many of the responses to Topic 1 in this Online Forum, and takes them forward in the context of the second Topic.

While the focus of this second topic on evidence of benefits and risks is important, there is now a general recognition that we cannot ignore the role of regulatory and governance systems in interacting with scientific research and innovation process to determine future outcomes, particularly for biodiversity. Given that this Forum is intended to inform regulatory decision making for the next generation of innovative biotechnologies, it seems unwisely reductionist to discuss evidence of benefits and adverse effects without also considering the regulatory context that will have such a formative impact on innovation trajectories and hence on the future emergence of effects on biodiversity, both positive and negative. Regulation/innovation interactions go well beyond merely preventing products with unacceptable risks from being marketed. They will determine the innovation trajectory of entire industry sectors, including the research choices of scientists, the extent to which small companies are able to participate in shaping the product range of a sector, the balance between disruptive and incremental innovation in a sector, and eventually the relative competitive advantage of nations and regions[[1]](#footnote-1).

We should recognise that these issues are also of concern for citizens in both positive and negative senses. In many cases, particularly in the less developed parts of the world (see the references to Africa below), innovations arising from synthetic biology and gene editing can contribute significantly to major societal needs. It will be important to achieve a governance framework that allows citizens to take advantage of safe and effective benefits in a range of sectors, e.g. health, food security, and environmental protection. Failure in this endeavour will lead to such benefits being foregone and potentially avoidable harms being allowed to occur. As with potential adverse effects (already widely discussed under Topic 1), evidence of such benefits will not necessarily emerge from a short-term focus on specific technological solutions. This further emphasises the need: (i) to ensure that the regulatory decisions we make today do not lead to serious deficits in innovation and its governance in ten to fifteen years’ time; and therefore (ii) to ensure that future regulatory systems are able to be adaptive to the needs of innovative technologies as our knowledge and understanding progresses.

Current regulatory systems for GMOs are often described loosely as being either ‘product-based’ (in the USA and Canada), or ‘process-based’ (particularly the EU and the CBD).The process-based regulatory approach has been most widely criticised as having no rational basis, particularly that of the EU[[2]](#footnote-2), [[3]](#footnote-3) which is closely modelled on the CBD and its conventions. However, the US attempts to adapt their product-based system to the regulatory needs of gene editing have also been criticised[[4]](#footnote-4) and there is a growing consensus that the regulation of innovations based on advanced biotechnologies needs a radical re-think.

Governments internationally are now aware of these interactions and are adjusting their guidance to regulators accordingly. For example in the EU three principles are now in place to guide regulatory decision making - the innovation principle**[[5]](#footnote-5)**, backed up by the regulatory principles of proportionality and adaptation[[6]](#footnote-6). A recent report[[7]](#footnote-7) from the Netherlands Commission on Genetic Modification (Cogem) makes the points that: (i) only large companies can afford the high costs of meeting the current EU regulatory requirements and so avoiding the GMO legislation has become a driver for innovation in synthetic biology and gene editing; (ii) given the need for regulatory reform, in future more emphasis will be placed on ‘the product’ rather than the techniques used to create it; and (iii) analysis of the risks of biotechnology applications should be weighed against the benefits or value. Similar moves are under way in other parts of the world, particularly Africa[[8]](#footnote-8), [[9]](#footnote-9).

These factors are behind the frequent contributions to this Online Forum that reopen discussion of the definition of synthetic biology. This is inevitable because how we define the process of synthetic biology or gene editing is not a neutral decision – it will determine the extent to which these technologies are captured by the existing regulatory system with all its perceived disadvantages. And once a definition has been accepted as the basis of a regulatory system, it is no longer able to be modified, limiting the extent to which the regulatory system can be adapted to future needs of an innovative technology. There is very considerable, and justified, concern among many people working in this area that the current temporary operational definition of synthetic biology will become de facto the formal accepted definition if it is not further explored and discussed when opportunities like this arise. However, the central importance of the definition of synthetic biology would disappear in a regulatory system that is based on the properties of the product rather than the process (synthetic biology) by which it was developed.

The above comments make the case that the nature and mode of operation of the CBD and of its protocols should be part of these discussions. They will greatly influence the extent of the potential contribution of synthetic biology and gene editing to the conservation of biological diversity, the sustainable use of the components of biological diversity, and the fair and equitable sharing of the benefits. Rather than treating the regulatory system itself as an immutable constant and developing only those innovations that are able to meet its requirements, it is important to consider how we could, where necessary and appropriate, adapt the CBD and its protocols to the needs of innovative technologies, in order to maximise their benefits and their contributions to the CBD objectives.

Discussions so far in this Forum have demonstrated that the scale and diversity of scientific discoveries and potential innovative developments in this area cannot be addressed without evolution and adaptation of the regulatory provisions of the CBD itself, to allow a range of different regulatory provisions to be applied to different developments of synthetic biology and gene editing, rather than the current process based approach that has only two options – to capture or not to capture synthetic biology and gene editing within the provisions of the current CBD and its protocols.

Considering how such adaptations might be achieved, a project funded by the British Standards Institution and the UK Economic and Social Research Council, has considered how standards can contribute to such an adaptation process[[10]](#footnote-10). This project has been supported by the SBLC, as contributing to Recommendation 4 of its Synthetic Biology Strategy: “Develop a supportive business environment by ensuring that regulation and governance systems are proportionate and appropriate to the needs of industry and that these are aligned with the needs and desires of stakeholders”[[11]](#footnote-11). Standards can have an important role in adapting existing regulations to meet the needs of innovative technologies. In addition, most relevant to this discussion, they can have a role in the early stages of considering how to regulate a new and disruptive innovative technology. In advance of making a final decision on the relevant regulatory regime they can allow considerations of safety, quality and efficacy to be included in the development of an innovation while discussions on the most appropriate mode of future regulation take place. In some cases, through this approach, decision makers could conclude that there is no need for formal regulatory oversight and that standards and guidelines could be used to deliver an acceptable outcome, thereby moving some innovative developments into a more proportionate regulatory space.

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