MINUTES
Sixteenth meeting of the Synthetic Biology Leadership Council (SBLC)
Governance Sub-Group (GSG)
13:30 –16.30, 26th February, 2019.
BEIS Offices, 1 Victoria St., London.

Attendees

Joyce Tait (JT) (by phone)	SBLC GSG Chair
Lionel Clarke (LC)	SBLC Co-chair
Janet Bainbridge (JB)	DIT and SBLC
Rob Wellens (RW)	HSE
Rocky Cranenburgh (RC) (by phone)	Prokarium/BIA
Paul Henderson (PH)	BEIS and SBLC
Julian Hitchcock (JH1)	Bristows
Jamie Parkin (JP)	UKRI/BBSRC
Hilary Sutcliffe (HS)	Society Inside
Louise Ball (LB)	DEFRA and SBLC
Paul Freemont (PF)	Imperial College and SBLC
Richard Kitney (RK)	Imperial College
Jonathan Hoare (JH2) (Observer)	BEIS
Alberto Mogollon (AM) Andrew Firman (AF)	Guest speakers, British Standards Institution

Apologies: Paul Henderson, BEIS

Introduction

JT was unable to attend in person and joined the meeting by phone, as did RC and JH1, and the meeting was chaired by Lionel Clarke.

1. Minutes of last meeting – action points and matters arising

The minutes from the 15th meeting of the GSG on 18th October, 2018 (Paper 16.1) had been approved by GSG members by email and were then approved by the SBLC meeting on 21st November, to be uploaded to the SBLC website.

Carried forward from earlier meetings:

Action 1.1 Paul Henderson to circulate the UK Biosecurity Strategy as soon as it is available. Paul Henderson will update us.

Given the length of time this has been sitting in the list, it was agreed to delete this action point from the list to be followed up, and to reinstate it if need be in future.

Action 1.2 JT to follow up with the Wellcome Trust how they would like to take forward their interactions with the GSG, in the context of our revised terms of reference.

Not yet completed

Action 1.3 The proposal to facilitate a meeting with key regulators in the life science area is inevitably linked with the Brexit context.
The GSG, through the SBLC, should seek opportunities to arrange such a meeting as soon as there is an opening (after March 2019). AC noted that HSE Bioeconomy Sector Plan deals with these issues in

the context of safe innovation and could contribute to extending this thinking more widely (http://www.hse.gov.uk/aboutus/strategiesandplans/sector-plans/bioeconomy.pdf).

Given future uncertainties in this area, likely to continue over a number of years, we agreed to delete this action point from the list to be followed up, and to reinstate it at an appropriate point in future.

Outstanding from the GSG meeting of 26/2/18:

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

Completed.

Action 3 LB1 to let us know whether there are any useful contributions that the GSG could make to future CBD-related discussions.

Completed

Action 4 JT to invite Jaco Westra to the first GSG meeting in 2019.

To be invited to the next meeting

Outstanding from the GSG meeting of 19/6/18

Action 1 LC to raise issues about funding silos at future SBLC meetings.

Completed as far as possible; to be continued through SBLC interactions with the Bioeconomy Strategy.

Action points from the GSG meeting of 18/10/18

Action 1. PH agreed to follow up with Lord Henley's office on the SBLC letter related to the CJEU decision on gene editing

Completed

Action 2: JT to revise the TOR based on this discussion and send it to GSG members for final approval

Completed

Action 3: JT & LC to raise with SBLC the need to develop a strategic approach to regulatory issues in the context of deliberate release of products developed using SB and GE.

Completed – the meeting held with Lord Henley in January for JT and LC.

Action 4: LC and JT to engage with AC to explore future links with SBLC that could support this HSE initiative.

LC and JT had a meeting with Andrew Cottam and RW on 23/11/18, and the outcome was a suggestion that we should hold joint scenario development workshops to consider how regulators should react to specific events in future. This has been on hold due to Brexit-related distractions for HSE, but HSE will let us know when there is capacity to take it forward.

Action 1 RW to set up this initiative when HSE has capacity.

Membership information

JT reported that Haydn Parry had decided to step down from membership of the GSG due to pressure of other commitments.

We are also looking for a replacement for Linda Brookes.

2. Update on SBLC Developments – LC

The next SBLC meeting will focus on the delivery plan for the Bioeconomy Strategy via the Sector Deal. The current funding committed to the SB Research Centres is nearing completion for those funded in the first round with some having extensions to their contracts. Overall the expectations from the original SB Roadmap have been delivered very successfully, including embedding Responsible Research and Innovation in centres and companies (now ~100 – a huge step up). There are also increasing amounts of private investment.

The focus now is on the process of translation – skills, frameworks and the operating environment for companies.

The now-published Bioeconomy Strategy has re-stated government interest in this area, and relevant policies, building on synthetic biology and industrial biotechnology platforms. It will be a big challenge to get to the target scale of development by the 2030 delivery date.

From now till end of March, a process is being set up for a number of Working Groups to develop the basic material for a Sector Deal to benefit the UK economy. The SBLC will develop its own views on how to input to this process. The working groups will mirror the five foundations of the Industrial Strategy – Ideas, People, Infrastructure, Business Environment, and Places, and leadership from the bioeconomy sectors will be harnessed to help delivery. Some of the things emerging from the Working groups will feed straight into the sector deal and others will need to happen independently.

In discussion it was noted that current initiatives in AI, robotics and data-driven innovation are proceeding as if biology and biotechnology were irrelevant to them and that this lacuna in government thinking needs to be addressed to get synergies rather than fragmentation. Also noted was that large multinational companies had given a mixed reception to the Bioeconomy Strategy, given its low profile launch and the lack of accompanying funding. The five Working Groups were seen as a way of enabling industry and government to work together on this and to link up with other government strategies. Through Innovate UK, ISCF money is already available to deal with issues like plastics and this is technology-agnostic.

Action 2. JH2 to introduce JT to the teams dealing with robotics and other future sectors and to make connections with the office for AI.

The point was also made that much of synthetic biology related innovation is about the creation of entirely new business models and value chains in small start-ups at an early stage of development, leading to completely new global industry sectors and not relevant to current multinational company business models. Asking companies at this stage of development for matched funding is unrealistic. The UK is missing out on this stage of development from synthetic biology and risks becoming a late adopter rather than in the vanguard of new developments as in the USA.

Action 3. PF and RK to send a note elaborating on this point.

3. BEIS/BSI project on development of a standard for responsible innovation – Alberto Mogollon and Andrew Firman, British Standards Institution.

The slides presented at the meeting are included along with these minutes and are referred to below.

Slide 3 describes the BSI structure, as the government-recognised national standards body for the UK, AM and AF being part of the National Standards Body (LHS) and slide 4 describes the international system of standards bodies of which BSI is a member. In the Brexit context standards have been described as an antidote to regulatory divergence, promoting regulatory alignment and access to markets, and this is facilitated by the fact that the EU standards bodies (CEN and CENELEC) are private, and not EC, bodies. It is important to BSI to retain its membership of all these regional and international standardisation bodies including also ISO and IEC (Slide 5) and ninety-five percent of BSI's standards catalogue is international. BSI aims to be the first to publish a standard that will become international.

The consensus standards produced by BSI follow WTO principles and are market and stakeholder-led. They undergo systematic review and can be used to demonstrate compliance with regulations (Slide 6). They play a vital role (Slide 7) in boosting productivity, catalysing innovation and facilitating international trade, AR's role being to consider how standards can support and accelerate innovation by: enabling knowledge diffusion and coordination of innovative activities; supporting the consolidation of emerging supply chains; de-risking investment in new technologies; and promoting consumer confidence and public acceptance.

BSI adopts a systems-based approach in supporting emerging industries (Slide 9) considering how actors in the sector relate to one another in the context of 4 elements- intellectual property, regulations, metrology and standards. They have a major role to play (Slide 10) in shaping how emerging industries evolve over time to become the new industries of the future. Systematic use of standards will vary according to maturity of the technology, the nature of the technology and the industry sector, and standards should be considered in emerging technology strategies, technology roadmapping and public procurement decisions (Slide 11), as is already being done in Germany, Japan and the US.

BSI is working with the UK Government on the Industrial Strategy to support bringing new products and services to market faster and to maximise the impact of investment in the Industrial Strategy Challenge Fund (Slides 12 and 13). As part of this agenda, they are working across innovative sectors to consider how corporates can demonstrate responsible behaviour through development of a Standard for Responsible Innovation (Slide 17), and slide 18 presents a range of issues from innovative technologies in 2017-18 that had attracted public or government attention and would be amenable to such a standards-based approach.

The role of AF as part of the Research and Insight Team in BSI is to support the project to develop a Publicly Available Specification (PAS) Framework Standard for Responsible Innovation, initially by conducting market research to understand the level of interest in this Framework Standard before committing further funding (Slide 19), covering Artificial Intelligence and Big Data, Life Sciences, Robotics, Social Media, and Novel Materials (Slice 20). About forty qualitative interviews will be conducted with a good spread across all categories, some people representing two or more sectors, including SMEs and large organisations, 'business to business' and 'business to consumer' categories (Slide 21).

A question was raised about the biases inherent in this kind of sampling process, and these difficulties are inherent in much of market research. In this case interviewees were drawn from a variety of different sources to guard against any consistent biases. Another question related to the existence of other standards for different purposes in most of these technology areas, and care will be taken to ensure that there is no duplication of coverage. However, this is unlikely given that pre-existing standards are likely to be serving different purposes from the one proposed here.

After reporting the findings back to Innovate UK, the next stage will be to do a landscape mapping exercise to cover everything published in this area so far.

In response to a question on how authoritative the standard is likely to be, AF explained that interviewees are being asked (i) if it is important to cover this area (the answer so usually being a straightforward 'Yes'), and (ii) how useful it will be (the answer being more qualified in that it will depend on how it is implemented). (The survey is not yet completed so these findings are tentative.) Following the landscape review, a steering committee will be set up including people with a good oversight of the area and the gaps that need to be covered. The PAS type of standard proposed can be agile and be developed rapidly with the potential eventually to become a full BSI Standard and an international standard.

Further comments related (i) to the need to build monitoring of the effectiveness of compliance with the standard into the development of the standard itself, and (ii) to ensure that there are no problematic interactions between the requirements of the standard and those of the regulatory systems that will be

applied in each sector covered. Another emerging point in the discussion was whether the value of the standard was perceived to lie in risk reduction, accelerating progress with an innovation, or public reassurance, and the answer was 'all of these'. People want something to satisfy themselves that they are being responsible.

In winding up, we discussed how the availability of the standard will be communicated and also how company adoption will be monitored, and BSI will be keen to follow up such questions given that this is a new type of initiative for them. In the context of social media given that this is so much in the news headlines, we considered whether this might undermine the value of the standard if it did not solve the problems of this technology. There were also questions about how a single standard could cover such a broad range of technologies and this was seen to depend on the outcomes of the research now being done; it would be possible, for example, to envisage a generic process for setting standards for any technology that would support companies in developing a specific version to suit their own circumstances.

At the end of this item there was general enthusiasm among GSG members to be available for further comment as the project progresses.

Action 4. JT to invite AM and AF to discuss the BSI Standards project when it reaches an appropriate stage of development.

4. CBD-related Developments

The three main areas currently being discussed under the CBD are risk assessment (RA), risk management (RM) (both under the Cartagena Protocol) and digital sequence information (DSI) which is a separate thing. On the current consultation, there is not much that the GSG could do that will make a difference to the outcome. The key thing is to have somebody connected to the AHTEG (PF in our case).

RA has not kicked off yet. A new AHTEG will be set up and the Royal Society will be nominating somebody to take part in that for the UK. DSI is also new and an AHTEG is being set up, the question for discussion being how to design systems to capture this technology; here countries that hold genetic resources are keen to have the same requirements as for genetically modified organisms to ensure access and benefit sharing.

The synthetic biology discussion is already under way through the existing AHTEG and at the moment there is not much that the GSG can contribute. The on-line forum (OLF) is beginning on 4th March, and we could contribute comments but this is likely to be a lot of work with very little impact. It is interesting to follow what the different voices are saying and those who are interested to do so could sign up if not already a member.

The AHTEG will meet in June and will develop a report based among other things on the contributions of the OLF; the report will then go to the next COP-MOP meeting in Beijing in 2021.

Beyond the CBD two interesting initiatives are under way:

- The International Treaty on Plant Genetic Resources for Food and Agriculture has published a report on synthetic biology and DSI and how they could complicate the benefit sharing system that they are working on. This work could be taken over by the CBD committee;
- The International Union for the Conservation of Nature are about to publish a report on biodiversity, conservation and synthetic biology that is likely to be influential.

The GSG should be keeping its ear to the ground and working to ensure that a moratorium does not arise from this process. (This was seen to be an unlikely outcome given the success so far, through the COP MOP, in avoiding getting international agreement for this action.)

Action 5: PF to send a link to the Plant Genetic Resources report and (once published) to the IUCN report; also to the article he is publishing with US colleagues

On the question of whether there is a strategic approach that the GSG could develop in this area, the response was made that a lot of the debate is just noise and we should not contribute to the noise, particularly in such a fast-moving situation. The most important issue is likely to be DSI and benefit sharing, where ownership will be impossible to establish and monitoring will also be impossible.

The GSG should be looking for something constructive and positive that we can put our support behind. We should continue this discussion and suggest how to pick this up at our next meeting.

Action 6. JT to include this item at our next meeting.

5. Issues related to human genome editing

This discussion related to the Chinese case where He Jiankui developed gene edited babies, and the fact that several prominent US academics knew about the project before the research began. LC questioned what the research community should do in such a case: many people apparently knew what He was planning to do and some advised against it, but nobody raised any concerns publicly. If a similar case should arise again, should people feel obliged to report it and if so who should they report it to.

Whether we would have known about the research if He hadn't announced it and, in the context of other potential issues of this nature, whether we should focus on the DIY community are pertinent questions. Currently available DIY kits are not seen as potentially threatening but as the technology advances they may become so in future and the law is not prepared for this. Risks are most likely to arise from out-of-control individuals no matter what the motivation, but the DIY community was seen as highly responsible and unlikely to be the location of bad practice.

The most effective ways of dealing with such issues were seen to be (i) setting up systems to encourage people to provide early warnings, e.g. whistle-blowers, requiring a change in current cultures, and (ii) providing a contact point who would know how to deal with the issue. The UK model currently in place for dealing with potential bio-security issues, as developed by LC, is an example of such a system. However, SBLC and the GSG are not well placed to deal with health-related issues like that involving He, including any potential risks to the babies concerned, and the Human Fertilisation and Embryology Authority (HFEA) would be a more natural home for considering such questions. (In the HFEA context, He's work would be illegal in the UK.)

6. AOB

(1) For information, the UK has taken up its seat on the Biotechnology, Nanotechnology and Converging Technologies Technical Working Group of the OECD Committee on Science and Technology. PF will feed any follow-up comments or

(2)

(3) papers to the GSG.

(4) LC and JT, along with PH, had a meeting with Lord Henley in January and discussed potential follow-up from the letter we sent to him following the CJEU ruling on gene editing. We proposed that our suggestions could be taken forward through the regulatory initiatives that had arisen from the Council for Science and Technology letter to the Prime Minister last autumn and this suggestion was welcomed. It was also similar to an initiative from The Royal Society on how to regulate synthetic biology and gene editing in future.