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| Dr. Braulio Dias  Executive Secretary  Convention on Biological Diversity  393 Saint-Jacques Street, Suite 300  Montréal, Québec, CANADA H2Y 1N9 | | **31 October 2013** |

Dear Braulio,

The UK is grateful to the Secretariat for preparing for peer review the papers published on the New and Emerging Issues page of the CBD website on synthetic biology, in follow up to CoP Decision XI/11. The documents provide a good starting point, but we are of the view that a number of improvements could be made to facilitate the discussions at SBSTTA18. This letter presents an overview of the UK’s comments on the Secretariat’s papers. We are providing full comments separately in the annexed template as requested.

1. Balance between Risks and Benefits

We are of the view that consideration by the CBD of the issues raised by the innovative techniques in synthetic biology should take account of both the risks inherent in new technologies and the potential benefits such technologies have to society. Scientific advances and the appropriate use of new technologies are critical to meeting the challenges we face, in all countries, to halt the decline in biodiversity and its impacts on human wellbeing. Any review of evidence on risks of new technologies and potential for regulation should be framed in this context. The CBD has an important role to play in this regard as a champion of innovative approaches that help to address the three objectives of the Convention.

Indeed, the similarities between synthetic biology and genetic modification suggest that any risks could be most appropriately managed by adopting, at national level, similar risk-based approaches to synthetic biology as have been adopted by some Parties in respect of conventional genetic modification. It is not apparent that the papers have taken into consideration, for example, the EU system for regulating the deliberate release, contained use and transboundary movement of genetically modified organisms. Within the EU, this involves a case-by-case assessment and identification of the most appropriate containment for the work. Consent is typically required for higher risk activities under contained use and for any deliberate release work. The papers’ analysis of the risks involved could be strengthened by a consideration of how similar risks have been mitigated in other contexts.

1. Evidence developed through Contained Use

We feel the papers could be improved by mentioning the role that research carried out under conditions of contained use can play in the development of reliable evidence relating to synthetic biology. The reports could usefully emphasise the pivotal role of contained use as a means to develop robust evidence on how to regulate, with mitigated risks, any future commercial or other applications of synthetic biology that involve deliberate release. Additionally, it is important to note that any contained use strategy comprises multiple processes used in combination to minimise risk.

1. Existing Regulatory Frameworks

A necessary corollary to scientific research derived from contained use is an analysis of the existing regulations in different Parties covering GM and related research activities. Importantly, some Parties are already conducting such analyses. The UK’s Synthetic Biology Leadership Council is currently developing an approach to synthetic biology governance (including regulation, stakeholder engagement, and responsible research and innovation) which the UK would be pleased to share with the Secretariat upon its publication. The approach will enable us to respond in an equitable and balanced way to future societal needs and concerns.

The Secretariat’s papers would be improved by a more comprehensive review of how Parties regulate GM and related research activities, though we recognise that that this has not been possible within the scope of the current exercise. We are of the view that it would be useful as a future follow-up action from this report to seek input from Parties on how they currently regulate such activities. This would enable Parties to develop a fuller understanding of the effectiveness of current or future regulations and therefore provide an evidence base for any future action by the CoP. By dealing with these complex issues in a more integrated manner, solutions to potential problems will emerge that may elude us if we deal them in a piecemeal manner.

We would note that there are also existing international agreements which work to mitigate some of the risks currently identified in the papers. For instance, while it is true that advances in synthetic biology could be exploited for harmful purposes, including by creation of new biological weapons agents, such activities are prohibited by Article I of the Biological and Toxin Weapons Convention (BTWC). This was most recently reaffirmed in Article I of the Final Declaration adopted by the Sixth Review Conference of the BTWC, which states that *“all naturally or artificially created or altered microbial or other biological agents and toxins, as well as their components, regardless of their origin and method of production… [are] covered by Article I”*.

1. Sources used in the Papers

CBD Decision IX/29 states that “*proposals for emerging issues should, where possible, be accompanied with… credible sources of information, preferably from peer-reviewed articles”.* As such, the UK would welcome the inclusion in the report of a clear distinction between the weight given to evidence derived from peer reviewed sources and from documents produced by special interest groups. This will ensure an appropriate balance in the papers, which will enable the Parties to approach their discussions on the basis of the best available evidence and in full understanding of the provenance of that evidence. We would note that several documents are referenced multiple times despite not having been peer-reviewed and would question whether such prominence should be given to documents of this nature. The papers could be strengthened by the inclusion of additional information relevant to synthetic biology; references to two such papers are provided in the footnote below.[[1]](#footnote-1)

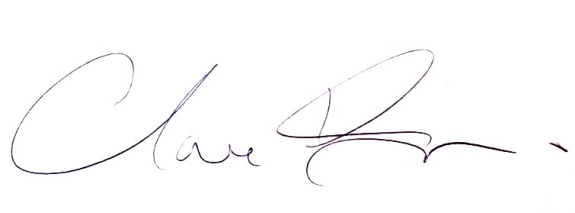
1. Clarity of Definitions

It is helpful that the papers highlight the lack of agreement over the definitions of synthetic biology and its related terms such as GMO and SMO. However, the papers do not attempt to resolve these competing definitions. The present situation complicates consideration of what does or does not fall within the scope of synthetic biology. In the UK, the regulatory and science communities are of the view that the majority of the applications of synthetic biology are already covered by EU and UK legislation on genetically modified organisms. This underlines the need for a fuller consideration of the regulatory frameworks already in place in different Parties and how such mechanisms could be used in respect of synthetic biology.

1. Precautionary Approach

The precautionary approach with regard to Synthetic Biology products, components and devices is referred to throughout both documents as a potential standpoint from which to regulate the field of Synthetic Biology. The precautionary approach can be interpreted in many different ways, with varying impacts. The papers would benefit from a fuller understanding of the types of risks involved if they are to inform a suitable and proportionate precautionary approach.

Yours sincerely



**Mrs Clare Hamilton**

**Head of International Biodiversity Policy**

1. *Synthetic biology—A review of the technology, and current and future needs from the regulatory framework in Great Britain* (2008). Prepared by the Health and Safety Laboratory for the Health and Safety Executive.

   *Event report: SynBio Workshop (Paris 2012)—Risk assessment challenges of Synthetic Biology* (2013). Journal of Consumer Protection and Food Safety. Pauwels, K et al. [↑](#footnote-ref-1)