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WORKSHOP ON SYNTHETIC BIOLOGY – FROM SCIENCE TO POLICY AND SOCIETAL CHALLENGES

10 December 2015
Maison du Savoir (University of Luxembourg), Belval, Luxembourg

WORKSHOP REPORT

The workshop on synthetic biology "From science to policy and societal challenges" was co-organised by the European Commission and the Luxembourg Ministry of Health under the auspices of the EU Council Luxembourg Presidency.

The **main objectives** of the workshop were:

1. To present the various ongoing activities in the EU on synthetic biology (SynBio), namely the Opinions of the scientific committees, and to discuss the emerging risks in science and innovation, taking into account the increasing interest in the field of SynBio among different stakeholders and the novelty of the topic;
2. To exchange ideas and provide the opportunity for establishing new fruitful collaborations between scientists and different stakeholders interested in the SynBio topic;
3. To offer the audience a thought-provoking discussion that analyses SynBio from different angles by organising a discussion panel made up of scientists, representatives of the European Commission and the Scientific Committees.

67 participants from the Commission services and agencies, EU Member States, universities, national institutes and industry from Europe and abroad attended the workshop.

The welcoming speech was delivered by **Mr Xavier Poos**, *Conseiller de direction adjoint* at the Luxembourg Ministry of Health, who represented the Luxembourg Presidency. He expressed his appreciation that the University was chosen as venue for the workshop and pointed out that Luxembourg created a new Centre for Systems Biomedicine, which is a part of the national health initiative aiming to transform the Grand Duchy into a center of excellence in the area of personalised medicine.

Mr John F. Ryan, acting Director of DG SANTE in the European Commission, welcomed the participants. In his speech, he highlighted the applications of SynBio in producing new lifesaving

medicines, making chemical manufacturing cleaner and more efficient and designing innovative environmental technologies. Promoting scientific innovations is an important contribution towards achieving the core Europe 2020 objective of smart, sustainable and inclusive growth. Science and innovation have a key role to play in fostering competitiveness - and SynBio in particular will contribute to the objective of the Commission to boost jobs, growth and investment. He stressed that there may be risks as well as rewards, which must be anticipated, assessed and taken seriously. He also emphasised that proper risk communication on SynBio is crucial.

Mr Paul Freemont, Professor at Imperial College London, made an introductory speech on 'What is SynBio? What are the fields of its application?' In his impressive presentation, he discussed current international trends and applications in SynBio. He presented activities like SynBio standards development, automation and cloud laboratories and SynBio accelerators.

The **first part of the workshop** focused on the Opinions developed by the EU Scientific Committees.

Mr Stefan Schreck, Head of Health Information and the Scientific Committees unit of DG SANTE, introduced the three Opinions on SynBio prepared by the EU Scientific Committees. He outlined the importance of the Scientific Committees in providing the Commission with risk assessment and sound scientific advice and in drawing the Commission's attention to new and emerging problems related to consumer safety, public health and the environment. The fact that the request for scientific Opinions on SynBio came from 4 different Commission Directorate-Generals (DG SANTE, DG RTD, DG ENV and DG GROW) illustrates the complexity of the topic. The Opinions address 11 questions in total, related to scope and definition of SynBio; methodology for risk assessment; and risks for the environment and biological biodiversity and research priorities. He pointed out that the UN *Ad Hoc* Technical Expert Group on synthetic biology, which was set up under the Convention on biodiversity, has adopted the SynBio definition developed by the EU Scientific Committees. This shows that although the Scientific Committees' Opinions are primarily intended to be used by other Commission departments, they have much broader impact at international level.

Mr Theo Vermeire, Chairman of the working group on SynBio and member of the SCENIHR, presented Opinion I on the scope and definition of synthetic biology. The first Opinion proposes an ‘operational’ definition based on present knowledge and understanding of the field of SynBio. However, this definition may change as the understanding of the SynBio concepts, tools and applications evolves. In addition, it provides a summary of relevant regulatory aspects in the

European Union (EU), in other countries such as the USA, Canada, South America, China, and at the United Nations.

Mr Markus Schmidt, an external expert in the working group on SynBio, made a presentation on the second Opinion addressing the risk assessment methodologies. Though present risk assessment methodologies are appropriate for assessing potential risks of SynBio activities and products, the Scientific Committees suggested improvements. Currently available safety locks used in genetic engineering such as genetic safeguards are not yet sufficiently reliable for SynBio, because of mutation and positive selection pressure for mutants. The recommendations of the Scientific Committees include developing a clear strategy for the analysis, development, testing and prototyping of applications based on new forms of biocontainment and additional layers of containment using orthogonal systems.

Ms Michelle Epstein, the Rapporteur of the working group on SynBio and a SCENIHR member, presented Opinion III, which addresses risks to the environment and biodiversity related to SynBio and research priorities. In this Opinion, the Scientific Committees reviewed the state of the scientific knowledge concerning specific risks to the environment and pointed out major gaps in knowledge to be filled for performing a reliable risk assessment. In addition, the Scientific Committees provided research recommendations on the main scientific gaps, including methodological guidance on the experimental design and on the requirements of the proposals to ensure data quality and comparability, as well as the usability of the results for risk assessment.

In the **second part of the workshop,** various activities on SynBio of the European Commission were presented.

Ms Dorothee André, Head of Unit on Biotechnology in DG SANTE, made a presentation on interconnections between SynBio and GMO. Ms André acknowledged that the SynBio definition of the EU Scientific Committees is applicable to a number of genetically-modified organisms defined under Directive 2001/18/EC on the deliberate release into the environment of GMOs. Future SynBio applications may raise questions on whether certain organisms fall under the scope of the existing legislation on GMOs. She explained that the Commission is currently addressing the same question for a number of new breeding techniques and is engaged in a legal interpretation of Directive 2001/18/EC. The legal analysis will provide some general elements for interpretation of the current GMO legislation, which might be helpful in the future to address new approaches and technologies, also in the field of SynBio.

Ms Anne Teller, Senior Expert from DG Environment made a presentation on the possible impact and influence of SynBio on biodiversity, which covers the variability among living organisms from all sources, including inter alia terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part, this includes diversity within species, between species, and of ecosystems (cf. Article 2 of the Convention on Biological Diversity). She stressed that there are scientific uncertainties associated with the development of synthetic life, cells or genomes and their potential impact on the environment, the conservation and sustainable use of biological diversity and human health. The 12th Conference of the Parties established an *Ad Hoc* Technical Expert Group on synthetic biology. The *ad hoc* working group adopted the SynBio definition proposed by the EU Scientific Committees. The Secretariat of the Convention was requested to prepare an updated report on relevant information on components, organisms and products resulting from SynBio techniques that may impact the conservation and sustainable use of biological diversity. On this basis, the Conference of the Parties will consider a draft decision on synthetic biology at its 13th meeting that is planned for December 2016 in Mexico.

Ms Carmen de Vicente Coll from DG for Research and Innovation presented SynBio from the perspective of the European Research and Innovation policy. Biotechnology is considered a key enabling technology driving European innovation and competitiveness in different sectors. The European Commission is funding research on biotechnology under Horizon 2020, with an indicative budget of €360 million. One of the biotechnology pillars is "Boosting cutting-edge biotechnologies as future innovation drivers", aiming to lay the foundations for the European industry to stay at the front-line of innovation, also in the medium and long terms.

Due to the sudden unavailability of speakers from DG GROW on Alternative Feedstock for the Chemical Industry and from European Medicines Agency on Medical applications of SynBio, these presentations were cancelled.

Ms Sigrid Weiland from DG for Research and Innovation presented the new Scientific Advice Mechanism (SAM). SAM is a recently created system for high-quality, independent and transparent scientific advice in the European Commission, requested by Commission President Jean-Claude Juncker from Carlos Moedas, the Commissioner for Research, Science and Innovation. It builds on the expertise in the European Member States and within the services of the European Commission.

The **third part of the workshop** concentrated on SynBio activities in several EU Member States, which were presented by Ms Sanda Pasc from the Ministry of Health in Austria, Ms Dagmar Friese

from the Federal Ministry of Health in Germany and Ms Julie Tham from the Ministry of Infrastructure and Environment in The Netherlands.

Ms Sanda Pasc highlighted that national actions on SynBio in Austria are in the early stages of development. The Austrian Federal Ministry of Health funded a study to analyse the challenges SynBio presents for risk assessment and risk management. SynBio raises a number of questions in relation to technical, biosafety, security, regulatory and ethical standards. According to Austria, strengthened efforts are needed to set internationally agreed high standards for regulations with a focus on SynBio.

Ms Dagmar Friese pointed out that a broad public debate on SynBio is necessary. In Germany, several scientific organisations and parliamentary committees, including the German Ethics Council, have contributed to this debate. Some of their opinions will be summarised to enlighten the current discussion in Germany[1].

Ms Julie Tham explained that The Netherlands is currently assessing how well the regulatory and policy frameworks meet the scientific and policy-making challenges in relation to SynBio. She stressed that collaboration among EU Member States and the Commission is indispensable, since the legal framework on biosafety is mostly set up in a global and European context. She called for an EU policy agenda aimed at a shared understanding of SynBio and ensuring its safe and secure use while at the same time contributing to health and sustainability. Using the example of gene drive, she argued that swift and major changes may ask for adaptation of our policy on biotechnology.

In the **fourth part of the workshop**, the panel discussion, all participants had the opportunity to pose questions to the speakers (researchers, risk assessors and policy makers at EU and national level).

Several questions were asked in relation to the follow-up to the Opinions of the Scientific Committees. Industry raised concerns that further regulation and safety constraints could limit progress in the area. The experts from the SynBio working group replied that the Opinions address risk assessment and that the decision on whether and what kind of regulation is needed is a question for risk managers. They also pointed out that one of the questions posed by the Commission in the mandate (Question 5) concerned the appropriateness of existing methodologies for assessing potential risks. The Scientific Committees concluded that the current methods outlined in Directives

[1] This part has not been validated by the speaker

2001/EC/18 and 2009/EC/41 are appropriate and adequate for the management of the risks of SynBio activities.

There was a remark from the audience that having a clear goal in the definition of SynBio would also be helpful for risk managers and risk communicators. The experts from the SynBio working group did not agree to include goals in the definition. In their view, the Opinions address the perspective of risk assessment and risks assessment methodology from different angles.

On the question regarding the purpose of definition of SynBio, the experts from the SynBio working group replied that it is an operational definition which is supposed to steer the discussion with regard to risk assessment.

The Scientific Committees were asked to identify the most difficult discussions during the development of the Opinions. The experts agreed that the discussion on definition was the most problematic. They also recognised the difficulty of defining the relationship between genetic modification and SynBio on the basis of quantifiable and measurable inclusion and exclusion criteria.

Ms André was asked about the process of involving Member States and stakeholders before publishing the Commission legal interpretation on new breeding techniques. Ms André replied that the Commission's legal analysis will be presented to Member States, European Parliament and stakeholders before final adoption.

Another question raised the issue why the discussion on benefits is not taken into account. Ms André replied that the GMO legislation does not take benefits into consideration and that the aim of EU legislation is to ensure that GMOs and related products are safe and properly labelled. It is up to the companies to show and prove the benefits of their products.

There were several questions related to the labelling of medicinal products and stevia but these could not be replied to as they do not fall under the GMO legislation.

Citizens science was also addressed as a quickly-evolving area of science which is becoming available to an increasing number of people who do not have scientific backgrounds. It was stressed that this brings benefits but may also pose risks.

It was agreed by the panel that risk communication in SynBio is needed and that clear communication messages to the general public are very important.

The closing speech was delivered by Mr Stefan Schreck, Head of Health Information and the Scientific Committees unit of DG SANTE. He stressed a common aim - to ensure that SynBio, an

exciting area of science with great potential for further research and innovation, is not hindered from potentially bringing great benefit to people's everyday lives, while the Commission continues to keep vigilant watch over developments and any foreseeable consequences to ensure a high level of protection for human health and the environment.