Synthetic Biology Leadership Council:

3rd Meeting, Governance Subgroup: Minutes

13:30 – 16.45, Monday 17th November 2014.

Room C33, 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)	Shell (Co-Chair SBLC)
Tim Fell (TF)	Synthace, BIA
Matt Goode (MG)	Research Councils UK
Julian Hitchcock (JH)	Lawford Davies Denoon
Roland Jackson (RJ)	Sciencewise
Michael Paton (MP)	Health and Safety Executive
Hilary Sutcliffe (HS)	MATTER

Tim Higginson (BIS, Head of the BBSRC Sponsor Team), Julian Jackson and Sarah Cundy (DEFRA, Access and Benefit Sharing) also joined the meeting.

Apologies: Janet Bainbridge, Linda Brooks, Alastair Kent, Richard Kitney, Nick Pidgeon

It was also noted that Aisling Burnand had decided to stand down from the Governance Subgroup.

Agenda 1 Welcome, minutes of the last meeting and feedback on actions

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

Minutes of the meeting of 6th June were accepted. All actions were completed, with the following qualifications:

Action 1: the appointment of a new member to join the Subgroup carried forward (LC)

Actions 6, 7, 8, 10: these issues were raised at the last SBLC meeting, follow-on action pending.

In the context of Action 11 (engagement and dialogue) Lionel Clarke reported on his ongoing discussions with the Agritech and Industrial Biotech Leadership Councils and will provide an update for the next meeting; Roland Jackson noted that the Global Food Security Programme Public Panel, for which he chairs the oversight group, might be generating initiatives that will overlap with the remit of the Governance Subgroup; and Hilary Sutcliffe mentioned ongoing public dialogue on nanotechnology products (as opposed to the technology per se).

Action 14 on health-related applications of SB was deferred to the next meeting.

Agenda 2: Recent Developments related to the bio-enabled production of detergents (Solazyme/Ecover).

This discussion was led by Hilary Sutcliffe, stimulated by the challenge, from US Friends of the Earth and the Canadian ETC Group, along with a number of other NGOs, to the plans of the company Ecover to use products generated from algal culture (manufactured by Solazyme) to replace current products generated from fossil fuels and palm oil. The areas of concern (mainly environmental risk, societal impacts and the lack of regulation) were related to previous challenges from anti-GM advocacy groups. Synthetic biology was described as adding new challenges compared to those arising from GM technologies ("extreme genetic engineering") referring to "synthetically modified organisms" (SMOs) – a phrase that might become the frame that is attached to microbial SB related developments. An open letter to Ecover urged them to commit *not* to use SMOs in their development processes.

Two initiatives were described that have arisen from this challenge:

1. Forum for the Future (FFF) are collaborating with BBSRC to map the stakeholders and the issues arising from SB developments raising the question “Is there a role for this technology in a sustainable world?” “What would need to be true for that to be the case?” They are hoping to produce guidelines to help stakeholders make their own decisions based on informed standpoints. The transparency of the process is presumed to make it acceptable.

   FFF are being paid by Ecover, but the largest amount of cash for this initiative (to Friends of the Earth (England, Wales and Northern Ireland) (FoE EWNI)) is coming from BBSRC (~£50K) as part of a collaborative approach, rather than a tendered contract. The outcome will be branded under FFF and FoE, in collaboration with BBSRC.

   The extent to which this process is expected to deliver outcomes that are generally applicable to companies working in this area is still ‘work in progress’ but the guidelines that emerge from this process could be seen to be applicable to industrial biotechnology companies in general.

   Regarding the potential for consensus to emerge from this process, outcomes are expected to be quite high level. Demands for a moratorium on SB research are seen as a deal-breaker.

   A question was raised on the role of FoE, as an organisation that takes a critical role on many environmental issues, potentially leading to the outcome of the project being seen as biased in that direction. However, robust governance processes, including openness and transparency, were seen to be in place so as to allow all parties to sign up to the outcome.

2. Solazyme, based in California, have hired Robertsbridge, a consultancy also with links through its senior members to FoE, to advise them on how they as a company can operate sustainably. They are also working with FoE (US) and ETC.

An important question to arise from these events is whether, if Ecover and Solazyme had undertaken more thorough stakeholder engagement before announcing their plans, they could have avoided this challenge. However, the business community is now much more prepared for this kind of challenge.

Discussion of this item included the EC Opinion on the definition of SB, in the context of moving towards regulation of SB - “SB is the application of science, technology and engineering to facilitate the design, manufacture and/or modification of genetic materials in living organisms”. This excludes organisms that are not capable of replication. The concern is how that slots into everything else and the breadth of the definition in the absence of current regulatory decisions on SB. Two other EU Opinions will cover risk assessment and research priority areas.

The non-participation of some NGOs in the Solazyme process is related to Solazyme’s lack of willingness to consider a moratorium on SB related developments. ETC and 30+ other NGOs are proposing a moratorium on the use of SB until regulation is in place. This is in comparison to the FFF process which is not taking an initial position on this question. (The discussion at this point reflected uncertainty over whether the proposed moratorium related only to the release of organisms or to the further development of such organisms for contained use.)

One of the points that inflamed the issue from the point of view of the NGOs involved was the use of the word “natural” in the context of synthetic biology. It was seen as important to develop effective regulatory processes that are effective but ‘light touch’ to incentivise innovation but that don’t drive people underground. However, this issue is not primarily about regulation (given that the product is regulated and has passed all relevant regulatory hurdles). The main points are about purposes, definitions and descriptions.

There is a need for a more generic, proactive approach than we have in place at the moment, linked to initiatives on Responsible Research and Innovation.

Subgroup members were encouraged to contribute independently to shaping the conduct and outcomes of these initiatives where they felt able to do so.

Action 1. The voice of the Governance Subgroup as a whole was seen as relevant to this discussion and we should be involved in some way as an important voice in oversight of the process to contribute of maintaining overall balance. We should have the possibility to see and comment on interim reports and we should have an opportunity to comment on reports and processes at the end of the stakeholder mapping exercise. (Timing Spring 2015)

Action DEFRA and BIS

Action 2. We should have further discussions in the Subgroup on the 'description' of SB and what it covers and how it might then be used.

Action Julian Hitchcock

Agenda 3. Update on Convention on Biological Diversity related discussions and the UK government position at the meeting in South Korea in October.

Sarah Cundy, Julian Jackson and Martin Cannell updated Governance Subgroup members on the proceedings of latest CBD SBSTTA meeting in June and the following COPMOP meeting in Korea in October.

Martin Cannell described the processes in the run-up to the SBSTTA 18 meeting in June, arising from the 2012 CBD meeting where a request was tabled to gather evidence on whether SB should be considered as a 'new and emerging issue'. In Sept. 2013, 2 consultation documents were produced covering (i) the potential impacts of SB on conservation and biodiversity and (ii) gaps and overlaps with existing provisions of CBD. Based on a UK consultation organised by DEFRA, a UK response was submitted to these two documents, centred on the lack of balance relating to risks and benefits, over-reliance on non-peer reviewed literature and failure to consider existing regulations that would apply to SB-related products. Reference was made in the UK response to the comments from the SBLC.

In April 2014, redrafted information documents were published along with a summary document intended for use as a pre-SBSTTA meeting at the Montreal meeting in June 2014, including recommendations for the COP, some of which were quite prescriptive with reference to regulatory aspects, expressed in a way that didn't give confidence in the understanding of the risk assessment process. Useful comments were received from the Governance Subgroup that were used in the deliberations. DEFRA's intentions were to ensure that any recommendations that came out of the Montreal meeting would be based on sound evidence, subject to rigorous scrutiny and show scientific credibility, recommendations would be pragmatic and proportionate and related to clearly identified risks to humans or the environment, and consistent with existing regulatory frameworks, avoiding recommendations that would present unnecessary burdens on innovation and growth.

Views at the SBSTTA meeting were divided: (i) that existing risks are low, existing regulations are sufficient, but there is a need for more information and better understanding (including the UK position and to a large extent the EU); (ii) emphasising the precautionary principle and the need for new risk assessment methodologies, including setting up an international regulatory framework before any further work continued and pushing for a moratorium on SB.

During 'Contact Groups' views put forward included: state of knowledge of risks and benefits; adequacy of existing regulations. SB was described as 'of high relevance' rather than being 'a new and emerging issue', with implications for what CBD is allowed to pick up on, i.e. it is not yet agreed whether SB is a new and emerging issue, and therefore whether CBD has competence to look at this issue. Most of the text of the report from the SBSTTA meeting was

in square brackets indicating that the parties could not come to an agreement. Progress was made on peer review and setting up an online expert forum.

Sarah Cundy then described the process at the CBD meeting in Korea. The extent of disagreement underlying the SBSTTA text from the Montreal meeting made it difficult to make progress. Unlike SBSTTA where EU members speak independently, at CBD meetings the EU speak with one voice. The EU position was that the current regulations on GM crop developments capture everything coming out from SB and we should not be imposing a moratorium.

Key aspects included:

- there will be no moratorium on SB and there was no agreement that there should be further international regulation, despite strong urging by some Parties to commit to a new regulatory regime.
- the recognition that most countries will have a risk assessment process in place, set out at a national, regional or international level;
- field trials will continue to be allowed provided a risk assessment has been carried out (in the EU context 'risk assessment' does not include socio-economic aspects);
- capacity building was recognised as important, particularly in developing national risk assessment processes

Most of the discussion was about moving beyond the current impasse to enable an agreed position to be reached in future. An open participation online forum is to be set up, limited to a 2 year period. An Ad Hoc Technical Expert Group (AHTEC) will also be set up with 5 – 8 representatives from each of the UN blocs plus a similar number of observers. An Annex to the decision sets out the remit of this group: differences between GM and SB; the extent to which current regulation covers SB; what risk assessment/management processes are in place particularly under the Cartagena Protocol and how those might apply to SB.

On the question of how the Governance Subgroup can collaborate most successfully in that process, Online Forum is a useful thing to be involved in, provided it is well moderated. Sensible pragmatic views can help to shape what comes out of the process. Our input into these discussions could be useful in shaping the paper that will go to the next CBD COP meeting. While the CBD COP meeting will make changes, the paper itself will be very influential in the outcome. We should have another discussion on this at a later meeting.

Action 3. The nature of the active role we could play in this process to be discussed at the next Governance Subgroup meeting.

Action Joyce Tait

The important role played by NGOs in submitting comments and reports to these UN processes, was discussed. Encouraging a broader range of views to be contributed to the process would be helpful, but will not be enough to overcome the problem. The lack of an industry presence at these meetings is problematic but it can be an uncomfortable position to be representing industry at these meetings.

Action 4. The Governance Subgroup to consider what might be an appropriate and reasonable outcome from this process for SB as a contribution to DEFRA thinking, potentially funded by BIS and the UK Research Councils. A set of bullet points to be prepared to be circulated to the Governance Subgroup as a stimulus for further discussion.

Action Lionel Clarke and Joyce Tait

The fact that the Governance Subgroup and the SBLC are not seen as representative of civil society was noted as potentially problematic. We need to find ways to engage representatives from a broad range of civil society in these processes.

Action 5. It was also seen as useful to have a list of all the people involved in these questions, across Government, so that we can know where best to address specific questions or observations.

Action BIS

We were reminded that this is just the start of a potentially very long process.

Julian Jackson also updated the Subgroup on progress in discussions at the CBD meeting in Korea on the Nagoya Protocol, particularly Article 10. Most of the language that the UK had taken to previous meetings had been adopted. Discussions were mainly about the entry into force of the new protocol. Detailed discussions on the Global Multilateral Benefit Sharing Mechanism were deferred. However, the Clearing House mechanism was agreed so that regulators will know when something is in scope. This will be the benchmark in the UK for knowing when and where something has to be enforced. This will also be the tool to communicate where you have to go to get your prior informed consent etc., and a repository for the internationally recognised certificate for compliance, which will follow a genetic resource around so that regulators can recognise that this is a bona fide genetic resource.

Fears that discussions could develop in different directions did not materialise. It was confirmed that, generally, the UK/EU position is that sequence data are not included under Nagoya, unless it is specifically mentioned in the Mutually Agreed Terms. Something that is publicly available already will not be caught by the Protocol. For new data generated in future, countries that are Parties to the Protocol may decide to regulate sequence data under their national regimes and this could be included in the Mutually Agreed Terms (which are negotiated contracts between users and providers).

AOB

Mike Paton updated the Subgroup on the Scientific Advisory Committee for Genetic Modification (SACGM) role in discussing the safety of particular constructs and organisms rather than products. Two items on the agenda of the last meeting of the SACGM related to SB:

(i) Following the EU decision on the definition of SB, the next stage is to look at risk assessment, the discussion focused on the types of SB application that might challenge risk assessment. Examples included minimal genomes, gene driving (driving inherited characteristics through a population), and a medical application involving bacteriophage as an alternative to antibiotic treatment. These did raise issues for risk assessment, for example the ability of phage to evolve continuously to overcome the resistance of the bacteria that they infect. However, these tend to be the exceptions.

(ii) When things are very safe, how can we use the mechanism within the EU regulation for recognising that fact. A list of safe organisms can be included in an Annex, justifying through risk assessment that these organisms don't present any risk to people or the environment. Since the regulations were brought in in 2000 this Annex has not yet been populated. The arsenic biosensor currently going through the regulations (Bacillus subtilis) has FDA approval for use as a probiotic and is being modified to make it even safer. SACGM is looking at how much information would have to be included in a proposal to the EC and the committees that report to them in order to get onto the Annex. The danger is that the amount of information required is so great that it sets a precedent that no other organism will be able to meet.

Action 6 Mike Paton offered to circulate the minutes of the committee meeting when they are produced.

Action Mike Paton

Due to shortage of time the remaining two items on the agenda were left for separate correspondence via email:

- Governance Subgroup contributions to the SBLC Open Meeting, 27th Nov.

- Issues to be tabled for the next meeting