Sixth meeting, of the Synthetic Biology Leadership Council (SBLC) Governance Sub-group
13:30 – 17:00, Thursday 1st October, 2015.
Room C20, BIS Conference Centre, 1 Victoria Street, London, SW1H 0ET.

Attendees

Chair: Joyce Tait (JT), Innogen Institute, University of Edinburgh (SBLC)

Governance Sub-group:

Lionel Clarke (LC)	Co-Chair SBLC
Matt Goode (MG)	Research Councils UK
Julian Hitchcock (JH)	Denoon Legal
Sir Roland Jackson (RJ)	ScienceWise
Alastair Kent (AK)	Genetic Alliance
Michael Paton (MP)	Health and Safety Executive
Hilary Sutcliffe (HS)	MATTER
Martin Cannell (MD)	DEFRA
Suzannah Lansdell (SL)	Sciencewise
Patrick Middleton (PM)	BBSRC
Tim Higginson (TH)	BIS
Shami Ahmed (SH)	BIS

Apologies: Janet Bainbridge (UK Trade & Investment, SBLC) Richard Kitney (Imperial College, SBLC), Nick Pidgeon (Cardiff University), Linda Brooks (Thermofisher), Tim Fell (SynthAce, BIA, SBLC), Sally Devine (BIS).

Agenda Item
1. Minutes of last meeting and feedback on recent activities

Welcome and apologies. No comments on the minutes from the 4th meeting on 18th June other than that the attendee list was not included.

JT updated on actions that have been carried over from previous meetings.

Outstanding actions from previous Sub-Group meetings:

- Appointment of a new member to the sub-group is still on-going. LC advised that there is an expression of interest to join the sub-group but SBLC members have not as yet discussed this proposal.
- KTN post vacated by James Brown - LC advised that the post should be filled shortly.
- Plans for a Parliamentary event on health research – no progress to report.
- Harmonised specification for genetic components. Too premature to lobby anyone, until details are clearer. Will re-visit after the new SynBio strategy has been published.

Action (JT): Add attendees to minutes of last meeting.

2. Feedback on Convention on Biological Diversity (CBD) related developments since the last meeting

MP spoke to this item. MP had provided an update at the last meeting on the CBD's ongoing programme to consider SynBio. The CBD were overwhelmed by the number of responses and level of interest in the recent CBD open online forum on SynBio. Around 600 pages of views were summarised from the responses, which informed the subsequent meeting of the Ad Hoc Technical Expert Group (AHTEG) in Montreal in Sept 2015. MP was the nominated expert from the UK at the meeting which comprised representation from around 40 nominated experts (29 from Parties, 1 from non-Party and 10 from organisations). With organisations including civil society, industry and academia, a divergent range of views were presented at the meeting. The list of representatives can be found on the CBD website.

Seven topics, related to the CBD, its protocols and SynBio, were covered at the AHTEG meeting to share views and understand others' views. A draft report of the meeting was produced and circulated to attendees for comments before the end of the AHTEG meeting, and the final report will be published on the CBD website for peer review. Publication is expected to be in October. The report along with any comments from the peer-review will be discussed at the next meeting of the CBD's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) in April 2016. The SBSTTA will then make a recommendation with respect to SynBio at the Conference of the Parties in December 2016.

MP had noted that views expressed at the meeting had tended to be based on a precautionary approach. However, there had been a lot of discussion on benefits, which made the report of the meeting more balanced. Some representatives were of the view that any work that could spread beyond national boundaries should not go ahead and wanted a moratorium, while others recognised that there may be risks, and that these need to and can be addressed responsibly. UK has a balanced approach to SynBio. MP noted that while the CBD's definition of SynBio is a slightly adapted version of that used by the EU Commission, it is not a regulatory definition. Its purpose is to frame discussions on the topic but not for assessment of compliance with the Convention or its Protocols. Topics discussed at the meeting included:

- SynBio and biodiversity – what the issues are; positive and negative impacts including social and environment impact. A view held by some is that SynBio is an extension of biotechnology while others felt that it is a step beyond GM. Risk assessments were discussed and the difficulty in assessing impact on ecosystems. UK argued that the intention of SynBio is to engineer biological systems so that they behave more predictably and emphasised the need to focus on real examples not hypothetical scenarios.

- Organisms, components and products from SynBio – the CBD guidelines focus on living organisms presently, so there are no clear definitions for products such as proteins and components such as DNA. The Cartagena Protocol applies to living organisms, and not non-living products. A number of organisations asked if this was appropriate. Questions considered included - should products and components be covered? Is there a gap? There was a lot of debate on this, and it was recognised that there is a need to clarify by CBD, the existing definitions in the Convention and its Protocols. This particularly applies to GM products, which can be living or non-living depending on the application. Are further guidelines therefore needed? Should products rather than processes be regulated? Products can mean different things to different people; for the UK, a SynBio product that is brought to market, could be a microorganism, or an enzyme or medicine and would be

authorised in different ways. In meeting discussions it was thought that products cover more than just living or non-living. In the EU, classifications are tied to processes. HS mentioned that some work on this is being undertaken in the Netherlands.

Adequacy of national/international instruments – there was lots of discussion on this topic at the meeting. Many representatives felt that present risk assessments procedures and methodology are adequate, and different of SynBio products are covered by sectoral regulations. However methodologies may need to be adapted for future technologies.

- However some felt that there were gaps that need to be covered (e.g. RNAi, DNA methylation). It was thought that while the various regulations cover different sectors such as for chemicals and medicines, the frameworks are separate and distinct. It is not practical to have one set of regulations for SynBio. It was suggested that some work might be required to consider how more links between existing regulations can be made and how regulators might work together.

- Risks and benefits – the risk of polarisation of views was avoided by the composition of two sub-groups that considered risks and benefits. The list of possibilities are included in the report with some appearing under both risk and benefit categories. Socioeconomic impacts need to be considered in the context of national policy and international agreements. This is a non-mandatory part of the Cartagena Protocol, although some parties have made it mandatory (e.g. Norway).

- Recommendations to SBSTTA – review regularly SynBio technologies, including how this affects the SynBio definition. The various AHTEGs looking at different themes (e.g. socioeconomic impacts; risk assessment methodologies) which overlap with SynBio and should work together with the SBSTTA on this. Other suggestions included working with other international organisations (e.g. OECD) to develop consistent guidelines, and engaging with a wider SynBio audience.

MP concluded that the report is more balanced than anticipated prior to the meeting and considered the full range of views. HS wondered if this was because of consensus or some views being ignored. MP advised that views may not have been as polarised as previously due to the sharing of information. For instance, when it was explained that xenobiology is in very early stages.

The question was raised whether there were areas that the UK should be giving more thought to. MP noted that there had been more convergence of views due to better understanding of SynBio. This was enabled by talks from SynBio experts such as Paul Fremont explaining the different areas that SynBio covers and realistic consideration of their stage of development. A question to consider is how do we make SynBio more accessible and understandable?

MP was asked what areas the UK needed to prepare for? He noted that there are different ways of dealing with issues. For instance, in the UK regulatory priority is given to high level containment (CL3 and 4), and we should consider how to support activities at lower levels in a pragmatic and proportionate manner. There may be some challenging new areas, such as GM insects. More work may be required on integrating or signposting the different sectoral regulations. NGOs asked about regulatory processes for products (e.g. a new vaccine) and considered the approach to be fragmented.

It was also noted that a one size fits all framework cannot be applied to regulations, given experience of this with for example, EU medicine regulations. What worked well in that area was to

have scientists to provide advice at meetings but the regulations that emerged from the EMA process are still subject to criticism from those required to implement them not a good example.

It was noted that for stem cell research and cell-based therapies there is an online tool for companies/researchers that is intended to make regulation process less intimidating.

Action (MP): Forward published report from meeting to GSG members.
Action (JT): Monitor European activity in this area, potentially through the RRI consortium that involves the six SBRCs and the KTN.

3. Update on Synthetic Biology Roadmap/Strategy Refresh

LC updated the group on the Roadmap refresh work. Workshops held since launch of the original SynBio Roadmap have informed the development of the future direction of SynBio. As part of the refresh a large workshop was held in Birmingham in July – this and other activities led to a synopsis of ideas and conclusions. LC created a framework and invited groups of SBLC members to input into designated sections. It has been an iterative process, and the aim is to have a final report of around 20 pages (similar to the original Roadmap). The final draft will be circulated to the sub-group via JT for feedback.

The intention is to have five high level recommendations, with a focus on productivity. To enable productivity tools and ability are required, as are a skilled workforce. The recommendations will consider how to facilitate translation of research into commercialisation, and need to create an ecosystem to manage all of this such as appropriate governance, responsible research and innovation (RRI). Within each section much of the detail has emerged from activities such as the workshop.

Some of the recommendations can be implemented fairly quickly while others will need more consideration and discussion.

The Roadmap refresh report is a strategic plan for SynBio for the next few years. Other countries look to UK as leading on a strong modus operandi. Recognising that finances are being reviewed (through SR) the recommendations will mainly set out how to continue to progress SynBio with existing resources, skills and expertise. This will mean more coordination and networking around the country, facilitated by the SBLC. Increased coordination will require some additional resources.

The working document is being shared with BIS and the final report will be shared with a limited audience (outside of the SBLC) for review. The aim is to publish by the end of the year.

A question was raised on who was responsible for RRI being embedded into processes from research to applied research and translation, since Belinda Clarke's departure from Innovate UK. PM advised that while RRI is less visible it is still being applied. Research Councils are looking at how RRI can be embedded in their activities as funders

It was noted that all the SynBio Research Centres (SBRCs) have RRI components and are working together on this, with meetings scheduled. RRI was described as a living activity that continues to evolve and that a meeting to revisit this topic may be required in future.

Action (LC): share final draft of SynBio Strategy document with JT for review and feedback from GSG members.

4. Group discussion on public /stakeholder engagement on synthetic biology, what it might achieve and how it could be realised

RJ introduced this item, with SL. This exercise stems from previous discussions about public/stakeholder engagement. It was noted that any views expressed are those of the sub-group, and therefore not representative of the SBLC as a whole.

It has been five years since the original SynBio dialogue. At the time of the dialogue, the emphasis was more on SynBio research, but developments since then mean there are now some SynBio applications and products. Some group observations and issues to consider:

- There is a range of enabling technologies classed as SynBio that have the potential to lead to a diverse range of applications and products.
- Potential of engineering to mass produce chemical and biological products.
- It was recognised that in public perceptions, there is some tension between the origin of something being synthetic or biological. The perception appears to be that something synthetic has less intrinsic value.
- Development of biological components or parts of nature is also viewed as problematic.
- Incorporate responsible research and innovation (RRI) into all grant applications; judging on technical merit alone isn't sufficient.
- Tension between characterisation of scientists' work and the whole field of SynBio as transformative.
- Regulation – in dialogue, want to open up to public scrutiny. Not just technical debate about risk, but social issues, including benefits.
- Regulations are seen as primarily about safety - the public feels this is important but not only criterion.
- The public may not accept a new technology/application/product just because it has been classed as safe.
- Recognise that opposite of risk is not benefit

SL led the engagement exercise. With a background in public dialogue work, she has kept in touch since the original SynBio dialogue and feels that there is very much a sense of what else can be done.

Questions that were considered:

- What is happening in SynBio that makes now a good time for engagement? Eg. something coming to market?
- What would you want at the end of engagement that you don't have now?
- What could engagement now potentially inform or influence?

The group was split into three groups and, over 30 minutes each group spent 10 minutes on each of these questions in rotation.

<u>Next steps</u>

- The Summary Report from this activity (attached as Annex 1 to these Minutes) to be taken along with the minutes to the next SBLC meeting.
- Include timelines for actions if possible
- By next GSG meeting, RJ and Sciencewise could work up some recommendations for engagement activities.

- SBLC have case studies that might be used – some are SynBio concepts, some are start-ups.

JT thanked RJ and SL for a very helpful session.

Action (SL): Circulate a summary of the output.

5. AOB

The House Of Lords Science and Technology Committee are presently undertaking an inquiry into GM insects. RJ has been invited to give evidence at a session on 13th October. The group noted that it would be interesting to see the outcome of the inquiry. The Committee will produce a report by the end of the year.

RJ is also involved with another S&T Committee inquiry that reports in November.

Action (JT) – circulate a Doodle poll for future sub-group meeting dates in 2016.