

Minutes of the Fifth meeting of Synthetic Biology Leadership Council (SBLC) Governance Sub-group

13:30 – 17:00, Thursday 18th June, 2015

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

Attendees

Julian Jackson, Defra; Charles Secrett and Rob Bailes, Robertsbridge Group (Agenda item 5)

Apologies

Patrick Middleton

Agenda 1 Minutes of last meeting and feedback on recent activities

Joyce Tait welcomed the members of the SBLC Governance Sub-group and visitors to the fifth meeting.

Minutes of the 4th meeting on 10th March, 2015, were accepted. All actions were either completed or are on the agenda for this meeting, with the following qualifications:

- **Action 1 from the meeting of 6th June**, the appointment of a new member to join the Subgroup is being carried forward, the process for membership is currently being reviewed by the Leadership Council (**Action LC**)
- **Action 1 from meeting of 10th March**, the SBLC should be more proactive in the area of health related Issues and lay the ground for a parliamentary debate. These actions will be captured in the Roadmap Refresh (**Action LC**)
- **Action 2 from meeting of 10th March**, James Brown has left the Knowledge Transfer Network. Work with the KTN to offer workshops in support of the SBLC to bring together clinicians, researchers and regulators providing information for parliamentary debate will commence again once the post is filled.
- **Action 5 from meeting of 10th March**, the SBLC should lobby for the creation of a harmonised specification for genetic components. There was talk of a need to bring BIS into the process of harmonisation and standards. Action carried forward to next meeting. (**Action JT and LC**)

Agenda 2: Feedback on CBD related developments since the last meeting, Julian Jackson, Defra

Update on Access and Benefit Sharing, Nagoya Protocol

- EU legislation is in the process of being finalised and the Nagoya Protocol will be implemented from October 2015.
- An awareness raising programme will take place over the summer targeting Trade Associations and Sector leads.
- Parallel work is taking place to develop guidance on the implementation of the protocol, primarily at an EU level but the UK may offer separate guidance.
- Industry is keen to have guidance on issues of 'out of scope', it is hoped that this will be picked up in the EU guidance.

- The UK would like the EU guidance to mention that the protocol does not apply to sequence data. Some Member States would rather this was left open to discussion at a later time. If this is not included in the EU guidance it will be in the UK guidance.
- It is possible that industry will be asked to assist by providing sector specific guidance related to access and benefit sharing.
- Guidance will incorporate case studies to provide examples alongside interpretations of the legislation.
- Check points in the EU regulation won't apply to pure research, however, there is an obligation to make it clear what research findings, covered by the Nagoya Protocol, can be used for.
- It is anticipated that as part of the pure research contract there will be a mechanism for going back and renegotiating terms for commercialisation.

Action: Presentation on awareness raising to be shared with the group

**Action: Julian Jackson, Defra
(Completed)**

Convention on Biological Diversity (CBD)

- The online community has had a vibrant participation in the CBD Clearing House Open Ended Forum on Synthetic Biology (<https://bch.cbd.int/synbio/open-ended/discussion.shtml>) and widespread representation; including NGOs, Universities, policy makers and regulators, and Companies.
- There were 136 forum participants, possibly three or four from any one particular organisation. This includes nine government observers, and seventy seven organisations as observers. Observers have been proactive in participating.
- Debates around the current 5 topics have been balanced with opinions being respected and parties understanding where others are coming from.
- There is a strong view that the benefits of biological diversity need to be amplified, with recognition of associated risks where necessary.
- Future debate topics are on regulatory systems:
 - Are national and international systems sufficient?
 - Is the framework that exists sufficient to deal with the impacts any given risk?

Next steps

- At the end of the discussion periods the CBD will reflect on the submissions around each topic and produce a summary.
- Selected individuals from the online community will form an Adhoc Technical Advisory Group responsible for bringing these summaries into one report with recommendations.
- This report will be peer reviewed and the online community will be given an opportunity to comment on the report.
- Based on the report the technical meeting of the CBD will make a recommendation to the next meeting of the Office of the Parties.

Action: contribute comments and evidence to topics on the forum particularly future topics but also past topics if possible.

Action: All, Governance Sub Group

Agenda 3: Synthetic Biology Roadmap Refresh and public engagement initiative, Lionel Clarke

The aim is not to rewrite the current roadmap, it is a refresh. The primary vision remains the same.

Our vision is of a UK synthetic biology sector that is:

- economically vibrant, diverse and sustainable: where businesses have successfully developed and introduced new products, processes and services – leading to significant revenues and employment
- cutting edge: leading scientific advances and with a resilient platform of underpinning technologies – delivering clear advantages in application development
- of clear public benefit: an exemplar of responsible innovation, incorporating the views of a range of stakeholders and addressing global societal and environmental challenges within an effective, appropriate and responsive regulatory framework.

Discussion:

- Concerns were raised around the use of the word “sustainable” and whether “sector” is the most appropriate descriptor.
- Synthetic Biology is not generally understood to be an economic sector in the commonly understood sense.
- It’s one of the eight great technologies and an enabling technology underpinning a lot of sectors.

Suggestion to use “vision is of a synthetic biology in the UK that is economically, vibrant, diverse and *progressive*”, rather than “sustainable”.

Lionel sought feedback from the group on recommendation three: *Invest to accelerate technology responsibly to market.*

Key questions for the group to consider:

What have we learnt since the last Roadmap? Are we on the right track? Are we going fast enough? And, what are the next challenges in supporting development in this field?

Process:

- The key messages from a recent workshop in Birmingham, involving academia and industry, will feed into the SBLC on 2nd July in order to outline what the recommendations are starting to look like.
- A briefing note to ministers will be provided before the summer recess.
- Draft of the refresh by mid-September.

Agenda 4: BBSRC initiatives on scoping the stakeholder landscape, and work with Solazyme, Patrick Middleton

A report will be produced by Friends of the Earth and Forum for the Future funded by BBSRC. There is a role for the SBLC and GSG to influence the context into which these two documents will be delivered and to contribute to the evolution of the governance process for synthetic biology research and innovations. Joyce Tait will take a proposal to the SBLC on 2nd July to suggest a role for Sub group in the development of this process.

Discussion:

We are rather bad at technology foresight and cannot predict at the research phase what innovations will emerge 5-10 years in the future.

The roadmap refresh should emphasise that we are in a learning process, and global communications are enabling us to learn very quickly. In most cases we already have regulations in place that will guard against future risks.

In citizen dialogue and consultations, there has been a perception from scientists of people trying to stop synthetic biology innovation. However, this is not usually the case; more often than not people are asking rational (sometimes irrational) questions about what it is that scientists do with regards to synthetic biology.

Due diligence processes mean that we always have to think about risks and impacts. What has not been done previously is to communicate the fact that this diligence is being carried out.

If an information void is left people will fill it. We should consider how we can be proactive in engaging people to raise awareness of the benefits of synthetic biology.

Agenda 5: Robertsbridge Group work with Solazyme: Charles Secrett and Rob Bailes

Robertsbridge have been working with Solazyme, an Industrial biotechnology company, to develop a positive sustainability strategy including listening to and working with a variety of stakeholders. JT and LC have been part of the stakeholder group.

What do Solazyme do?

Solazyme works with micro alga to produce a variety of triglyceride oils in standard fermentation tanks, speeding up the plant breeding process and producing oils more rapidly.

Feedstock inputs currently include corn, sugar beet and sugar cane. Solazyme markets its products as carefully tailored oils, naturally produced or genetically engineered for markets in fuels, chemicals, nutrition, skin and personal care.

NGO concerns about what Solazyme does

The company Ecover commissioned Solazyme to produce algal oil as a replacement for palm oil in its detergent production, based on achieving the following environmental benefits.

- Lower greenhouse gas emissions
- Reduction in water usage
- Less impact on biodiversity in tropical ecosystems

About a year ago, Ecover received a letter from 17 NGOs with consumer, environmental, women's health, and related concerns, urging them not to use synthetic biology ingredients which they defined as "extreme genetic engineering for which there are no regulations yet in place to deal with the implications of these new synthetic organisms".

The accusations did not conform with the reality as measures are in place to regulate synthetic biology including closed fermentation tanks, triple redundant safety measures and

working within closed buildings. Also, when a final product makes it to market there is no trace of the original genetic modification.

However, there are legitimate themes that underpin stakeholders' concerns about genetic engineering along the spectrum to synthetic biology including:

- Sustainability and environmental impact
- Impact on the developing world, for example livelihoods of small farmers
- Control of the food biomass by large corporations that hold patents.
- The regulatory environment and the overall control of the sector
- The need for consumer informed choice including labelling, transparency.
- The “yuck” factor.

These legitimate public interest concerns have to be addressed by industry and companies, based on evidence, transparency and engagement. Robertsbridge was asked to help Solazyme with this public debate by developing an appropriate response and engaging with stakeholders.

The response of Solazyme

The Solazyme outreach strategy, whether dealing with industry associations, clients, customers, academics, government agencies or different NGOs is based on 4 core principles:

- **Intention matters** - stakeholders must understand that the core business of synthetic biology has been about trying to do good for people and the natural environment, but there is also an element of making money. There is a responsibility to stakeholders but there is also a responsibility to shareholders.
- **Radical Transparency** – to educate and be open and transparent (within the obvious limitations of commercial law around product development).
- **Engage** – Seeking to address stakeholder concerns by understanding their goals while explaining the goals of synthetic biology.
- **Amplify** – to tell the story, why what they do matters, what does it mean, and to develop the narrative of the business and what it does in as open a way as possible.

Stakeholder round tables were held by Robertsbridge in the UK and US starting in October 2014. The 2nd UK stakeholder roundtable will be held in July 2015 to help develop the Solazyme sustainability plan intended to be published in October/November 2015.

Six principles form the basis of the new sustainability plan, these commitments are embedded in the business plan of the company:

- Transparency and Labelling
- Prior informed consent / consumer choice
- Supply chain integrity
- Independently verified safety studies at all stages of the business.
- Supporting progressive coalitions to work with governments around governance and regulatory frameworks that promote accountability.
- Open rigorous dialogue and regular engagement with, and reporting back to, stakeholders

Robertsbridge are finding that engagement is generally working. As part of this process they have come across two types of individual.

- Reasonable relativists, people who have a whole set principles, standards and criteria they expect to be met. You can engage with them in a moral or evidence based way.
- Absolutists, who have a particular view of the world and how they want it to be and if you/your work do not fit into that then they are always going to disagree.

Absolutists tend to be the minority but they must still be engaged and listened to.

Shifting public opinion on to the side of evidence and reason is an iterative process that takes time. Public debate around evidence is possible and tends to be the way most journalists and newspapers work.

An open invitation was extended from Robertsbridge to all members of the Governance Sub-group, to attend a workshop being held on Friday 10th July, 0900 – 1230 at RSA, to discuss the sustainability plan and other business developments.

**Action: Joyce Tait to forward invitation from Charles to rest of group.
(Completed)**

A.O.B

Julian Jackson, Defra, highlighted a paper on "[Thinking a Global Open Genome Sequence Data Framework for Sustainable Development](#)"