Synthetic Biology Leadership Council: 1st Meeting of the Governance Sub-group
Conference Room C21, Department for Business Innovation and Skills
27th January 2014, 12:00 – 16:30

Attendees

Chair: Joyce Tait, ESRC Innogen Centre, University of Edinburgh (SBLC)

Governance Sub-group:

Janet Bainbridge	UK Trade & Investment (SBLC)
John Betts	Research Funding Unit, BIS (SBLC)
Linda Brooks	Thermofisher
Martin Cannell	Defra [Teleconference]
Belinda Clarke	Technology Strategy Board (SBLC)
Lionel Clarke	Shell (Co-Chair SBLC)
Ron Egginton	Research Funding Unit, BIS (SBLC)
Tim Fell	SynthAce, BIA
Matt Goode	Research Councils UK
Julian Hitchcock	Lawford Davies Denoon
Alastair Kent	Genetic Alliance
Claire Marris	King's College London
Sharmila Nebhrajani	Association of Medical Research Charities (SBLC)
Michael Paton	Health and Safety Executive
Hilary Sutcliffe	MATTER

Apologies: Roland Jackson (ScienceWise), Nick Pidgeon (Professor of Environmental Psychology, Cardiff University)

1 Welcome and Introductions

Joyce Tait welcomed the members of the Synthetic Biology Leadership Council (SBLC) Governance Sub-group to the first meeting.

2 Terms of Reference and Guidelines for Governance Sub-group

Members discussed the Terms of Reference and Guidelines draft paper.

Key points covered included:
- Reporting lines for the Sub-group
- Scope of coverage of the issues addressed by the Sub-group

    - Consideration of issues raised by regulatory systems at national and international levels, including provision of advice to the SBLC and through them to the UK government
- Transparency
- The need to retain a data-driven approach to the use of evidence in governance decision making
- Clarification of language used in ToR paper, for example 'balance', 'governance', 'innovation'
- Dealing with engagement issues, in line with commitments made in the Roadmap

An additional point raised was the composition/balance of Sub-group membership, including whether additional members should be included, e.g. to bring in particular perspectives or areas of expertise. The conclusion from that discussion was that the Sub-group would have the ability to engage with stakeholders with additional areas of interest and expertise, as needed, for specific meetings or discussions without adding to the formal Sub-group membership.

Action: Joyce Tait to revise the SBLC Governance Sub-group Terms of Reference and Guidelines paper, based upon discussions in the meeting. Revised paper to be circulated, and any final revisions to be made, before the final ToR/Guidelines paper is put to next SBLC meeting for final approval.

Action: Lionel Clarke to make reference to the Governance Sub-group on the SBLC website (along with approved minutes and papers from the meeting accordingly).

Action: Joyce Tait and Lionel Clarke to consider the scope and composition of the Governance Sub-group.

Action: Belinda Clarke to draft a mission statement for the Governance SBLC Sub-group based upon the Terms of Reference and Guidelines paper.

3 Genetic Modification (Contained Use) Consultation

Mike Paton delivered a presentation on the consolidation of the Genetically Modified Organisms (Contained Use) Regulations.

Key Points
- Genetically Modified Organisms (Contained Use) Regulations are based on the EU Directive (2009/41/EC) on contained use of genetically modified microorganisms, which was implemented in GB in 2000
- Barriers are put in place to limit the contact between GMOs and humans or the environment. Barriers can be physical, chemical or biological and are often used in combination

- Joint Competent Authority - HSE lead (Defra and Scottish Government are part of CA) but take technical advice from the Scientific Advisory Committee for Genetic Modification (Contained Use)
- Coalition Government Initiative 'Red Tape Challenge' (including Lofstedt recommendations) aims at removing bureaucracy and hence decreasing the regulatory burden on business and thus encouraging growth of the economy
- The consolidation will replace 4 sets of regulations, with one consolidated set – in the process, the opportunity has been taken to make the regulations more risk based, flexible and proportionate whilst maintaining health and safety standards
- Pre-consultation fact finding engagement with UK and European stakeholders undertaken to flag up issues
- Consultation widely publicised (>5000 stakeholders alerted to consultation document (CD263)) – 850 downloads of CD; 42 responses received
- Key changes: Containment measures (applying evidence based decision making to the operating procedures – based on 14 years experience regulating these technologies) and format of regulations (structure, language and layout)
- Two questions on synthetic biology (SynBio) submitted as part of the consultative document – 12 respondents did not answer the questions:
    - *Application of GMO(CU) to SynBio* – 70% (21 responses out of 30 answering the question) did not envisage any practical problem
    - *Are there any better-fit regulatory models* – no suggestions were provided
- Guide to the Regulations (L29) will support the regulations, where necessary providing additional explanation (technical content is in the SACGM compendium of guidance)
- On-line community used in feedback of draft Guide to the Regulations
- SynBio needs to feature more heavily in the Guide to the Regulations; *opportunity here for the Governance Sub-group to provide comment*
- Summary:
    - Overall, the proposals were positively received; between 60-93% support (depending on the specific proposal)
    - the Guide to Regulations is currently being revised
    - The SACGM Compendium of guidance will be updated
    - GMO(CU) 2014 regulations – expected to come into force Oct 2014

The Governance Sub-group discussed that for current SynBio organisms, the Contained Use regulations appear to be appropriate for use (and backed up by the response to the question posed in the consultation document), however, further downstream, the deliberate release of such organisms may present more of a challenge.

Question relating to what applications (type and numbers) there are coming up to market that may need to be regulated under the Deliberate Release Regulations? Feedback in the consultation document question highlighted that there may be some blurred lines between Contained Use and Deliberate Release, e.g. de-centralised bioreactors and the biosensors.

There was discussion around HSE/SACGM and Defra/ACRE, with advice that it would be wise to ask the leading practitioners what they are currently developing, but also where the technology is going, so that future regulatory issues can be understood. A very interesting issue in terms of Deliberate Release Regulations is that of alternative regulatory frameworks. This question was raised in the HSE GMO (CU) consultation document, and the lack of responses suggests that it has not been given due consideration. At this point in time the Deliberate Release Regulations, as implemented by the Competent Authority (Defra) would apply, however this is an opportunity for fresh thinking about what might be developed in the future to supplement this existing framework in terms of regulation or advisory committees. Developments in SynBio for Deliberate Release may not be on the immediate horizon but ought to be anticipated.

Discussion included the change in the consolidation document so that activities at Level 1 no longer require an in-house safety committee, but must get technical advice from a competent body. Relating to SynBio 'DIYbio' activities, the development of a network of biological safety advisors to assist in providing competent information was raised at the American Biosafety Association meeting in 2013. The individuals must still register the premises with HSE before commencing any activities and indicate the type of work that is being undertaken there.

> *Action: Joyce Tait, with contribution from the Governance Sub-group, to provide comment on the revision of the Guide to the Regulations (Genetically Modified Organisms (Contained Use) Regulations) (look to comment on a draft by May).*
>
> *Possible future action: Martin Cannell/Janet Bainbridge to report back to the Sub-group on any SynBio applications (and any that are likely to be on the horizon in the near future) for which the Deliberate Release Regulations would need to be applied (submissions to ACRE).*

4 Advising Policy Makers

Janet Bainbridge provided an overview of the scientific advisory committees that she has either chaired or been a member of, including the SACGM and ACRE. Discussion considered the excellent scientific advice on applications considered by these organisations, and there will be significant knowledge that can be learnt from similar technologies in terms of process, product and environmental safety. Impression that SynBio deliberate releases for commercial applications will be some time off but that consultation with these bodies will be imperative in order to ensure responsible policy making which allows for evidence based regulatory decision making. It was also discussed that it is important to look at technology developments not just in the UK but internationally.

5 Responsible Research and Innovation

Joyce Tait introduced the role of Responsible Research and Innovation and made note that a great deal of investment and research is already being undertaken in this field. Joyce Tait explained that the role of the Governance Sub-group would be to identify any areas that weren't already covered and where value could be added in terms of SynBio.

Belinda Clarke explained how the TSB has introduced the Responsible Innovation Framework (RIF) into two competitions to date. Work has been undertaken to draw RIF closer to Horizons, as this is an already existing cross-sectoral initiative. BSI has been commissioned by TSB to look at framework standards in SynBio, to explore with key stakeholders the appetite for, and relevance of, a PAS (Public Available Standard) for Responsible Innovation in SynBio.

Discussion around how RRI does not relate solely to SynBio, but is applicable to all research and innovation. Question relating to how this is implemented in other technology sectors.

> *Action: Lionel Clarke to discuss with the other Leadership Councils how Responsible Research and Innovation is approached in their respective sectors.*

In terms of EU Commission funding, it was discussed that, at present, funding in this area is believed to primarily be focussed on Responsible Research, rather than Innovation, and is also heavily driven in terms of stakeholder and public engagement. Whilst the SBLC Government Sub-group focus in terms of RRI relates to SynBio, it is recognised that whatever approach is established, may be applicable to a range of other technologies. There was a concern noted that companies could accrue significant additional regulatory burden if required to support an additional RRI framework if not implemented in a responsible manner.

> *Potential future action: Julian Hitchcock to explore EU regulatory landscape to determine what proposals are proceeding in terms of RRI specifically for SynBio.*

It was also noted in the Governance Sub-Group meeting that the SBLC has an embedded committment to implement RRI as part of its remit to implement the recommendations of the Synthetic Biology Roadmap:

Recommendation 2.2 Embedding responsible innovation. Public sector investment in synthetic biology should take into account social, ethical and regulatory issues and increase awareness of responsible innovation via training programmes. This will include on-going stakeholder engagement and dialogue with wider social groups.

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It was discussed that a strong definition of SynBio was needed, including indication as to where the borders lie between SynBio and other related technologies.

Review and Close

Joyce Tait thanked all members for attendance and participation in the discussions. No date set as yet for the next Governance Sub-group meeting but this will occur after the next SBLC meeting (19th March 2014).

> *Action: John Betts and Joyce Tait to organise the date for the next meeting with members of the Governance Sub-group.*

Lionel Clarke explained that the discussion and actions of the Sub-group would be reported to the SBLC members at the next SBLC meeting.

> *Action: Joyce Tait to report back to the SBLC at the next group meeting (19th March 2014).*

Summary of Actions

#	Action	Lead (participants)	Deadline
1	Revise the SBLC Governance Sub-group Terms of Reference and Guidelines paper	Joyce Tait	For approval before next meeting
2	Make reference to the Governance Sub-group on the SBLC website	Lionel Clarke	ASAP
3	Consider the scope and composition of the Governance Sub-group	Joyce Tait and Lionel Clarke	Before next Sub-Group meeting
4	Draft a mission statement for the Governance SBLC Sub-group	Belinda Clarke (all)	As Action 1
5	Provide comment on the revised Guide to the Regulations (L29)	Joyce Tait (all)	Look to comment on a draft by May
6	Report back to the Sub-group on SynBio applications (current and near future) for which the Deliberate Release Regulations would need to be applied	Martin Cannell and Janet Bainbridge	Next Meeting
7	Discuss with the other Leadership Councils how Responsible Research and Innovation is approached in their respective sectors	Lionel Clarke	Next Meeting
8	Organise date for the next meeting with members of the Governance Sub-group	John Betts and Joyce Tait	ASAP
9	Report back to the SBLC at the next group meeting	Joyce Tait	SBLC 5 (19th March 2014)

Appendix

Agenda

Time	Item	Item Lead(s)	Papers
12:00 – 12:30		**Arrival and lunch**	
12:30 – 13:00	1	**Welcome and Introductions** Joyce Tait	
13:00 – 14:00	2	**Terms of Reference and Guidelines for Governance Sub-group** Joyce Tait	Paper 1
14:00 – 14:30	3	**Genetic Modification (Contained Use) Consultation** Mike Paton	
14:30 – 15:00	4	**Advising Policy Makers** Janet Bainbridge	
15.00 – 15.15		**Coffee/Tea**	
15:15 – 16:15	5	**Responsible Research and Innovation**	
16:15 – 16:30		**Review and Close**	

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John Betts	Research Funding Unit, BIS (SBLC)
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Roland Jackson	ScienceWise
Nick Pidgeon	Professor of Environmental Psychology, Cardiff University