MINUTES

Thirteenth meeting, of the Synthetic Biology Leadership Council (SBLC) Governance Sub-group
13:30 –16.30, Monday 26th Feb., 2018.
Business Design Centre, Islington, London N1 0QH.

Attendees

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

Governance Sub-group:

Lionel Clarke (LC)	SBLC co-chair
Janet Bainbridge (JB)	DIT
Martin Cannell (MC) & Renaud Wilson (RW) (for Louise Ball)	DEFRA
Alistair Kent (AK)	Genetic Alliance UK
Hilary Sutcliffe (HS)	Society Inside

Apologies: Louise Ball (LB1), Linda Brookes (LB2), Andrew Cottam (AC), Tim Fell (TF), Jackie Hinton (JH2), Richard Kitney (RK), Patrick Middleton (PM), Julian Hitchcock (JH1).

1. Minutes of last meeting and feedback on recent activities

The minutes from the 12th meeting of the GSG on 19th October, 2017 had been approved by email prior to the last meeting of the SBLC on 8th Nov, 2017 and were then approved by the SBLC meeting, to be uploaded to the SBLC website.

With the exception of the following, all actions were either completed or are covered by one of the agenda items for this meeting.

Action 1 **Jackie Hinton to circulate the UK Biosecurity Strategy as soon as it is available. (still ongoing)**

Action 2 **(All) to consider how Wellcome Trust and GSG could usefully pool resources in future.**

Action 3 **Kathleen Littler to share relevant updates and information and to invite one or more people from GSG to the meetings of the Group that Wellcome co-convenes with other key players.**

Action 4 **Kathleen Littler to keep GSG informed of Wellcome initiatives in the international regulatory context with a view to developing joint initiatives in future.**

For Actions 2 – 4 JT is seeking a meeting with the Wellcome Trust

Action 5 **GSG to facilitate a meeting/briefing with key regulators in the life science area to consider different regulatory approaches and their outcomes for innovation (JT is seeking opportunities to arrange such a meeting)**

Action 8 **Lalitha Sundaram to host a workshop in Cambridge, involving members of the GSG and others with relevant expertise, to consider how cell free sensor systems could be governed effectively, supported by a brief introductory paper describing the issues.**

2. Report from SBLC meeting, 8/11/17: LC

The last SBLC meeting was an open meeting. It introduced the progress that has been made on setting up a national biosecurity contact point. This is creating trust that we are managing this in an open and transparent way.

In discussion there was a recommendation to encourage more industry people to attend the open meeting, particularly 'big business', perhaps jointly with the Industrial Biotech Leadership Forum. This probably should not be as part of an open meeting, preferably a series of structured 1:1 meetings or small sector-specific workshops. This is already working for Medicines Manufacture and the other large chemicals producers. There is a need to consider who is best-placed to 'own' this initiative, given that the SBLC is only an advisory body.

Action 1 LC to take a suggestion to the next SBLC meeting for such a joint initiative.

The Bioeconomy Strategy has been signed off by BEIS and is now sitting on the Minister's desk for final release. There will be a follow-up Sector Deal, to be completed in a week's time, where synthetic biology is included as a disruptive technology. If the deal is approved in principle, there will then be a stage where the basic ideas around synthetic biology are fleshed out in discussion with UKRI.

3. Report on Further Development related to the PAGIT Project: JT

JT reported on possible policy outcomes from the project of Proportionate and Adaptive Governance of Innovative Technologies (PAGIT), funded by BEIS/BSI, and adopted by the SBLC as contributing to Recommendation 4 of the SBLC Strategy, *Biodesign for the Bioeconomy*, "Develop a Supportive Business Environment".

These items also relate to issues raised under AOB in the last meeting:

i. The question of what we, as the GSG, should be contributing to developments related to responsible research and innovation (RRI).
ii. The potential government influence on innovation through the regulatory systems for life sciences to create a country which is the go-to place for investment.

In the current framework for regulating innovative therapies, e.g. gene transfer for severe combined immune deficiency syndrome where there are only two hospitals in Europe where you can benefit from this technology, there is still no route to a commercial product and the hospitals do not have the capacity to deal with the demand. Part of the problem is the naiveté of the start-up companies about the regulatory hurdles they will meet and the naiveté of the regulators as to what the biology is telling them. We need to make the law obey the biology, rather than making the biology obey the law. An approach that doesn't bring in the law until later in the development process will have benefits, avoiding the capture of innovation for the sake of preserving the status quo. This kind of thing will be an important part of the development of the bioeconomy in the health care sector.

Synthetic biology is multi-faceted with applications in several sectors and finding a way to maintain safety, quality and efficacy without having adverse consequences for the development of the innovation will be a problem. A modified crop with a trait that might not be sufficiently contained, and a human treatment that will require expensive clinical trials are two very different challenges.

For GM crops today we have one aspect of the regulation that deals with research and another that deals with translational developments and this framework has a natural progression of one to the other that also needs some consideration. An advantage also is that there is no inclusion of benefits as part of the regulatory system, particularly when you think of the different risks and benefits of health and agricultural applications, but it is included within the consideration of responsible governance and innovation.

4. PAGIT Report on the RRI Case Study: JT

The approach proposed is an attempt to move RRI into an area where it is clearer to companies and those conducting RRI initiatives what they need to do at different stages of product development, for different kinds of product, and how to demonstrate to the wider stakeholder community that they have been 'responsible'. It is important in the proposed approach to distinguish between what should be seen as responsible at the early research stages of developing a technology (upstream) and at later (downstream) stages.

Terminology was seen as important for getting traction on this approach with companies. It is important to embed the concepts into terminology that is in everyday use in companies. You need something that is as generic and umbrella-like as possible.

It was also seen as important to ensure that the approach resonates with the purpose, rather than focusing on the criteria proposed by the EU.

Adoption of such a standards approach by an organisation like the BSI would be a useful contribution to enabling this approach to be taken up by companies across a broad range of sectors.

People need to feel that there is a framework in place that is robust enough to reduce the chances of rogue operators taking actions that are unacceptable to stakeholders.

Action 2 JT to invite somebody from BSI to the next GSG meeting to discuss how they would develop standards for this area.

5. DEFRA and Convention on Biological Diversity (CBD) Update: (MC and GW, for LB1)

The key focus for DEFRA just now is BREXIT, meeting the government's commitment to roll over the existing EU regulatory frameworks into UK law. There are currently no plans to move beyond this position. In the GM sphere, the problem is more with the implementation of the EU law rather than with the law itself. When we are outside the EU we could take the current EU provisions and make them work because we will be in control of them. For gene editing, the EU Court of Justice advocate general's preliminary ruling, although not a definitive answer, will require the EU to achieve clarification on the question whether it should be regarded as a GM technology for regulatory purposes. The full Court ruling is expected in the summer.

DEFRA's core argument has been that there are circumstances where gene editing should be regulated as GM, but not where you could achieve the same outcomes through traditional plant breeding. These decisions will still have to take account of our global trading ambitions and the need to protect markets by meeting the required standards. However, with gene edited crops in the UK, there may be no EU market to lose.

Considering the point that the existing EU regulatory system for deliberate release of GMOs is not seen as onerous for multinational companies but would be severely inhibiting for small companies wanting to develop innovative business models based on synthetic biology and gene editing, a less onerous system could be devised, based on standards, that did not imply lower levels of safety, quality and efficacy. DEFRA's analysis suggests that there are currently no opportunities to significantly reduce the regulatory hurdles involved before releasing a GM crop into the environment.

Under DEFRA's ownership of the EU rules, they would make sure that the system is as proportionate as it could be, on a case-by-case basis, or as suggested, potentially moving to a 'class-by-class' approach.

It's important in this conversation to include the cost of doing nothing. We need to think of new ways to continue doing existing things, particularly in the BREXIT context. How do we encourage those with a vested interest in the status quo to realise that the consequences of doing nothing will be adverse?

Commenting on the DEFRA's CBD-related work streams:

- The Cartagena Protocol (CP) Synthetic Biology AHTEG met in December and has produced a report, circulated to GSG members and discussed at the last meeting. This report suggests that understanding aspects of risks and benefits of synthetic biology may not be fully developed yet and carrying out risk assessments in certain cases may be a challenge with current levels of knowledge. It refers a lot to dual use and gene drives and suggests developing internationally agreed standards for working with organisms containing gene drives under laboratory (i.e. contained use) conditions and developing guidance before any environmental release of an organism containing an engineered gene drive can occur.
- Comments are requested by the end of this month. The UK response is likely to highlight the useful work already going on in this area. HSE have written a report on gene drives to be published soon. Comments on this document will be taken into account at SBSTTA in June this year and then to COP in November.
- The CP Risk Management/Risk Assessment AHTEG, focused on gaps requiring further risk assessment and some respondents included a long list of topics, including synthetic biology. This will be considered at SBSTTA and recommendations made to COP MOP.
- Digital sequence information (DSI)– there is a new AHTEG on this which met earlier this month to discuss 2 reports, (i) Synthesis of Views and (ii) Fact Finding and Scoping Study. The AHTEG will report on these in April and DEFRA will use that to develop and consult on their position in advance of SBSTTA. Any action from the GSG on this topic would be after April. The EU position continues to be along the lines that it recognises the importance of DSI to vital research but does not consider it equivalent to a physical genetic resource, making it not appropriate to be considered under Nagoya. The broad outcome of the DSI AHTEG meeting was that the issue of DSI remains unresolved and will continue to be discussed.

Work on gene drives is currently restricted to contained use rather that deliberate release.

DEFRA will be monitoring the upcoming discussion on public awareness and intervening as necessary. SBLC might find it interesting to follow the discussions.

Action 3 MC to discuss with LB whether there are any useful contributions that the GSG could make to this discussion.

6. AOB.

The organisation RIVM in the Netherlands is working on ideas for new governance approaches and it would be useful to invite, e.g. Jaco Westra, to a future meeting of the GSG, after we have had a chance to hear from the BSI.

Action 4 JT to invite Jaco Westra to a future meeting.