**Seventh meeting, of the Synthetic Biology Leadership Council (SBLC) Governance Sub-group**
**13:30 – 17:00, Wednesday, 2nd March 2016.**
**Room C22, BIS Conference Centre, 1 Victoria Street, London, SW1H 0ET.**

**Attendees**

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

*Governance Sub-group*:

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| Lionel Clarke (LC) | Co-Chair SBLC |
| Julian Hitchcock (JH) | Denoon Legal |
| Sir Roland Jackson (RJ) | Sciencewise |
| Michael Paton (MP) | Health and Safety Executive |
| Hilary Sutcliffe (HS) | MATTER |
| Janet Bainbridge (JB) | UK Trade & Investment, SBLC |
| Martin Cannell (MD) | DEFRA |
| Suzannah Lansdell (SL) | Sciencewise |
| Richard Kitney (RK) | Imperial College, SBLC |

*Apologies:* Alastair Kent (Genetic Alliance), Nick Pidgeon (Cardiff University), Linda Brooks (Thermofisher), Matt Goode (BBSRC), Jackie Hinton (BIS); Tim Fell (BIA, SBLC)

**Agenda Item**

**1. Minutes of last meeting and feedback on recent activities**

Welcome and apologies. No comments on the minutes from the 6th meeting on 1st October 2015 other than that the initials of the speakers will have to be removed in the discussions – only the agenda item speaker will be identified – and some typos will be corrected before the document is put on the webpage.

JT updated on actions that have been carried over from previous meetings.

**Action still outstanding**:

- Appointment of a new member to the sub-group still on-going. LC advised that Rob Doubleday in Cambridge would be glad to join. The other members of the subgroup agreed to it, and a formal invitation will be sent.

Other actions required following the publication of the Strategic Plan:

- The case studies relating to item no 3 'Synthetic Biology Strategy' were supposed to be added at the same time as the main report on the website appear to be missing.
- Some typos (including a missing 'not') need to be corrected in the Strategy Roadmap.

**Action (JT):** Remove speakers' initials in discussions and correct typos in previous minutes. **Done**
**Action (JT):** Send a formal invitation to Rob Doubleday to join the Governance Subgroup. **Done**
**Action (JT):** Email Amy Tayler about missing link to Case Studies on the Strategic Plan webpage. **Done**
**Action (LC)**: Continue reviewing/correcting typos in the Roadmap in the online document. **Done**

**2. Feedback on Convention on Biological Diversity (CBD) related developments since the last meeting**

***i. Recent consultation on Summary of the Open-ended Online Forum***
*(Paper 7.1 - SBLC submission and subsequent discussion)*

JT introduced this item. An email had been sent to the subgroup members prior to the meeting, with the SBLC consultation response to the 'Convention on Biological Diversity (CBD) Notification 2015-139 – Peer review of the outcomes of the process in response to decision XII/24 on synthetic biology' submitted in Jan-16, as well as a document showing the exchange of correspondence following the submission of the response. This correspondence included in particular two comments showing some useful support for the view we had expressed.

The comments on this topic included the following:

- Some of the CBD parties are heavily influenced by NGOs with lack of balance in the representation of views in the summary of the online forum that may have implications for future decision-making.

- The CBD's perceived need for a definition which did not cover non-living products was perceived as positive, in line with the UK stance. Some clarification may be required for the SBLC response, which supports not extending the regulations to cover non-living products and also supports the case for a product-based approach to regulation. The CBD considers a product to be a non-living entity (a chemical or a protein) as opposed to a living organism whereas the UK includes living entities like a gene therapy virus as a 'product'. The subgroup considered that a 'phenotype'-based approach, based on the properties of the organism, should be used for organisms, rather than the process which produced it. Components or products as defined by the CBD are already covered by numerous regulations and would be beyond the remit of CBD, however the CBD can be justifiably involved if the products have a negative impact on indigenous populations.

- The issue of the legality of any definition was raised, especially as it came up recently at an EU expert group meeting discussing the consequences of any definition being adopted or not by the CBD.

- The aim of the AHTECH meeting was to air different views, and therefore no consensus was necessary. However for the next step which is the Technical Committee of the CBD, only countries representatives will be able to make recommendations, so other parties will no longer be involved.

- The 31 responses (which can be accessed on line) from various countries including the USA were on the whole very supportive about the report. Almost all countries mentioned the definition, judged either good because all encompassing or bad because too broad so it cannot differentiate synthetic biology from what's normal biotech. Some countries advised caution on the basis that if a definition is adopted, it will be used for regulatory purposes, and the CBD report seemed to imply so, whereas others viewed it as an operational definition, therefore open for discussion.

- Regarding the adoption of a definition, there was likely to be push back on any recommendation that the CBD should adopt the current proposed definition, due to concerns that the CBD might use it to impose restrictions. It would then mean adding a large number of exceptions and sub-rules, unless the CBD breaks down the definition into the several points which might cause concern, with individual rules. An alternative solution proposed would be not to have a definition at all, as for the term 'Invention' on legal terms. On the other hand, a definition is needed to capture a technology for regulatory purposes. Nano technologies were mentioned as another example of a similar problem.

- The question of the involvement of the CBD in synthetic biology was raised, as the vast majority of synthetic biology activities that take place under contained conditions present no risk to biodiversity. Some NGOs' proposals to treat contained use as equivalent to deliberate release may be justified if the number of synthetic biology applications intended for environmental release increases, but there is no such threat at the moment.

- Caution is required to avoid the risk of polarizing discussions by casting NGOs as the enemy, especially with regard to their influence over parties, or regulations as always being problematic as the expression 'regulation creep' seems to imply. Also with general statements about the good of a particular technology, like the reduction of use of pesticides with GM crops cited in the SBLC response, when they are in fact very context-dependent and there may be issues, as with glyphosate attached to Monsanto GM crops.

- It may not so much be about balancing benefits against disadvantages or even risks of a technology, but rather about having the option to do something against not having that option when you might need it.

***ii. Next steps***

MP and MC spoke to this item. MC has been selected to represent the UK position. A document outlining this position has been circulated to relevant parties, including the SBLC. A paper based on the peer reviews and comments will probably be published shortly before the SBSTTA meeting in Montreal on the 29th of April. MC plans to get comments from as many people as possible to feed into that, with the caveat that there won't be much time to circulate it to get feedback for the 29th.

The comments made included the following:

- It is important for the UK to be seen to have a robust but positive stance on the regulatory side if they want to be seen as a lead in science, technology and engineering, while encouraging investments for new technologies which could be killed by cumbersome regulations.

- New technologies should be assessed on a case by case basis. The questions about any new technology should be what is likely to go wrong and what would the impact be? And then design and test the appropriate safety systems to address this in a contained environment until satisfied that it is safe. The regulations should be able to address the situations as they arise and make sure that there is a process whereby the new technology will be properly assessed. It is important not to over-focus on contained uses of the technology, given the many future potentially useful applications arising from release of organisms that can be categorised as safe.

- In the EU there is a category for organisms similar to the Generally Recognised as Safe (GRAS) organisms used in the US, with a much lighter touch regulatory system, but no organisms have been listed in that category as yet. This route is being tried for a biosensors and could provide an opening for other new biotechnologies.

- To make a decision about the value of a new technology the decision makers need some rigorous and balanced evidence about the benefits it actually brings as opposed to the potential ones, and the practical decision should be made at a Government level, so above the regulatory systems. The Government has taken steps in the Health sector to request the regulatory bodies to consider and improve if possible their impact on innovation. The same pressure was confirmed as applying in fact across the board in the UK – and maybe the EU -, not just in health. However the effect of this measure is still to be felt.

- The evidence of *not* doing something to measure its impact is hardly ever requested, only the impact of doing it, although both have value. NICE takes this into account for the health sector but this is not yet considered for GMOs.

- There is a strong possibility that this issue will not be resolved in the current round of discussions at CBD due to the divergence of opinions, and it could end up in limbo for a number of years.

**Action (MC):** Email (with CBD-related email subject in caps to flag) the report to SBLC Governance sub-group as soon as possible to allow feedback before the meeting of the 29th of April. **Done**
**Action (all):** Send back comments to MC directly, before the meeting of 29th April. **No comments submitted.**

**3. Synthetic Biology Strategy Paper, its launch and next steps**
(Strategy paper 'Biodesign for the Bio-economy')

LC thanked everyone who had contributed to this paper, and mentioned that the process itself of getting and putting together everybody's views was extremely valuable in itself.

The objective was to be succinct, not over-prescriptive in an evolving landscape and capture the sense of 'what next?'. The paper included 'Proposed actions' as a challenge to do something, requiring a response.

The launch on the 24th of Feb-16 appears to have been very successful, generating a lot of interest and over 8 000 downloads. The Government, and George Freeman MP in particular, are very interested. But things will only happen in synbio if it offers cheaper and better ways to do what is already being done, so it is increasingly being positioned in terms of the bioeconomy.

Going forward, the UK is still not very good at nurturing start-ups to commercialise them. Some of the questions are: what proportion of a start-up does a university wish to take, or what standards should be put in and when and how, etc. ? If the sector is to grow, are the necessary skills all available in the country or do they need to be brought in? By getting everyone involved, working together and sharing best practice, the UK would not have to spend as much money as the US or the Chinese will in the near future.

The UK's coherent approach to synbio has received good feedback from other countries and it is hoped that working in partnership with those countries will allow the UK's way of working to 'rub off'. The Chinese in particular approached LC before Christmas 2015 to help them design their own roadmap. As the UK has been seen to take the lead on this, it is important that they carry it through.

The critical step now is: how to address the public opinion, public engagement?

One important item for the SBLC meeting on 10th March will be to consider what to do in practice and who will take responsibility now that the actions have been mapped out. The minister is keen on metrics, so the SBLC has to show that they are making progress in the right direction.

Discussion items raised under this topic:

- The lack of government funding for the sub-group to carry out its work. Also the potential threat of KTN deciding to remove their key support person who has provided invaluable assistance to the group. A marketing budget will be needed to hold the synbio project together, maybe in collaboration with other leadership councils. Work has already begun on a cost assessment.

- Additional resources will be required to develop and support a business environment. The lack of funding for the Leadership Council will be raised at the SBLC meeting with the ministers the following week (10th March), in view of its importance for the UK economy.

- Another question is: what kind of link can fill the gap between company-led and basic research-led activities? The technology is there, but people need to be educated about synthetic biology, and the technology itself needs to be 'sold' to the industry.

**Action (LC):** Raise funding issue for business environment support at SBLC meeting of 10 Mar-16 with the ministers. **Done**

**4. Group discussion on public /stakeholder engagement on synthetic biology**
(Paper 7.2 – Engagement Note from GSG Meeting 6)

LC proposed to focus on Action Point 4.4 in the SBLC Paper '*Bio-design for the Bio-economy: "The SBLC and its GSG to build on recent and current initiatives on engagement and dialogue, involving representative stakeholders, to ensure that RRI is incorporated as a core value in decision making on synthetic biology, and to continue to develop appropriate standards for RRI*.'

RJ, HS and SL led the discussions.

The following comments were made:

- The frequent use of responsiveness-related words in the document was seen as a positive thing, however this document, like others on the subject, always refers to Responsible Innovation (RI) in terms of public dialogue when it is much more than that. A recent presentation on Responsible Robotics showed that it should also include the benefits (social in particular), whether it was efficacious, and the need for evidence of benefits, with the loss of opportunities being also factored in, assessing and understanding impact (cultural / social / environmental /…), and involving all stakeholders (individual researchers, government) as to their respective responsibilities.

- The roadmap may not focus sufficiently on building confidence in the technology, and in particular the *trustworthiness* of the processes which would come from the evidence gathered in support of the technology.

- The document should address to a greater extent the requirements/recommendations for each stakeholder group in order to help them identify whether they already follow the correct procedure(s) or not. The questions they need to answer would include: what areas are they choosing to do research on, how they assess benefits and impact, how they are involving people and looking at governance, and how open they are about the way they are doing research in these areas.

- Several points were made about the benefits of an innovation:

    - They should not be restricted to social benefits only; they could be social, cultural, environmental, ethical and economic. So making money for instance would have a positive effect by freeing funding resources for other areas and creating jobs.

    - It should be about the *net benefit or disbenefit* of an innovation, and where the benefit or disbenefit falls. For example a disruptive innovation could create jobs but also destroy some. This type of issue is not part of the remit of the regulatory system, it belongs to the political debate, but any innovator and Leadership Councils should be aware of this issue.

    - There are many cases where innovations have proved to be hugely beneficial in ways that were unexpected and it is important to avoid leading people to move away from research and innovation areas because of presumed excessive regulatory hurdles. Since decisions have to be made, the question is what is the basis for the choice and who makes the choice? The level of "appliedness" of the science should be taken into consideration, and innovation should be understood in the sense of application. RI should recognise that there are unknown potential benefits and that there is intrinsic value in the knowledge acquired, and should not be restricted to social benefits only. But funding has to be decided in advance of knowing anything about safety or application and the bottom line for RRI is about not doing something that you could anticipate is likely to go wrong.

    - The underpinning of the document is that RI has to show clear public benefit and involve public dialogue and stakeholder consultation, so first you need to have a better understanding of the public's and stakeholders' concerns and aspirations for the technology as a frame/context in which the science is being done. Public dialogue can help find issues that the regulators had not thought about and could not have known, and identify public priorities.

- A question to put to the SBLC would be: what does RRI mean for the different actors involved? The talk on RRI so far has been a lot at research level rather than regulator/strategic decision-making/policy level.

- Synbio should not be considered as a whole because the end message is 'it depends'. You need to look at specific areas (e.g.biofuels which raise concerns about land use), look at a suite of examples in each area (materials, health, etc.), and ask what the issues and uncertainties might be for people. In addition, once you have a focus on a specific case, you can define who the stakeholders are. It would be useful to check what the projects involved were and what the findings of the consultation were in the public dialogue already been done at the time of the first synbio catalyst project,.

- Considering Point 4.2 in the Strategy Report ("*The SBLC and its GSG should continue working with BSI to identify opportunities for standards to contribute to more adaptive regulatory systems that meet the needs of rapidly evolving industry sectors while retaining high standards of safety and efficacy*"): The regulatory systems' existence was viewed as aiming to preserve the public interest, not to 'advance rapidly evolving industry sectors' and there should be a balance between protecting the needs of human health and the environment on one hand, and optimising development in that context on the other. However the item could be read as similar to attempts to shift EU law to harmonize the market by having a set of common rules, with the primary aim to make the European market work, so with an economic priority.

- The minimum would be to try and identify potential pitfalls ('banana skins') so the ground can be prepared if they cannot be avoided completely.

    - A market research exercise could be useful to help identify pitfalls, but would not replace a dialogue with the public and stakeholders The process which allowed the mitochondrial transfer project to go to Parliament was cited as a good approach, including safety analysis, stakeholder consultation with a range of stakeholders and a public-facilitated dialogue.

    - Another potential pitfall comes from potentially damaging statements circulated by the media and there is a need to build resilience in public understanding to prepare for these.

    - It could be useful to anticipate where there are potential pitfalls so that decisions could be made in context, with the ability to explain that an issue had been considered, and the decision maker is not in a defensive position.

- A template was suggested to develop a strategy for RRI governance, incorporating all the elements discussed and using the capacity offered by the Governance Subgroup with a range of different perspectives to draw issues together. This strategy could be about which aspects should have predominance in response to a particular challenge or opportunity. The group would then be in a state of instant readiness to act when a challenge arises. The following actions were proposed for information gathering for this strategy:

    - Find out from the SBLC's Science, Technology and Innovation communities what issues they see emerging that the subgroup should be paying attention to.

    - Students could be asked to do some horizon scanning on the information already available, and make a list of potential issues. The Governance subgroup would then

work on them on the basis of the proposed template. This horizon scanning exercise might be able to attract funding.

- Each of the six Synthetic Biology Research Centres already has a RRI component in their research programme and their teams consult with one another. The Governance Subgroup could learn from them, given that each centre will have a different view point depending on their science focus and their social scientists. Representatives of the RRI Group (from BBSRC and SBRC) could make presentations to inform the GSG.

- If possible, ask for anonymised information from the BBSRC about all synbio-related bids made to research councils / Innovate UK in areas where synbio can make a difference and/or to provide an anonymised analysis of topic areas.

- The European Commission has made a list of RRI issues that they deemed important and HS will send a link to this list. HS also made a list of all RRI frameworks and can provide it to those interested.

- Update on Sciencewise:

  - Sciencewise's programme funding ends 31 Mar-16. As the Government has not lined up any new funding yet, it is likely that Sciencewise will be put on hold until Autumn.

  - Sciencewise has been running workshops bringing together a whole variety of people to work out what a dialogue might look at. One is scheduled the following week for robotics, and it would be interesting to see how they went about that, why they did it and what they did.

**Action (MG):** Check which projects were involved in the Innovate UK consultation for the 1st synbio catalyst project, and what the findings of the consultation were. **Done**
**Action (JT)** Propose to SBLC that the Governance Subgroup deals with the proposed governance strategy for RRI. **Done**
**Action (all):** Ask contacts in Science, Technology and Innovation communities what issues they think the Governance Subgroup should be paying attention to. **Ongoing**
**Action (JT):** Arrange for BBSRC / SBRC representatives from the teams working on RRI to make presentations to inform the subgroup. **Ongoing**
**Action (MG)** Check if it is possible to get anonymised information from the BBSRC on synbio-related bids made to research councils and Innovate UK, and/or an analysis of the areas involved. **Done**
**Action (HS):** Send a link to the list of RRI issues from the European Commission**. Ongoing**
**Action (SL):** Send to JT information on the Sciencewise Robotics dialogue (covering how / why / what questions). **Done**

**5. AOB**

The 4th March is the deadline for submitting observations to the House of Commons Select committee on the 'Impact of regulation in Europe on Life Sciences'.