CBD Notification 2015-139 – Peer review of the outcomes of the process in response to decision XII/24 on synthetic biology

Thematic area: Cartagena Protocol on Biosafety- Ref.: SCBD/BS/CG/MPM/DA/85140

NOTIFICATION No. 2015-139

Response from the UK Synthetic Biology Leadership Council.

Prepared by Joyce Tait[1] and Lionel Clarke[2]

The main body of comments below was prepared by Joyce Tait and Lionel Clarke on behalf of the UK Synthetic Biology Leadership Council (SBLC) and its Governance Subgroup. Additional comments from three members of the SBLC or the Governance Subgroup are included at the end of the paper.

UPDATED REPORT AND SYNTHESIS OF VIEWS IN RESPONSE TO PARAGRAPH 7(b) OF DECISION XII/24 ON NEW AND EMERGING ISSUES: SYNTHETIC BIOLOGY

We were impressed by the broad range of views expressed in the submissions and on-line interventions undertaken through the Biosafety Clearing House and feel that this report is a balanced and representative summary of many of these contributions. However, in a few cases, as indicated below, we feel that some of the issues widely discussed in the Open-Ended Online Forum (OEOF) are not reflected in this summary.

REPORT OF THE AD-HOC TECHNICAL EXPERT GROUP ON SYNTHETIC BIOLOGY

The comments below in response to this document also include some points that it does not address but which we believe are important.

3.1. Towards an operational definition of synthetic biology comprising inclusion and exclusion criteria

Para 21 of this document and paras 29 and 30 of the 'Updated Report' refer to the need for a definition in the context of informing efforts in policy making and risk assessment and indicating whether new approaches to regulation are required. The need for a definition of the synthetic biology process with this purpose in mind only arises because of the focus of the CBD on 'the process' of synthetic biology or in the case of genetically modified organisms (GMOs) the process of genetic modification. There were numerous submissions to the OEOF making a convincing case for moving to a more 'product-based' regulatory system, as is the case in the USA and Canada. Such a move would resolve this and several other problems raised by the focus of the CBD and its protocols on the processes of genetic alteration as a basis for risk regulation.

3.2 Relationship between synthetic biology and biological diversity

This section is written in terms of 'organisms, components and products' of synthetic biology (e.g. paras 26 and 29) but the definition does not refer to products and indeed para 32 specifically excludes extension to include 'products' under the scope of the Cartagena Protocol. It is important that this form of regulatory creep does not become embedded in discussions of the operation of the CBD.

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In this section, there is a generally balanced consideration of potential positive and negative impacts and a useful emphasis on the need to base decisions on the best quality evidence-based information. However, this balanced approach is not always extended to later sections where there is a reasonably strong case to be made for some expected benefits, while dis-benefits consist of vague conjectures repeated in a formulaic manner (see for example the tables of Potential Benefits and Potential Adverse Effects on pages 7 – 10). It will be important to have a balanced approach to implementing the precautionary approach referred to in para 29, and not to ignore a considerable benefit of high probability because of a vaguely specified negative scenario of much lower probability.

3.4. Adequacy of other existing national, regional and/or international instruments to regulate the organisms, components or products derived from synthetic biology techniques

Para 38 extends the point made above about the inclusion of the *products* of synthetic biology within the scope of coverage of the CBD. It is a useful aspect of the proposed definition that it does not include coverage of 'products' and the opportunity could be taken at this point to remove the anomaly of their inclusion in the CBD but not the Cartagena and Nagoya Protocols by removing them also from the CBD. There is no reasonable basis for the CBD to extend its regulatory reach into areas that are already well covered by other regulatory bodies. If the regulations in some countries are not adequate to control these products, the CBD is not an appropriate instrument to deal with this issue.

3.5. Potential benefits and risks of organisms, components and products arising from synthetic biology techniques to the conservation and sustainable use of biodiversity and related human health and socioeconomic impacts relevant to the mandate of the Convention and its Protocols.

The title above and para 44 again refer to the products of synthetic biology, which are not included in the definition. These references should be removed.

This section lapses into an over-emphasis on uncertainty and the possibility of adverse effects. It is important to acknowledge that most of the precautionary projections of adverse impacts from GMOs have not come to pass; indeed there have been considerable benefits to biodiversity, and to the lives of small farmers, from the reduction in use of pesticides where GM crops have been adopted. In line with developments in adaptive governance in other regulatory systems this should lead the CBD to consider whether some of its current provisions are indeed necessary for existing GMOs, rather than automatically proposing their extension into next generation technologies on the basis of equally speculative conjecture. The balance between the two tables in this section, referred to above, is also an example of this trend. In particular, it is important to note that greater complexity and greater depth of intervention can enable greater control rather than implying greater uncertainty. It is also important that forward looking scenarios are based on balanced and plausible assumptions.

The need to develop effective technological solutions to increasing global challenges (as for example arising from climate change and increasing human population), especially where current technologies are proving inadequate and synthetic biology has the potential to generate new options, reinforces the need for a more balanced approach to their assessment. The application of an over-precautionary approach risks prematurely excluding routes towards potentially more effective solutions that may be increasingly required in the longer term.

This section also considers ethical implications for societal views about nature, with the underlying assumption that there is international consensus on these ethical questions. In practice there is a very broad range of perspectives on such issues, and no democratic basis for giving priority to one particular set of values in making decisions about the future use of GMOs or synthetic biology.

Para 50 refers to "the difficulty of distinguishing which socio-economic changes result from the introduction of synthetic biology". The following sentence suggests introducing "appropriate methods from relevant scientific disciplines to take socio-economic considerations into account". It

should be acknowledged that the relevant methods are likely to come from the social sciences, not the natural sciences. In addition such methods should be encouraged to consider potential socio-economic solutions to such problems rather than dealing with them through technology-specific restrictions.

3.7. Degree to which the existing arrangements constitute a comprehensive framework in order to address impacts of organisms, components and products resulting from synthetic biology, in particular threats of significant reduction or loss of biological diversity

In the above title and in para 60, the references to 'products' should be deleted.

This section repeats some of the earlier points about complexity and uncertainty and our previous comments are also relevant here. Where there are reasonable grounds to expect adverse environmental impacts from the uncontrollable spread of modified organisms the CBD could usefully advocate investment in research on biological containment techniques – synthetic biology could play a major role in developing such techniques.

Para 60 recognises that the views of members of the AHTEG diverged on this question, but then goes on (in paras 61 – 65) to present only one side of the argument. These are areas where the operation of the CBD and its protocols could be criticized on the nature of their current role in governance of GM technologies and extending them further in future would be seen by many as a retrograde step.

ITEM 4. CONCLUSIONS AND WAYS FORWARD, INCLUDING ELEMENTS TO FACILITATE FUTURE DISCUSSIONS AND ACTIONS ON SYNTHETIC BIOLOGY UNDER THE CONVENTION

Para 66 j should not refer to the 'products' of synthetic biology.

General point

This consultation has missed the opportunity to bring the CBD more up-to-date with thinking elsewhere on the governance of innovative technologies, for example:

- where regulation has been based on the adoption of the precautionary principle, to adapt the regulation based on experience of safe use of the technology;
- to ensure that regulatory systems are proportionate to the risks posed; and
- to avoid unrealistic social amplification of uncertainty.

The CBD is by no means a perfect instrument and extending it in a straightforward manner to new technologies, far less adding new provisions to the existing set, are not the best way to improve its performance in protecting biodiversity from the negative impacts of new technologies.

COMMENT FROM JULIAN HITCHCOCK[3]

I am writing as a member of the UK's SBLC Governance Subgroup and a lawyer involved in the consultation process.

I have serious concerns about the proposal to define the term, "*synthetic biology*". In isolation, a glossary definition may well be useful in the context of a technical primer, for example. However, **very** considerable care must be taken when adopting a definition for legal purposes, especially when those purposes are not known, but may include restrictions. I vehemently object to any definition agreed by the Ad Hoc Expert Group being adopted at some later date by means of regulation, where the effect may be clumsily and irrationally restrictive or liberal. I was not encouraged by the proposed definitions, many of which appeared to import agendas such as utility that may be

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relevant in other contexts but not in a definition. Such a glossary-style definition may have a limited function in giving a working idea of the fields of synthetic biology to the uninitiated at a particular time, but even then the effect is likely to be negative. Far better to focus on individual elements.

The benefit of not defining terms associated with invention

It is important to note that, when a term is particularly comprehensive, it is very often wise **NOT** to define it. This is especially so when the subject concerns invention, because the prescriptive definitions will inevitably become out of date. For example, TRIPS, the European Patent Convention and the UK *Patents Act 1977* deliberately fail to define the fundamental term, "*invention*" and judges have, equally deliberately, avoided supplying one. It's a good example, because of course the technologies that we associate with synthetic biology are so varied and apt to move in unpredictable directions and across hierarchies. If, a few years' ago, there had been an attempt to define "*regenerative medicine*", it's unlikely that it would have captured the most important areas of endeavour to emerge from the advances that have taken place in the interim, notably the use of genetically manipulated autologous T-cells as anti-cancer agents. The European Union's *ATMP Regulation* thankfully avoided the term altogether, focusing instead on adapting an existing framework (medicines law) to specific classes of "advanced therapy medicinal product". These classes, each of which is defined in great detail, were the product of long and careful consideration. In this case, I strongly recommend that efforts are directed towards the identification of specific cases and issues and not to a quasi-ecclesiastical and generally pointless mission to define the obviously ineffable.

If the majority view is for a definition of the term "*synthetic biology*", then a broad definition would be unacceptable. Such a definition would be useless in practice: either different clauses that used the term would be riddled with different exceptions for particular subclasses in particular circumstances (which would be legally unworkable), or those subclasses and situations would be steamrollered under sweeping conditions and restrictions (which would be incapable of justification and completely unacceptable). Only the most detailed definitions of specific types of "*synthetic biology*", entailing detailed technical schedules and exceptions would be acceptable, provided that, even then, it was made clear that the definitions should not be used for legislative purposes. I would particularly request that genomic and genetic editing are excluded from any definition. While genome editing is of direct interest to the CBD, it ought properly to form part of a separate study. I would also ask that purposive qualifiers such as "*towards useful social outcomes*", "*useful*" and "*planned*" are not included in any definition.

I endorse the sentiments referred to in clause 34 of the Report of 4th September 2015.

COMMENT FROM CHRIS JONES[4]

Both documents are a balanced view with nothing that would surprise the companies or technologists that we support in the area. One substantial point is to stress the importance of clarity and consistency, especially in the area of benefit sharing where uncertainties as to the provenance and future benefit sharing arrangements are causing significant concern to some parts of the emerging industry landscape and is already biasing the plans of some companies.

The issue of 'commercialisation' gets little mention and the challenges of bringing some of the, well referenced, benefits to fruition through the actions of the private sector is underplayed although these discussions are understood to be challenging. It would be useful to see a reference to the

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importance of ensuring that the benefits are captured in a timely manner, recognising the importance of connecting the creative synthetic biologists with the well-established supply chains while recognising the importance of Responsible Innovation. Simply, the easier the regulations are to understand and implement the more likely they are to be used effectively.

COMMENT FROM ALASTAIR KENT[5]

The inclusion of 'products' in several paragraphs of the document is especially worrying in the medical arena, where synthetic biology may be used to produce novel therapeutic agents. Medicines, devices and diagnostics are already heavily regulated and to increase the regulatory burden because a new therapy is the result of SB would increase costs, deter investment reduce the potential for health gain where there is already a functioning framework under which producers have to demonstrate adequate standards of quality, safety and efficacy before they can market a new drug.

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