Synthetic Biology Leadership Council: 2nd Meeting, Governance Subgroup

Conference Room C21, Department for Business Innovation and Skills

6th June, 2014, 10.30 - 15:00

Attendees

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

Governance Sub-group:

Janet Bainbridge (JB)	UK Trade & Investment (SBLC)
Linda Brooks (LB)	Thermofisher
Lionel Clarke (LC)	Shell (Co-Chair SBLC)
Ron Egginton (RE)	Research Funding Unit, BIS (SBLC)
Tim Fell (TF)	Synthace, BIA
Matt Goode (MG)	Research Councils UK
Julian Hitchcock (JH)	Lawford Davies Denoon
Roland Jackson (RJ)	Sciencewise
Alastair Kent (AK)	Genetic Alliance
Michael Paton (MP)	Health and Safety Executive
Hilary Sutcliffe (HS)	MATTER

Apologies: Martin Cannell (DEFRA), Richard Kitney (Imperial College, SBLC), Sharmilla Nebhrajani (Association of Medical Research Charities), Nick Pidgeon (Cardiff University).

Agenda 1 Welcome and Matters Arising

Joyce Tait welcomed the members of the SBLC Governance Subgroup to the second meeting.

Minutes of the meeting of 27th January were accepted. All actions were completed, with the exception of those included on the agenda.

Additional item for information and discussion

In an off-agenda item at the meeting of 27th Jan, a member of the Subgroup (referred to below as 'the proposer') had requested permission formally to conduct social science research on the workings of the Subgroup while remaining a participant in its discussions. Given reservations about this request by some subgroup members, the SBLC meeting on 19th March, 2014 was asked to approve a recommendation that the proposer should be invited to be an observer of Subgroup meetings, but not at the same time to be a participant. In the intervening period, the proposer was asked if they were willing to remain a member of the Subgroup without acting as an observer, but this could not be agreed.

Reservations about this proposal were also expressed by some members of the SBLC at the 19th March. meeting. Nevertheless, the outcome of that meeting was that this could be a useful part of our work and that the proposer should be asked to prepare a draft information sheet describing the proposed research and a consent form to be signed by members of the Subgroup.

The requested documents were received and the information sheet contained the expected caveats on freedom of Subgroup members to withdraw from the research project at any time. Also, in recognition of the collective nature of any agreement to participate, the information sheet included the following assurance:

"The project will only go ahead if all the members of the Governance Sub-Group decide to participate. If, at any time, any individual member of the Sub-Group wishes to withdraw, then the observation of the Sub-Group will be discontinued".

The information sheet also included reassurance that members would not be named in any publications but recognised that, given the small size of the group, it may not be possible to guarantee full anonymity of participants. With this in mind, the information sheet also included the following reassurance:

"Written research outputs will be circulated to members of the Sub-group in advance of publication and if any concerns are raised concerning anonymity or confidentiality the document will be revised to satisfy those concerns."

These documents were circulated to SBLC members in advance of this Subgroup meeting, and did not meet with universal agreement. One SBLC/Subgroup member notified us that they would refuse to sign the consent form and it was clear that others remained uncomfortable with the request. In accordance with the above paragraph, Lionel Clarke then informed the proposer that it would not be possible for us to agree to the request to observe the proceedings of the Governance Subgroup. However, we assured them that we will be happy to discuss other ways to help with the proposed research and will seek other opportunities to include them in related activities.

The above full explanation of the process was given to Subgroup members at the start of discussion at this meeting and is repeated here in the interests of open-ness about our proceedings.

In the discussion, it was clear that members would have welcomed the contributions of the proposer as a member of the Subgroup and regretted the outcome. Some members also expressed strong regrets that the attendance of an observer had not been approved, considering that the Subgroup and SBLC would not now have the benefit of research which would have helped ensure that lessons are learnt from the work of the Governance Subgroup. However, other members felt equally strongly that the costs of this process would be too high.

A key issue was seen to be to balance the need for a trust worthy transparent process whilst allowing for frank and open discussion, uninhibited by concerns about how views may be interpreted or communicated more widely.

It was agreed that the Chair would convey the discussion within the Sub-group to the SBLC and the SBLC would be asked to determine the next step.

Action 1: A replacement appointment to the membership of the Subgroup will be made and the Chair asked for suggestions from Subgroup members.

Action LC

Action 2: The issue of observation of Subgroup meetings will be included in the agenda of the next SBLC meeting on July 3rd and the SBLC will be asked to consider the process outlined above and the outcome and either endorse the decision taken jointly by the Chairs of the SBLC and the Subgroup, or suggest an alternative outcome. (**Action JT)**

Action 3: There was a request for the minutes of the previous SBLC meeting to be included in the papers for each Subgroup meeting, in draft or final form.

Action JT and Secretariat

Agenda 2. A UK Framework for responsible research and innovation and the SBLC's role

As discussed at the first meeting of the Subgroup, continuing responsible research and innovation is a core theme of the Synthetic Biology Roadmap, and it is also one of the underlying principles included in the Terms of Reference of the Subgroup. As noted in the minutes of the first meeting, the Subgroup should identify where it could add value to the already-extensive body of work being undertaken in the EU.

Several members of the Subgroup had attended a meeting of the British Standards Institute to discuss the development of a Framework Standard for Synthetic Biology. There was support from that meeting for the BSI to develop such a standard with a strong recommendation that it should be applied to a broad range of technologies, not just synthetic biology. However, no funding had yet been made available to support this initiative.

The following points emerged in the discussion:

- A broad framework standard that did not single out synthetic biology would be helpful, for example across all the 'Eight Great Technologies'
- 'The effectiveness of addressing responsible innovation through a specific voluntary initiative was questioned and it was agreed that currently attention should be focused on the development of an appropriate regulatory framework and improving the understanding of risk and potential social and ethical issues
- Attention was drawn to Craig Venter Institute's recent report on the US regulatory framework for synthetic biology and to a report by the OECD 'Emerging policy issues in synthetic biology'
- There was acknowledgement that work involving synthetic biology is nevertheless leading the field and it is regrettable that other industry sectors are not following
- More work is needed on developing appropriate regulation for future deliberate release
- A multi-stakeholder approach to funding development of a standard is needed to engender public trust and to demonstrate independence
- Concerns were expressed about creeping regulation and bureaucracy

Action 4: To convey to SBLC that they should consider re-opening discussions on development of a framework standard by the BSI for responsible research and innovation, supported by a broad coalition of stakeholders, including industry. Leading roles could be taken by Innovation and Knowledge Centres for a range of advanced innovative industry sectors, the TSB, a range of Leadership Councils, and the UK Research Councils.

Action JT

Agenda 3. Revised Guidance for the 2014 GMO Contained Use Regulations

Mike Paton (HSE): HSE had successfully completed the consultation process on revisions to the Contained Use Regulations and responses were largely supportive of the consolidation. The final Genetically Modified Organisms (Contained Use) Regulations 2014 will be laid before Parliament to come into force on 1 October 2014. The documents circulated to the Governance Subgroup were the latest drafts of the revised guidance on the new regulations. The documents are intended to help users to understand how synthetic biology will fit into the regulations.

With respect to synthetic biology the HSE have incorporated it in Part 1 definitions in an approach that is similar to that of the NIH Guidelines in the US on 'recombinant or synthetic nucleic acid molecules', in both cases to reflect changes in advanced technologies. If necessary, there will be future opportunities to make changes to these guidance documents as new issues emerge.

Discussion included the following points:

- The Guidance documents could usefully give more examples to make points clearer.
- There is a need to stimulate scientific research that could contribute to better regulation in future; the contribution of research to regulatory processes is currently reactive, direct links from regulators to research councils are weak (as opposed to links via regulatory panel members);

- There is a need for a 'helicopter view' so that regulatory systems can be changed as knowledge becomes available – there is a potential gap here.
- In the context of the roadmap we need to be more creative and imaginative, but there is currently no process through which to support cutting edge 'regulatory science' that could contribute to minimising risks and reducing the time and money costs of regulatory compliance.
- In other areas of European regulation, e.g. Advanced Therapy Medicinal Products (ATMP) Regulation, poorly drafted regulations encouraged people to find ways to work round them rather than through them; effective regulation should take greater account of product-specific chartacteristics within the primary regulatory requirement of ensuring safety and efficacy.

In conclusion it was noted that this has been an interesting example of a regulator being willing to adapt a regulatory system as more is learned about working with a novel set of technologies and of doing so within a relatively short time scale – there may be lessons here for other regulators.

Action 5. Subgroup members are invited to comment on the documents circulated by Mike Paton, particularly the first two parts of the document and to send illustrative examples that might be helpful in understanding specific points, **by 23rd June**

Action All

Action 6. The SBLC to be requested to open discussions with UK research councils and the TSB on developing a *cutting edge* science agenda on contributions from current advanced innovative technologies, including synthetic biology, to the development of regulatory systems that are better able to meet the challenges arising from developments in biological sciences.

Action JT and LC

Agenda 4. Update on synthetic biology and the UN Convention on Biological Diversity (CBD)

There have been several occasions over recent months where SBLC members have been invited to comment on proposed revisions to the CBD and the associated Cartagena and Nagoya Protocols. There has been insufficient time to develop a coordinated response and LC and JT have drafted responses on behalf of the SBLC. Issues of concern addressed in these responses have mainly been related to further extensions of the precautionary principle incorporated in the CBD and related instruments, and extending this to applications of synthetic biology. We want to see synthetic biology, as for GM technologies, developed safely, but in a manner that enables society to benefit from new discoveries, rather than being constrained unnecessarily.

It is unrealistic to expect SBLC or Governance Subgroup members to come to an agreed common response in the time available. However these consultations are directly pertinent to the work of the Subgroup. We are therefore proposing that relevant consultations should be circulated to all Subgroup members, who will be invited to respond on their own behalf, copying their responses to SBLC.

Subgroup members were also invited to raise any issues they thought should be taken into account by JT and LC in drafting responses on behalf of SBLC.

Discussion covered the following points:

- How can we inject rigour into claims being made for economic, social and environmental benefits and risks, to balance the rigour of the scientific research.
- We want to avoid unreasonable wording that prevents sensible assessment of risks, or imposes requirements that are legally unworkable.

- This group is the best panel available to have a collective view on the issues raised by such consultations and we should make effective use of this resource.
- It may be useful to have a procedural analysis of regulatory processes to point up where regulatory and political stages of endorsement of regulations have exceeded their remits or the bounds of their competence in making regulatory decisions that are not fit for purpose. A resource is needed to analyse and assess what is going on.
- Subsequent to submitting responses from SBLC to consultations, there has been little formal feedback on how that was reflected in subsequent documents from UK Government departments.
- It would be very useful if Government Departments could give the Subgroup advance warning of upcoming consultations with expected dates and timings so that we could prepare in advance.
- When responses to consultations are requested, Subgroup members who do not have specific legal or regulatory expertise in a particular area need to have guidance on what are the key issues to be addressed.
- Given discussion on this and previous items, there is a need for a better resourced secretariat to serve the requirements of SBLC and the Governance Subgroup, as is the case for other Leadership Councils.

Action 7. RE to elicit specific feedback on how each SBLC response to a consultation has contributed to UK policy decisions.

Action RE

Action 8. RE (via SBLC) to request government departments to give us a draft timetable of future consultations and relevant meetings at UK, EU and UN levels and to update this regularly in future.

Action RE

Action 9. LC to support RE in developing a brief to provide greater resource for SBLC and the Governance Subgroup in supporting the synthetic biology community through the initiatives discussed at this meeting. In some, but not all, cases this could be delivered through better networking.

Action RE and LC

Action 10. SBLC to consider whether it could instigate a procedural analysis of the recent developments of CBD and related protocols from both legal and policy perspectives.

Action JT

Agenda 5. Public dialogue/consultation: industrial biotechnology

There is a long term commitment from the Synthetic Biology Roadmap, included in the remit of the Governance subgroup, to consider how we might use public dialogue and consultation to understand better what members of the public and various interest groups are thinking in terms of current and future synthetic biology developments. JT suggested that industrial biotechnology (IB) be used as an example where real products and processes are currently being developed, and discussions and deliberations can be more focused, for example the TSB-funded dialogue on Stratified Medicine, in collaboration with Sciencewise.

- The question was raised whether there are already plans for public dialogue on synthetic biotechnology through other routes; we need to learn what is going on in the IB space; dialogue can be most valuable at the point where basic science is beginning to be applied to novel products and processes.

- Several products of synthetic biology are already coming onto the market and it is not too soon to take up such an initiative, across a broad range of industry sectors, making a case for IB (in the sense of exploiting a platform technology) as a focus for dialogue.
- It will still be necessary and useful to conduct public dialogue in the early stages of development of new scientific research trajectories, as was done for synthetic biology[1]. This was influential on research council thinking in funding further research on synthetic biology.
- There is a need to sharpen up what would be the purpose of a deliberative public dialogue, what government decision making could it inform, and what else could it inform. Only then can you start to design a dialogue process. It might be useful now to have a dialogue about societal challenges for which industrial biotechnology might be a solution and to consider its role in comparison with other technological or societal solutions. This enables you to put any technology in its wider context. An example of a relevant challenge might be 'How do we move away from an oil based economy?', leading to discussion on where new sources of carbon would come from.
- Are there roles for both technology push and challenge pull in synthetic biology? And with 'challenge pull' synthetic biology will not be the only technology that can address the challenge.
- We should consider whether it would be useful to have a stakeholder dialogue about regulation – where are there gaps and where are the real lines of contention?
- It is also important to understand what the public perception is now on some of the products that are appearing on the market, but it is important not to focus on synthetic biology as anything other than just one of several ways of delivering the expected benefits. The question should be 'What do we need in the toolbox to address this particular issue?'
- It is important to consider what actions by government and others might be influenced as a result of a dialogue process.
- We need to clarify what we mean when we talk about 'the public' in this context.

An outcome of the discussion was that there are important issues related to industrial biotechnology, but they should be discussed in a broad context, and SBLC should not be the body charged with delivering such an initiative. However, SBLC should have an important role in such initiatives undertaken by others.

Action 11. LC to follow up on what engagement/dialogue initiatives are planned through other leadership councils and funded UK activities and to ask SBLC to ensure that the Governance Subgroup has an opportunity to contribute to such initiatives, in an appropriate challenge-led context. In the absence of any such initiatives, LC to suggest to SBLC that a dialogue should be set up in partnership with other relevant bodies.

Action LC and JT

Agenda 6. Shape and Conduct of Future meetings; programme of activities

1. *Timing of future meetings.*

JT asked Subgroup members if they would prefer to fit future meetings into either a morning or an afternoon session, rather than taking up a whole day.

The following points were noted in discussion:

[1] http://www.bbsrc.ac.uk/web/FILES/Reviews/1006-synthetic-biology-dialogue.pdf

- Conversations sometimes take time to warm up because some members need to get up to speed on issues that they are unfamiliar with. With half-day meetings it will be important to maintain the space to allow full discussion of agenda items, requiring the agenda to be more focused, on fewer items.
- This point also supports the action point on the need for better secretariat support in provision of background papers relevant to discussion items on the Subgroup agenda.
- We should make greater use of committee members in asking them to address particular issues relevant to their expertise that are coming up on the agenda.
- It would be useful for the Subgroup to be updated on a regular basis about relevant government department consultations as they as they come up or as they move beyond the point where we could have a useful input.

Action 12. This suggestion was welcomed, so future meetings will be organised on this basis.

Action JT and secretariat.

Action 13. Subgroup members are welcome to bring any new governance related initiatives on synthetic biology to the attention of Subgroup members and to initiate discussion on such questions at meetings.

Action All.

2. *Content of future meetings*

JT also noted that our discussions have not focused much so far on health-related applications of synthetic biology and asked any members of the Subgroup with interests in such areas to think about items that we should put on the agenda for future Subgroup meetings.

The following points were noted in discussion:

- A health related example would be future EC re-negotiation of ATMP Regulations that may relate to synthetic biology where a relevant question would be 'How could you create a regulatory framework for a synthetic biology type of development?'

Action 14. Subgroup members to put forward suggestions for health related issues to be considered in future meetings and to suggest specific approaches that we could take to such questions.

Action All.

Agenda 7 AOB

RE informed the Subgroup that an Entrepreneur In Residence is about to be appointed for synthetic biology, among other things to support the work of the SBLC and the Governance Subgroup.

Action 15. We were asked to set da\tes for the next three meetings of the Subgroup, to fit appropriately with future SBLC meetings.

Action Secretariat.