MINUTES
Eleventh meeting, of the Synthetic Biology Leadership Council (SBLC) Governance Sub-group
13:30 –16.30, Wed, 28th June, 2017.
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)	SBLC co-chair
Louise Ball (LB2)	DEFRA
Hilary Sutcliffe (HS)	Society Inside
Alistair Kent (AK)	Genetic Alliance UK
Julian Hitchcock (JH1)	Marriott Harrison
Jackie Hinton (JH2)	BEIS

Also attending:
Katherine Littler, Wellcome Trust (for agenda item 2); Tony Whitney (for agenda item 5)

Apologies: Janet Bainbridge (JB), Richard Kitney (RK), Tim Fell (TF), Linda Brookes (LB1), Patrick Middleton (PM).

1. Minutes of last meeting and feedback on recent activities not covered in the agenda

The minutes from the 10th meeting of the GSG on 12th April, 2017 were approved.

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

Actions brought forward from earlier meetings:

Action 2: (JH2) to send GSG members the UK Biosecurity Strategy when it is available. This item is on the agenda of the next SBLC meeting.

Action 1 Carried forward. JH2 advised that its approval is imminent and she will circulate as soon as it is available.

Action 5: (JT) to ask the research councils through the SBLC to consider the need to support further research on using synthetic biology tools to devise more efficient approaches to evaluation of the risks and benefits of new innovative technologies.

Action 2 JT to raise this at the next SBLC meeting.

Action 7: (JT) to contact the Science Media Centre about media preparedness on this issue.

Action 3 Carried forward to the next GSG meeting.

Actions from the meeting of 12th April, not covered in the agenda or not yet completed:

Several of these items are carried forward because there has not been a meeting of the SBLC since the last GSG meeting.

Action 4: (JT) to raise with the SBLC an item for discussion: "how should the SBLC engage in consideration of the governance of synthetic embryogenesis in humans and in the veterinary world?"

Action 4 Carried forward to the next GSG meeting.

Action 9: (PM) to share with GSG the Research Councils' joint response to the Green Paper.

Action 5 Carried forward to next GSG meeting

Action 11: (LC) to contact Lalitha Sandaraman with a view to developing a case study of her regulatory experiences working on the arsenic biosensor. Lalitha should contact David Brown at the HSE who has been involved in the regulatory aspects of this development. This could usefully be treated as a trailblazer for future innovative developments in in vitro diagnostics.

Action 6 LC to approach Lalitha Sandaraman and to invite her to attend the next GSG meeting.

2. Gene Editing – a Wellcome Trust Perspective, Katherine Littler, Wellcome Trust Policy Team

The Wellcome Trust has a particular focus on governance, ethical and societal issues. It has a global portfolio, including low income countries. It engages in global advocacy on subjects including emerging genomic technologies such as gene drives and stem cell research. In these areas, it takes a holistic approach, considering what needs to be taken into consideration to fund responsibly in this area. Wellcome is fortunate that it is well positioned to take a long term view, as some of these emergencies technologies may not realise their potential for a long time. It has strengths in neglected and tropical diseases and the technologies discussed in the GSG are very relevant to that. In particular, gene editing has the potential to contribute to the Wellcome Trust core mission, improving human health, not just in clinical applications but also through the basic research.

A statement was issued from the Wellcome Trust jointly with other research funders in Sept 2015 on human applications of gene editing, including engagement strategies, and the current UK regulatory environment. Also, Wellcome believes that a moratorium is not the right starting point for a conversation.

It is important to manage expectations and to engage with journalists and publics. Some of the discussion focuses on whether products developed using the CRISPR technique should be considered as a GMO. Considering other uses of genome editing, e.g. in animal research and agriculture, this may also affect perceptions of the technology.

Concepts such as 'synthetic biology' are not self-explanatory and difficult to define. Given this, it is challenging for the public to understand these and the onus is on the research community to think about effective ways to communicate what emerging technologies are and what they mean.,. 'Gene editing' is one proposed starting point but it will take time for the language to be 'socialised' and ideally the language needs to be sorted out before you start the engagement process. However, it is important to start discussions early to avoid contentious issues being hijacked by extreme views and alternatively there is a need to consider whether you are weighting the conversation or inadvertently 'hyping' it just by discussing the issues.

The Wellcome Trust is funding research in LMICs where they do not necessarily have compatible infrastructure and regulatory environments to those that exist in EU. They are doing preliminary

engagement research in UK to find out what various constituencies think and believe in order to get the language right in to feed into larger scale engagement work. It is important that decision makers need to listen to the outcomes of an engagement. and those doing engagement consider evaluation from the outset. There will be a meeting at Wellcome to discuss this report which should be attended by somebody from GSG. The point emerged in discussion that setting something apart from other things through an engagement initiative creates 'exceptionalism' and leads to public concerns that may not be necessary.

In response to the question, should we ask the public what they want to know, or need to know about new technologies, regulation and governance were mentioned. There is some evidence that people say that they don't want regulation that is not proportionate if it slows down innovation. We should only regulate if this is needed, but we also need to consider what governance mechanism (soft law) is then in place. A technology may not need to be regulated if it is well governed, e.g. through a principles-based approach.

In considering how to address being a responsible research funder for these types of emerging technologies, Wellcome is working with other funders to look at responding to the recommendations coming out of the US National Academy of Sciences report on Gene Drives (footnote – check title). This includes, looking at issues around regulatory capacity, appropriate governance structures, and engagement strategies.

It is important to treat regulation as a component of governance, and for regulators to be more comfortable with 'soft law' governance approaches being used in cases where formal legally based regulation is not proportionate and therefore not justified.

Action 7 (KL) to send a copy of the current version of the Wellcome glossary of gene editing related terms.

Following up on Wellcome's coordinating role, and noting the pressure to jump in and do engagement, Wellcome is doing some precursor work, bringing groups together. They are particularly interested in questions of regulation and governance and what people think about these issues, e.g. the Biobank people are happy with what is being done so long as there are governance mechanisms in place.

Action 8 (LB2) to send a link to the European Court of Justice case currently under consideration on regulation of new advanced biotechnology techniques

Action 9 (All) to consider how Wellcome Trust and GSG could usefully pool resources in future.

Action 10 (KL) to share relevant updates and information and to invite 1 or more people from GSG to the meetings of the Group that Wellcome co-convenes with other key players.

Action 11 (JT) to let KL know when our future meetings are.

Action 12 (KL) to keep GSG informed of Wellcome initiatives in the international regulatory context with a view to developing joint initiatives in future.

3. Request from Nuffield Council on Bioethics

An email from the Nuffield Council was circulated to GSG members, offering an extension to the 30th June deadline for responses to their survey and call for evidence related to their project on genome editing and human reproduction.

Action 13 GSG members to respond to this request on an individual basis as soon as possible if they able to do so.

4. Convention on Biological Diversity Update – Louise Ball

The discussion particularly focused on how the GSG can most effectively contribute to the current Open Ended Online Forum which starts next week and will involve 4 sessions discussing 5 topics. The second topic, to begin on 17th July, "Identify any living organisms already developed or currently under research and development through techniques of synthetic biology which do not fall under the definition of living modified organisms under the Cartagena Protocol" is probably most important. There could be hundreds of submissions to the forum so if there is an important point to be made, get in early and make it; otherwise it is necessary to follow and react to the discussions as they go on in real time. People in UK Government Departments will be tracking the conversations and "like-minded groups" (e.g. CropLife International) will be having discussions on how things are going and attempting to define common positions. Most members from SBLC are included in the online forum, and there is a need for people to be alerted to issues and opportunities as they arise. If you make good interventions people will pay attention to what you contribute in later sessions.

Genome editing is likely to come up under the second discussion topic. The regulatory status of organisms produced by genome editing is an on-going discussion in many different countries. In the second discussion, the discussion focuses on identifying organisms produced by synthetic biology that are not captured by the Cartagena Protocol. One way to move things in a more appropriate direction would be to consider whether there is a need for any formal regulation, or whether other governance approaches could be used to deliver an acceptable outcome, to get the innovative developments into a better regulatory space.

Re the Nagoya Protocol related discussions, digital sequencing is not currently captured under the Nagoya Protocol and the current dialogue relates to whether it should be captured. The deadline is September 6th to contribute to this dialogue. DEFRA is coordinating a general response and if we can get ours to DEFRA early we can also influence their response. They are also holding a meeting to discuss this issue in August to which members of this group will be invited.

Action 14 LB2 to send a note listing the 5 topics to be discussed in the Open-ended Online Forum.

Action 15 JT to act as focal point for any responses from GSG members.

Action 16 LB2 to send a note to all members of the GSG when a new opportunity arises and all GSG members to then send any contributions to JT for inclusion in a joint response.

Action 17 All members to contribute on their own behalf if they wish to.

Action 18 **LB2 to include members of GSG on the list for invitations to the August DEFRA meeting to discuss digital sequencing information in the context of Nagoya.**

Action 19 **TF and JT to draft a response on digital sequence information for the 6th September deadline and to share with DEFRA in advance of their August meeting.**

5. Responsible innovation and stakeholder dialogue.

The BSI PAGIT Project (Proportionate and Adaptive Governance of Innovative Technologies) was discussed with the SBLC at its meetings on 15th July and 24th Nov., 2016 as a contribution to meeting Recommendation 4 in the 2016 UK Synthetic Biology Strategic Plan *Biodesign for the Bioeconomy:*

> "Develop a supportive business environment by promoting strong and integrated governance, a proportionate regulatory system, excellent stakeholder relationships and responsible innovation."

This discussion focused on the components of the report from the PAGIT project that relate to responsible innovation and stakeholder engagement. The proposal is that innovations that are not disruptive of current business models and value chains, but are geared to incremental improvements that will make them more efficient, profitable or sustainable, are unlikely in most cases to be of much interest to the wider stakeholder community. In these circumstances, demonstration of responsible behaviour by a company could generally be dealt with through a behavioural standard based on the ISO Corporate Responsibility Standard, adapted to include any necessary innovation-related components. Disruptive innovation is more likely to attract public attention and to require a company to demonstrate that the innovation concerned meets societal aspirations and is being developed in a responsible manner. For a disruptive innovation, there will also be a need for stakeholder engagement specifically on the properties of the innovation concerned. The PAGIT Report proposes approaches to all three of these elements through: (i) a Responsibility Standard that encompasses two elements, a Corporate Responsible Innovation Standard and a Standard for Responsible Engagement and (ii) a simple framework by which companies can demonstrate on an ongoing basis whether a disruptive innovation meets societal expectations.

The following points were raised in discussion and included general aspects of the PAGIT Framework as well as those related to responsible innovation and stakeholder engagement:

Considering what is realistically possible in connection with standards, the EMA has struggled with the granting of market authorisation for innovative therapies for rare diseases, given very low affected populations. Decisions need to be made on the basis of a shallower and more patchy evidence base without compromising the principles of quality, safety and efficacy and without creating undue precedents. The evidence is of a different nature from that for a normal clinical trial. It falls within an area where there is already a regulatory requirement and discussions are ongoing in medical and other areas. It's important to continue to innovate but also to respond to health and patient safety needs. In some cases the relevant guidelines would need to be product specific or class-of-product specific.

The point was also made that the EU research on RRI has been disappointing, particularly its dominance by academia and its shaping around six key areas, several of which are not particularly relevant to responsible innovation. The related journal article came under some criticism, based on circulation to academic groups that have been involved in developing work on RRI with the EU and

UK research councils. A particular focus was on the way the research councils' AREA approach has been used in the proposed framework as a basis on which companies can demonstrate whether a disruptive innovation meets societal expectations.

The need for this aspect of the Framework to be further developed in consultation with industry, science, regulatory communities and stakeholders was stressed.

6. AOB

In the context of Agenda item 5, it was noted that the Sciencewise deliberative public dialogue programme has been re-launched and is now funded till March 2019.

Sciencewise now responds to pre-existing policy needs, identified by a government department with a pressing policy question relating to potentially controversial areas of science and to new technologies. Key areas identified are data, data sciences and gene technologies. Sciencewise are still in the process of liaising with stakeholders to see what the needs are. BEIS could perhaps propose an initiative related to the policy need to create a space into which companies can move with confidence. Mark Bale at the Department of Health is a key contact on genomics and gene technologies.

A range of other initiatives is now under way. The Royal Society has tendered for a project to conduct a dialogue on gene technologies, interpreted very broadly, to report by Jan/Feb 2018. They are currently developing materials related to these technologies including elements of synthetic biology, compiled by a range of experts to make, with input from NGOs and other stakeholders to ensure that the materials are a well-rounded and well-founded basis for the views they develop. The project will take 9 months and the information produced should help inform future initiatives.

The Wellcome Trust has commissioned the National Coordinating Centre for Public Engagement (NCCPE) whose remit is to help universities to engage with the public, to do a background literature review on all public engagement work on gene technologies over the past 10 years. They will be holding stakeholder workshops. They will report in about 1 year with recommendations on what has worked and what has not worked. These initiatives are mainly about engagement with the public and not with a broader range of stakeholders.

Action 20 Tony Whitney to send us a note of what is under way in the area of stakeholder engagement.