MINUTES

Ninth meeting, of the Synthetic Biology Leadership Council (SBLC) Governance Sub-group

13:30 – 17:00, Tuesday 1st November 2016.

BIS Conference Centre, 1 Victoria Street, London, SW1H 0ET.

Attendees

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

Governance Sub-group:

Jackie Hinton (JH2)	BIS
Linda Brooks (LB1)	Thermofisher
Julian Hitchcock (JH1)	Denoon Legal
Michael Paton (MP)	Health and Safety Executive
Janet Bainbridge (JB)	UK Trade & Investment, SBLC
Louise Ball (LB2)	DEFRA
Richard Kitney (RK)	Imperial College, SBLC

Apologies: Tim Fell, Robert Doubleday, Alistair Kent, Nick Pidgeon

Membership changes: Louise Ball has replaced Martin Cannell; Matt Goode has been replaced by Patrick Middleton (tbc); Roland Jackson has left the group.

Agenda Items

1. Minutes of last meeting

The minutes from the 8th meeting of the GSG on 7th June 2016 were approved. The minutes of the 6th and 7th meetings have been added to the SBLC GSG 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 6: to urge the SBLC to emphasise the role of synthetic biology in future planning for the bio-economy and to seek significantly enhanced funding to enable us to build on our current advantage, and to seek (through RCUK) stronger representation from EPSRC in fora where discussions are held and decisions are taken that are relevant to the role of synthetic biology in the bioeconomy – Amanda Collis (on SBLC) was seen to be the route to progress this action from now on.

Action 8 (PM): to send GSG members the results of the BBSRC funded stakeholder mapping initiative.

Action 1 (PM): to be reminded to send GSG members the results of the BBSRC funded stakeholder mapping initiative.

Action 9 (JH2): to send GSG members the UK Biosecurity Strategy when it is available.

Action 2 (JH2): Carried forward, not yet approved for circulation.

Action 11 (GSG): Discussion on public engagement and Responsible Research and Innovation will now be on the agenda for the November open meeting of the SBLC.

2. Update on CBD and Nagoya related developments on synthetic biology

LB2 led on this item. This is an EU competence at the moment and there has been no further movement on this since the Council conclusions already discussed at previous GSG meetings. The EU, in collaboration with its members, is developing position papers on implementation of recent decisions on the CBD, Cartagena and Nagoya Protocols. LB is involved in developing the Cartagena position paper on risk assessment and risk management. These guidances are voluntary but parties feel obliged to sign up to them, even where they might cause them problems, because of concerns about legal challenges. There is support for having guidance on synthetic biology, currently in the form of a systematic process for deciding where you need guidance before launching into the guidance itself.

In discussion, the point was strongly emphasised that gene drives have the potential to influence heavily the ongoing discussions on synthetic biology. It is important to flag up that these issues need to be treated with some degree of separation. Gene drives are a much wider issue, and the involvement of CRISPR-Cas9 in conventional gene editing and also gene drives creates the potential for confusion. There is a need for these techniques to be distinguished clearly for the media and the public and positive references were made to the work of the Nuffield Council and Wellcome. It is particularly important that we enable people to articulate things using the same language, particularly as these things end up as laws.

Action 3 (LB2): (i) to send GSG members the CBD guidance on synthetic biology. (ii) There will not be an opportunity to comment on these documents but GSG will be invited to submit views through LB2. (iii) LB2 to circulate the report of the meeting on 18th October.

3. Brexit and Synthetic Biology Governance: a role for SBLC

LC led on this item. He reported on the development of an industrial strategy for the UK, working towards a Green Paper for the Autumn Statement. This will be a starting point for wider discussion. There is a recognition that 'bio' will play a role in the future economy and that synthetic biology will be an important part of that role, with a common concern about how you get from research to something that has industrial benefit. Synthetic biology discussions on the international stage have tended to focus on the UK being regarded favourably by the US in terms of start-up company capabilities, although the US is clearly No. 1 in the volume, content and depth of resource they have contributed to the area. The Chinese see themselves as a long way behind, but also appreciate that the UK is putting together a package based on science and also social aspects including regulation and responsibility. They are keen to work with the UK.

There is a general question on the extent to which we in the UK are beginning to develop our own views on how best to develop the applications of synthetic biology, including a more effective system which focuses on products, achieving a system that has the appropriate checks and balances but is not over-encumbered by layers of bureaucracy. Moving forward in a post-Brexit world, we are looking to establish a globally recognised regulatory approach that could be seen internationally as a future model. This is about positioning the UK as a global partner of choice.

In discussion it was pointed out that there are two separate but related strands.
(i) On the effect of Brexit on commercialisation of technologies, across all sectors, large multinational companies say that there will be ups and downs but the world is bigger than Europe and the impact on business, trade and investment does not so far seem to be as great as was feared. We have a world leadership role along with the US and are working with them - the UK/US

synbio community is very powerful. We should look at the sub-sectors where synthetic biology may contribute (pharma, agriculture, food etc.) and compare the value of trade and investment from Europe to the rest of the world.
(ii) There is also a perfect opportunity to look at a combined UK/US regulatory framework, rather than the European one. If we go forward in that way, the regulation is in the same place as the expertise in the industry and the commerce.

Based on experience in recent meetings in the US, the Americans are keen to work with the UK because they see us as being in a good position. Beyond synthetic biology, other areas are biomedicine, and medical devices. Aligning ourselves with the US in a series of different ways makes a lot of sense, e.g. the experience of the arsenic biosensor which is being developed in the US because of EU regulatory constraints.

We have to avoid the impression that we are "trying to wriggle out of the hard stuff", and to be open, engaging and evidence-based. Also, if we are to do this according to a protocol, we will need common standards and we need to move forward with thinking about regulatory frameworks now, rather than waiting till the Brexit negotiations are under way. It will be important to envisage where we would like to be regulatory-wise so that we do not send mixed messages and Brexit-related discussions can take this into account. This process will be particularly important for small companies working in the synbio area. We actually need a pre-Brexit interim solution because big companies are already looking at pricing structures in the UK and we are going to be treated differently from the rest of Europe from now on.

In an ideal situation, if we can envisage the post-Brexit regulatory approach in various sectors (agri-tech, pharma or bio materials) it will be easier to negotiate; we need to explain why it would be easier, what the regulations would look like, and to describe those thickets of overlapping regulatory hurdles that currently slow things down and that we can envisage simplifying. This should be a consistent approach that we will apply in CBD and other negotiations going forward because it would be our position in the international arena not just in the European forum.

There was agreement that this is the way we should be thinking: start the discussions now, thinking about what the obstacles are currently and start to pull the data together. The challenge with synthetic biology is its diversity and scope - it covers a range of different things and there are overlaps so getting the evidence or collecting the information. This is reflected in costs to businesses. The important thing immediately is to make sure that when the European Communities Act goes, we have a regulatory system that's effective. This does not exclude discussing now on what a future revised regulatory system might look like. We should be speaking to people, getting ideas on what the challenges are, to influence what it might look like in the future, although the actual change will come after we leave the EU.

From a legal perspective, Section 18 of the European Communities Act, 2011, says that any bit of legislation which is part of our law as a result of the European Communities Act can become part of UK law by flicking a switch. In that sense it's easy you just identify it and say it's now UK law, but there is still a need to consider downstream regulation, who is going to be the regulatory body. That's the immediate crash-landing and we can then amend and should be preparing for that. In this context there are opportunities for risk assessment innovation, aligned to the regulation that could be part of a more innovative governance system and this should include business impact assessment.

If synthetic biology is going to become a major industrial field, we've got to make sure that our regulations are in line with the other major trading groups or we will be locked out. Whether we

get alignment with the EU or the United States, or preferably both, that's what we need to achieve, and the rest of the world are influenced by the US more than the EU. The Minister is saying that things are going to have to change and if synthetic biology is going to become a major industrial field the key question will be alignment with the other major trading groups. The problem with the EU is not really the legislation itself but the lack of will in the EU to make it work.

It's important that the Synthetic Biology Leadership Council establishes a view that can be expressed in this area rather than just saying we ought to do something - there are overlaps which get in the way but putting a finger on what we would do differently will take a bit of work. There's an investment requirement to say, for example, what would happen if we decided to develop a purple tomato using synthetic biology, what would be the blockers, what could one reasonably aspire to be able to do in the UK to facilitate the speed with which things can be approved or decisions made. Making it more attractive to industry by virtue of the efficiency of the processes is a longer term aspiration, considering whether there are aspects of the regulations that could be simplified. If we could bring the cost of meeting the regulatory requirements down to about £100K per product a large number of small companies could begin to develop products based on synthetic biology for niche markets and could create a whole new industry sector.

From a regulator's perspective it would help to have examples of where there are obstacles, based on feedback from the community. These could then be addressed using standards and guidelines.

Considering what we can do within the current government system in a way that actually feeds into government decision making, one option would be to build it into the bioeconomy strategy and from there into the industrial strategy. There will also be a direct route through the twelve-week Green Paper consultation period.

Action 4 (All): Use any opportunities to contribute to decision making or give feedback, and inform the GSG (JT) if you do so.

Synthetic biology could lead to a new approach to anticipating the benefits and risks of new products – there is a need for further research in this area. This (sometimes referred to as 'regulatory science') would fit well with the interdisciplinary agenda of the reorganised research councils and is an important area of future development to flag up to the research councils via the SBLC. It should include consideration of the governance interest and be supported by some case studies (e.g. gene synthesis and transiting of genes in and out of the UK; crops used to manufacture pharmaceutical products, vaccines, orthogonal systems (an area where the UK could lead)).

Action 5 (JT): 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.

On the question of gene drives and potential confusion in the public mind between that and the much less challenging gene editing, this discussion on stakeholder engagement processes will link to the agenda item on the next SBLC meeting which is an open meeting with presentations from representatives of the Synthetic Biology Research Centres, including a discussion of RRI.

4. Stakeholder understanding of gene editing, CRISPR-Cas9, and gene drives

Led by JT and HS, and as discussed also under the above agenda item, a potentially important issue on the horizon is to consider potential stakeholder understandings of CRISPR-Cas9 techniques and to enable understanding of their very different roles, from the point of view of regulation and ensuring safety and hence for public understanding of synthetic biology in general.

Discussion focused on the need for SBLC to have a strategy for dealing with these questions and for the GSG to advise SBLC on what that strategy should be. It should include making sure that we can anticipate some of the issues and that the media have access to appropriate information, as well as ensuring that these perspectives are taken into consideration in the drafting of UK policies and commercial strategies. Trusting that the engagement processes are fit for purpose, transparent and up to date will be important, as will the inclusion of case studies.

A draft stakeholder involvement strategy, to build the trustworthiness of synthetic biology and its applications, should be a major item on the next GSG agenda. We should involve the Science Media Centre and collaborate with them on developing briefing sheets.

We could also position this as a promotional video for British Science, explaining why synthetic biology is one of the Great Technologies.

Action 6 (JT): Develop a draft stakeholder involvement strategy for consideration at the next GSG meeting.

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

Action 8 (JH2): Explore the possibility of developing a promotional video for the British Science Association.

5. AOB

None.