MINUTES
Fourteenth meeting, of the Synthetic Biology Leadership Council (SBLC)
Governance Sub-group
13:30 –16.30, Tuesday 19th June, 2018.
Room 2.03A, Royal School of Mines, Imperial College, South Kensington Campus.

Attendees

Joyce Tait (JT)	SBLC GSG Chair
Lionel Clarke (LC)	SBLC Co-chair
Janet Bainbridge (JB)	DIT
Louise Ball (LB1)	DEFRA
Julian Hitchcock (JH1)	Marriott Harrison LLP
Richard Kitney (RK)	Imperial College
Hilary Sutcliffe (HS)	Society Inside

Apologies:), Linda Brookes (LB2), Andrew Cottam (AC), Tim Fell (TF), Jackie Hinton (JH2), Alistair Kent (AK), Patrick Middleton (PM).

Update on GSG membership

Several GSG members have moved to new posts which makes their membership of GSG no longer appropriate, and others have taken on new commitments which makes it no longer possible for them to attend meetings (JH2, PM, TF) and they will be replaced. We are also in the process of recruiting new members, including Haydn Parry who has already agreed to join the GSG.

1. Minutes of last meeting

The minutes from the 13th meeting of the GSG on 26th Feb, 2018 had been approved by email by GSG members and were then approved by the SBLC meeting on 21st March, to be uploaded to the SBLC website.

Several of the long-standing action items in the following list have been overtaken by events or are no longer relevant. They will be dealt with as follows:

Action 1. Jackie Hinton to circulate the UK Biosecurity Strategy as soon as it is available. JT to contact JH2 for advice on whether this is likely to be forthcoming.

Action 2. (For Actions 2 – 4) JT is following up with the Wellcome Trust given their plan to undertake a stakeholder engagement initiative on medical applications of genomic technologies.

Action 3. 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 will seek opportunities to arrange such a meeting based on discussions at this meeting)

Action 4. 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 (continuing).

Action items still outstanding from the GSG meeting of 26th Feb:

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

Action 3 MC to discuss with LB1 whether there are any useful contributions that the GSG could make to this discussion (Carried forward – LB1 to contact MC).

Action 4. JT to invite Jaco Westra to a future meeting (carried forward)

2. Update on SBLC developments

LC reported that the next meeting of the SBLC on 19th July will take stock of current developments, particularly any opportunities to contribute directly into any bioeconomy sector deal which may emerge following acceptance of the expected publication of the Bioeconomy Strategy and Delivery Plan.

Also SBLC has submitted an expression of interest to the Wave 3 Innovate UK programme, on the next level of translation to commercialisation.

Related to this a small group will be convened on 18th July to bring together outcomes from several meetings to determine the technical and governance ambitions for the next 5 years.

Items brought up in discussion included:

Concerns about the delay in publication of the bioeconomy strategy document.

Concern about the extent to which currently announced bioeconomy outputs are helping/ supporting the NHS and whether there will be new money available for other areas of the bioeconomy. LC was urged to raise the issue about boundaries between funding silos relevant to the bioeconomy at future meetings.

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

3. Reports on recent stakeholder engagement and argumentation training on new GM techniques.

Two papers from BEIS and Sciencewise were tabled for this discussion:

(i) Who's talking about non-human genome editing: mapping discussion in the UK (Paper 14.2); and

(ii) Genome editing for human health: report of a round table to explore future public engagement priorities (Paper 14.3).

Diane Beddoes for the Sciencewise team has expressed an interest in receiving feedback from the GSG on these two reports and mentioned future plans to talk to policy leads in several government departments on cross-cutting issues and whether there is scope for a future public dialogue. She would also welcome advice on any policy leads that she should be talking to. Introducing the two reports JT referred to the interest in combining food and health-related issues because of perceived overlaps.

The GSG discussions related to both reports emphasised the need to enable small innovative companies to survive and thrive in these innovative technology areas. This point arose in the context of supporting public understanding that the greater the regulatory and other barriers experienced by companies, the more innovation is concentrated in the hands of large multinational companies.

Non-human applications

For the paper on non-human applications, discussion focused on the three main recommendations in the report:

1. Build capacity for public discussion and debate;
2. Connect discussion to decision making; and
3. Hold open key moments.

Discussion included the question how genome editing (GE) is being defined and the extent to which it is being treated separately from broader issues related to synthetic biology:

- GE is just one core tool in a much broader genomic toolkit. From the synthetic biology (SB) perspective (that of the GSG) the questions are – can it deliver benefits, is there market pull and are there checks and balances in place to ensure safe and effective delivery? Then the interests of the SBLC are to ensure that as much value as possible arising from these new techniques is captured in the UK.
- The question was raised whether we should be discussing GE techniques themselves, or the novel products that will arise from their use. In the early research stages before it is clear what products will be developed then it is appropriate to focus on the basic technology with applications across the board. Once developments have progressed further downstream then it is better to shift to consideration of the eventual products.
- Several organic farming organisation leaders are beginning to think about how they could use GE and how to develop a multi-stakeholder strategy for its adoption by organic growers.
- Another important constituency of industry investors is considering aligning synthetic biology with artificial intelligence (AI) which will considerably expand the range of potential stakeholder perspectives.
- From the policy perspective, regulators are currently concentrating on GE rather than SB and in Europe the focus is on the technique itself rather than the products developed.
- The GSG has been discussing the question of stakeholder engagement for the last 5 years and saying that the time to have a discussion is when there are some potential applications to discuss and we are now approaching that time. We probably do need to work out how to describe GE as a basis for public discussion and it would be easier to discover whether citizens would be happy with GE per se, rather than considering the entire panoply of techniques that are covered by SB.
- The objective 'holding open key moments' seems related to the point in the second report on human health 'waiting for the policy moment' and in the case of non-health applications of GE, such a moment might be about to arise with the expected announcement on 25th July from the European Court of Justice, advising the European Commission on the future regulation of GE. This may trigger an upsurge of public interest in GE.
- The public will focus not just on the technology itself but also on how it will be governed and it will be important to include this in the consultation.
- There are some urgent issues that go beyond stakeholder engagement that are holding up development of societally useful applications of GE. Many companies, particularly in the industrial biotechnology area, have products that have reached a key point in the development process where major investment is needed and they are reluctant to move forward without greater clarity on how this technology is going to be regulated. IP issues are also a major blockage.
- For stakeholder engagement, rather than focusing on GE itself, it would be better to consider major societal issues (e.g. climate change, healthy food, waste, soil health) and the extent to which GE could improve how we deal with such issues, alongside a range of other potential technology and societal options. The GSG suggests that Sciencewise could take a

lead on developing 6-10 such archetypal GE developments with potential contributions to meeting societal needs as a basis for future dialogue.

Human applications

Discussion focused on the points in the section beginning on p 16 "What next for Sciencewise?"

- The report recommendations were seen as comparable with those being developed by other organisations, e.g. the Nuffield Council. Discussion covered contributions to the UK economy from such developments, going beyond engagement related issues, for example patent disputes related to CRISPR and the fact that data exclusivity can be more important than IP protection in these areas.
- The point about broadening the frame of reference was seen as particularly important, with a preference for referring to "benefits and risks" rather than the other way round.
- Most of our discussion focused on the proposal to cover humans, plants and animals in one overarching approach. This was seen as particularly tricky from a public perception point of view. For a variety of reasons public perception of health related applications of genomic technologies is generally positive, in contrast to the historic, more negative, ideologically-driven perceptions of developments involving plants and animals, linked to the pre-existing GM debate. This was seen as potentially causing problems in discussions on health-related developments, but we also recognised that things have moved on since these ideological positions were formed in the 1990s and for many sectors of society, GM technologies have become normalised. However, we are also aware that companies and policy makers are often still influenced by an outdated understanding of public attitudes, leading to risk-averse decisions that could re-ignite a more ideologically driven dialogue. The proposed re-framing will therefore face different challenges in the contexts of health-related and other applications and we believe it is premature to move directly to combining them in a single framework. We would like to propose that Sciencewise could have an important role to play in getting the message cross to policy makers that there is a need particularly to re-position non-health related genomic-related technologies to create a supportive public environment for these innovations that more accurately reflects current evidence on their existing and potential societal benefits and relative safety.
- We noticed that gene drives are mentioned in this report but there is only one fleeting reference in the non-human report. In our experience, whether deliberately or through ignorance, some NGOs are generating confusion around the properties of CRISPR technologies generally by claiming that all CRISPR-related developments will have the negative perceived properties of a gene drive. Public engagement initiatives should take care to 'de-bunk' this particular myth.

Action 2. JT to send the GSG comments on these two papers to Diane Beddoes at Sciencewise.

***Argumentation training on new GM techniques*.**

Related to issues of stakeholder engagement, the paper for this item (paper 14.4) was an invitation from an anti-GM advocacy group to take part in training on how to respond to questions on "new GM techniques". It was brought to the attention of GSG members so that they would have an opportunity to join the discussion with a view to becoming better informed on the concerns of those approaching the technology from this perspective.

4. Update on UK and international regulatory developments

EU regulatory developments

LB1 began by commenting on the European Court of Justice announcement expected on the 25th July. This is not expected to be an absolute conclusion; it will take a lot of unpicking, and the

European Commission is unlikely to act quickly. The UK government is also saying that this is something that will apply to us once it becomes EU law. Any UK-specific developments will be delayed till some time in the future, post-Brexit.

UN Convention on Biological Diversity (CBD)

DEFRA are building up to the CBD Conference and Meeting of the Parties in November in Egypt and there is an intercession meeting taking place in July in Montreal to develop recommendations for discussion in Egypt. The Egypt meeting will then develop plans for the next two years. The GSG discussions focused on: digital sequencing and synthetic biology.

Digital sequencing

The build-up to the discussion on digital sequences is still confused, with many very different views: producing countries in the developing world want this to be covered by the Nagoya Protocol whereas the user countries, including the UK, have concerns about how this would work so this may be a difficult discussion. The EU wants to understand what digital sequence information includes, e.g. does it extend to, e.g., photographs and birdsong. Most people agree that having digital sequence information is in itself important and don't want to do anything that compromises that through the Nagoya Protocol. This will lead to a recognition of the need for capacity building so that developing countries can make as much use of this technology as the developed countries. The discussion will then move on to whether, under the Nagoya Protocol, there is a need for prior informed consent before you can use such information. The pressure is for it not to be Nagoya but there has to be a proper discussion of the issues. Bringing in the issue of capacity building implies that it is relevant under the CBD but there are unlikely to be plans for an additional protocol to cover such issues. So far in the papers for the meeting there are no specific recommendations so the discussion is likely to be open-ended. There is general agreement that it is better if digital sequence information can be widely shared in order to support useful innovation. However, Brazil has already included digital sequence information in a prior informed consent agreement with individual researchers, on a project-by-project basis. The World Health Organisation has done some useful work on disease vectors and the costs to them of acquiring the sequence data for vaccines relevant to diseases of the developing world.

Synthetic biology

The Ad Hoc Technical Expert Group (AHTEG) is horizon scanning new SB applications and the gene drive is the controversial issue, particularly the need for more research and guidance before there can be any environmental release, including field trials. The problem with this is that, if guidance is required, there is unlikely to be agreement on the guidance, and this will slow down decision making to the point of being a de facto ban on development of gene drives. The EU position is that it would oppose such an outcome, given that currently in the absence of a requirement for guidelines research and development on this technology can continue.

As regards genome editing there are a number of developments that will require careful consideration. The EU response is that we will need to be more specific about the applications and where there might be problems with decisions based on the pros and cons of the technology.

The UK (applicable to England only) has decided that gene edited Camelina being developed by Rothamsted Research in collaboration with French researchers will not be regulated as GM. This means that the developers can take forward development of the crop (currently taking place in France) with no requirement to make public the data from the field trials. As Camelina is not one of the major crop varieties there will also be no requirement to be registered through the plant variety recognition system.

In discussion it was proposed that It would be useful for SBLC to be able to use this as a case with which to build public confidence in gene editing technology, but the potential lack of openness

about the data from the field trials may detract from the usefulness of such a case study. Making a comparison with the Rothamsted GM Camelina already under development this provides an interesting example of the difference in regulatory circumstances between GM and gene edited crops.

Action 3. Regarding the Cartagena Protocol online forum earlier this year on Public Awareness, LB1 to send the GSG the synthesis of the outcome.

There is an EU proposal aiming to increase transparency and sustainability on issues related to risk assessment, applying not just to GMOs, but also to chemicals and plant protection products. One suggestion is that applications should include all the studies they have on the product concerned, raising concerns in companies about giving away information on their plans.

Action 4. LB1 to send the GSG a link to this proposal

5. Governing the products of innovative biotechnologies – the roles of the SBLC and GSG.

JT explained that this agenda item was included to stimulate a re-think of how the GSG interacts with the SBLC so that both can have a greater influence on events. She emphasised that we assume "governance" to cover: formal, legally based regulatory systems; standards, guidelines and government policy; and stakeholder perspectives and influences. There are opportunities now to have a more effective influence on the future translation of basic research to practical application.

In discussion there was emphasis on the need for SBLC and GSG to give consistent messages and to gain advantage by joining up relevant activities from across a broad range of organisations with varying interests. The current arrangement where GSG minutes of meetings are presented to SBLC, to check that they also see similar priorities, is important but slow. The future relationship between SBLC and UKRI was seen as potentially beneficial, given UKRI's capacity to consider a more holistic picture. However, given the infrequent meetings of SBLC, we could usefully consider how to respond to events more rapidly in future where necessary.

The World Economic Forum has an initiative related to responsible innovation which is relevant to these discussions.

Action 5. HS to send WEF report to GSG members.

A suggestion was put forward that, in the context of legally-based regulation, there is a general need for a document that describes the current regulatory system in a format that would be useful for policy makers and industry, and also others with interests in this area, and that is refreshed as necessary. GSG members were not aware of any such documents currently available. [Point added by JT following the meeting: I think it is highly likely that such guidelines do exist, at least in companies and possibly in some policy areas, and also in EU regulatory websites so have added the following action.]

Action 6. All to follow up with contacts and to search relevant websites and to send to JT any relevant documents that emerge.

Given the smaller scale of UK investment and other activities relative to our main competitors in USA and China, our competitive advantage is likely to come from our agility and our capacity to anticipate future developments and both SBLC and GSG are key elements for success in these areas. We are currently good at identifying and discussing relevant issues and drawing conclusions, but we now need to change gear to find ways to contribute more actively to future practice in the UK.

6. AOB

None