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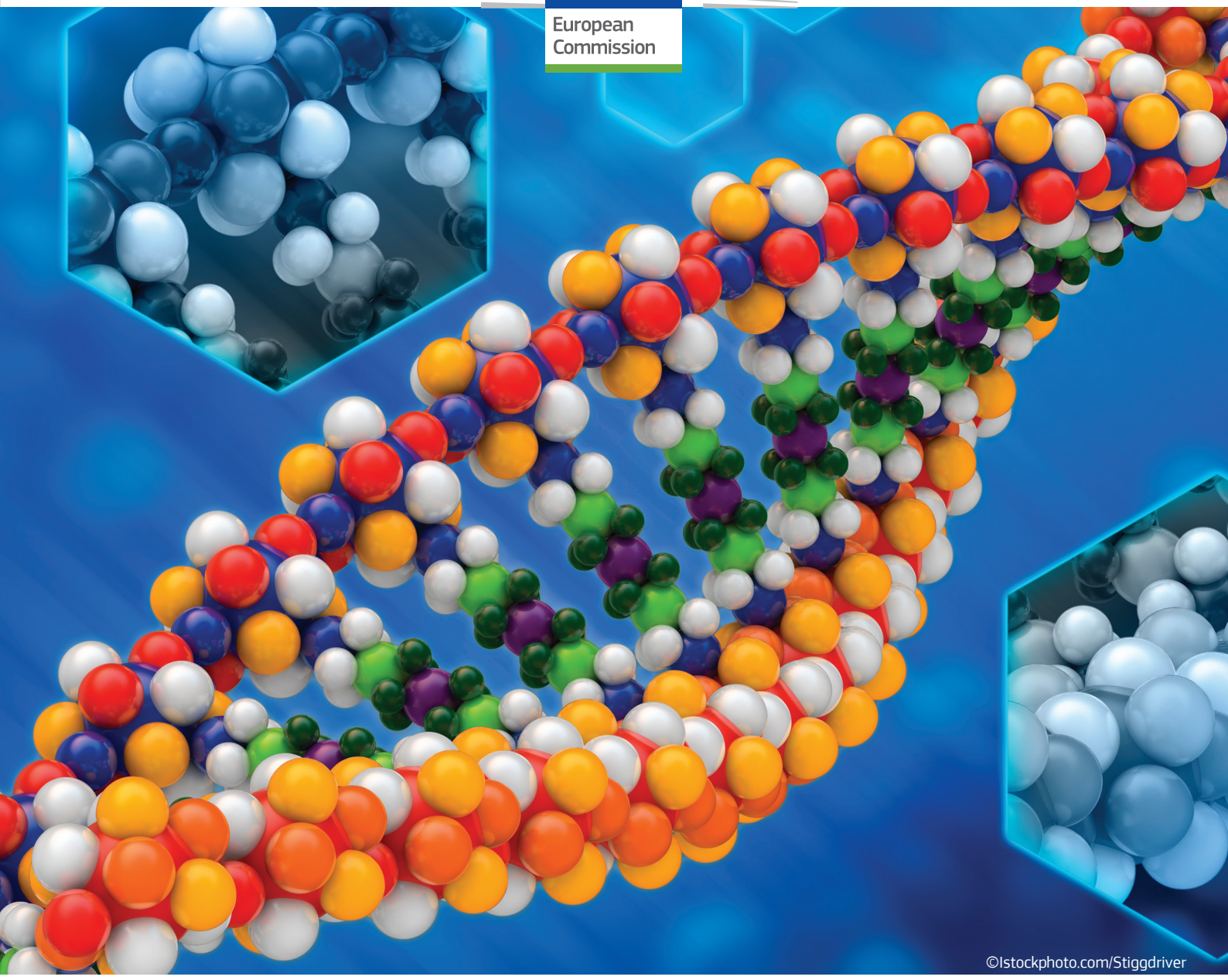

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Workshop on

Synthetic Biology

Luxembourg, 10 December 2015

Health and Food Safety

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Workshop on
Synthetic biology

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This event is co-organised by the European Commission and the Luxembourg Ministry of Health under the auspices of the EU Council Presidency.

Synthetic biology is one of the most promising areas of modern science, with a wealth of potential for developments in many areas such as healthcare and drug discovery, plant research and waste management. And yet all unexplored scientific territories may pose potential risks, which is why the Scientific Committees produced three Opinions on synthetic biology, ranging from providing a definition of synthetic biology to identifying potential risks to public health and determining the type of risk-related research that needs to be done in this field.

The workshop will provide an overview of these three opinions and the opportunity to learn more about the Commission's various activities in the area of synthetic biology. Moreover, it will present a unique occasion to exchange ideas and to join scientists and representatives of the EC and the Scientific Committees in a thought-provoking discussion that analyses synthetic biology from many different angles.

PROGRAMME

09:00 – 09:30	**Registration time**
09:30 - 09:45	**Welcome and opening** *Xavier Poos – Ministry of Health Luxembourg – Luxembourg Presidency* *John F. Ryan – European Commission - DG Health and Food Safety*
09:45 – 10:00	**What is synthetic biology? What are the fields of its application? Challenges and future developments.** *Paul Freemont – Imperial College London*
10:00 - 10:15	**Synthetic biology and the European Commission: Reasons for the mandate** *Stefan Schreck – European Commission – DG Health and Food Safety*
10:15 – 11:00	**Presentation of the SCENIHR opinions on synthetic biology** • *Opinion I – Definition (Theo Vermeire – Chair of the working group on synthetic biology, SCENIHR member)* • *Opinion II – Risk assessment methodologies (Markus Schmidt – External expert of the working group on synthetic biology)* • *Opinion III – Research priorities (Michelle Epstein – Member of the working group on synthetic biology, SCENIHR member)*
11:00 – 11:20	***Coffee break***
11:20 - 11:45	**Question time**
11:45 - 12:00	**Synthetic biology and GMOs** *Dorothée André – European Commission – DG Health and Food Safety*
12:00 - 12:15	**Potential impacts of synthetic biology on the conservation and sustainable use of biological diversity** *Anne Teller – European Commission – DG Environment*
12:15 - 12:30	**Synthetic biology from the perspective of the European Research and Innovation policy** *Carmen de Vicente Coll – European Commission – DG Research and Innovation*
12:30 - 12:45	**Alternative Feedstock for the Chemical Industry – Carbon Utilization** *Achim Boenke – European Commission – DG Internal Market, Industry, Entrepreneurship and SMEs*
12:45 – 13:00	**Medical applications of synthetic biology** *European Medicines Agency*
13:00 – 13:15	**New Commission scientific advice mechanism** *Sigrid Weiland – European Commission – DG Research and Innovation*
13:15 - 14:15	***Lunch***
14:15 - 14:45	**Member States initiatives on synthetic biology** *Experiences from Austria, Germany, The Netherlands*
14:45 - 16:00	**Panel discussion on synthetic biology: 'From science to policy and societal challenges'** Panel: Scientists, Member States, European Commission
16:00 - 16:15	**Closing remarks** *European Commission – DG Health and Food Safety and Luxembourg Presidency*

Welcome and Opening

SPEAKER: John F. Ryan,
Acting Director, Public Health directorate, DG Health and Food Safety, European Commission

09:30 - 09:45

John F. Ryan is Acting Director of the Commission Public Health directorate since March 2012. He is also the current Head of Unit responsible for health threats (communicable diseases, health security and bioterrorism) within the European Commission department for public health and food safety. This includes responsibility for issues such as surveillance of communicable diseases, strategies for prevention, vaccination, avian, pandemic and seasonal flu, preparedness exercises, EU and international cooperation on health security (EU Health Security Committee, Global Health Security Initiative).

He was previously responsible in the same department for the health information programme, the cancer programme, the pollution related disease programme, the drugs prevention programme, the health monitoring programme, the health promotion programme, the rare diseases programme and the injury prevention programme.

He was a Commission representative on the Board of the EU Lisbon Drugs Agency, and is currently the Commission representative on the Board of the European Centre for Disease Prevention and Control.

He also had the charge of dealing with tobacco control issues including product regulation directives, tobacco advertising, and the WHO international treaty negotiations for a tobacco convention.

He has previously worked in other European Commission departments dealing with the completion of the internal market, and on international trade negotiations. He is also an official of the Irish civil service (on leave).

What is synthetic biology? What are the fields of its application? Challenges and future developments

SPEAKER: **Paul Freemont,**
Imperial College London

Professor Paul Freemont (UK citizen) is co-director and co-founder of the EPSRC Centre for Synthetic Biology and Innovation (since 2009) and the National UK Innovation and Knowledge Centre for Synthetic Biology (SynbiCITE; since 2013) at Imperial College London. He is also currently Head of the new Section of Structural Biology in the Department of Medicine at Imperial. He was previously the Head of the Division of Molecular Biosciences (2005-2012) and Head of the Imperial College Centre for Structural Biology (2000-2005), having joined Imperial from Cancer Research UK London Research Institute. His research interests span from understanding the molecular mechanisms of human diseases to the development of synthetic biology platform technologies and biosensors and he is the author of over 170 scientific publications. He was elected an EMBO member in 2009 and is a fellow of the Royal Society of Biology (2012) and the Royal Society of Medicine (2014). He also holds a number of external positions including membership of the UK Medical Research Council MCMB board and was recently an observer member of the Ad Hoc Technical Expert group of the UN Convention on Biological Diversity and steering group member of the US NIST synthetic biology standards consortium.

09:45 - 10:00

Synthetic biology is a rapidly emerging interdisciplinary field that aims to establish a systematic framework for the design and/or redesign of living biological systems based on modular genetic parts and recoded genomes. The application of an engineering forward design approach is attractive as many engineering parallels can be identified in living systems. However, biological systems are complex, non-linear, functionally context-dependent and stochastic in nature and are therefore intrinsically difficult to forward engineer. In order to address these fundamental challenges and unlock the full potential of synthetic biology, there is a rapidly developing and expanded repertoire of approaches and tools, which are being applied either at the whole genome level or pathways/circuit design level.

In this presentation, I will discuss current international trends and applications in synthetic biology including activities like synthetic biology standards development, automation and cloud laboratories, iGEM (International Genetically Engineered Machine competition for students), entrepreneurship and synthetic biology accelerators.

Synthetic biology and the European Commission: Reasons for the mandate

SPEAKER: **Stefan Schreck,**
Head of unit, Health information & Scientific Committees, DG Health and Food Safety, European Commission

Stefan Schreck holds a doctorate in microbiology. After working for the German diplomatic service, he joined the Commission in 1996, in the area of research on vaccination.

In 1997 he moved to the public health directorate in Luxembourg, where he has been working in several units, in particular in the areas of communicable diseases, health threats, and substances of human origin.

In 2008, he became head of the health unit in the executive agency for health and consumers (EAHC), which is responsible for the implementation of the EU health programme.

10:00 - 10:15

In January 2011, he was appointed head of the health information unit of DG SANTE. Currently, this unit deals mainly with health information policy, and provides the secretariat for the non-food scientific committees of the European Commission.

Synthetic biology Opinion I: The definition

SPEAKER: Theo Vermeire,
Chair of the SCENIHR working group on synthetic biology

Theo Vermeire (1953), PhD, is a registered toxicologist. He studied (bio)chemistry and toxicology at the Universities of Utrecht and Wageningen in The Netherlands and obtained a PhD in risk assessment of chemicals at the University of Utrecht. He started his career in risk assessment as toxicologist at the Ministry of Housing, Physical Planning and the Environment. In 1987, he was employed by the National Institute for Public Health and the Environment (RIVM) and has served in a good number of scientific and managerial functions up to this day. His present position at RIVM is head of the Department of Nanotechnology, Occupational Health and Transport Safety of the RIVM Centre for the safety of Substances and Products. As an expert with a wide knowledge on toxicology and risk assessment, he has been involved in many expert groups developing guidance and tools for risk assessment (e.g. for IPCS/WHO, EU, OECD. EEA) and in a substantial number of training courses in this area in and outside Europe. He is a member of the Steering Group of the WHO/IPCS Network of Risk Assessment Institutes and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the European Commission and the Chair of the SCENIHR working group on synthetic biology.

10:15 - 10:30

This Opinion is the first of a set of three Opinions addressing a mandate on synthetic biology (synthetic biology) from DG SANTE, DG RTD, DG ENTR (now DG GROW) and DG ENV requested to the three Scientific Committees (SCs). This first Opinion concentrates on the elements of an operational definition for synthetic biology. The two Opinions that follow focus on risk assessment methodology, safety aspects and research priorities, respectively. This first Opinion lays the foundation for the two other Opinions with an overview of the main scientific developments, concepts, tools and research areas in synthetic biology. Additionally, 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 is included.

The Opinion proposes an 'operational' definition based on present knowledge and understanding of the field of synthetic biology. However, this definition may change as the understanding of the synthetic biology concepts, tools and applications evolves.

Synthetic biology Opinion II: Risk assessment methodologies and safety aspects

SPEAKER: **Markus Schmidt,**
External expert of the SCENIHR working group on synthetic biology

Dr. Markus Schmidt (Austria) is a founder and a team leader of BIOFACTION KG, a technology assessment and science communication company in Vienna, Austria. With an educational background in electronic engineering, biology and environmental risk assessment he has carried out environmental risk assessment and safety and public perception studies in a number of science and technology fields. He carried out several research projects, for example Synthetic biologySAFE, the first European project on safety and ethics of synthetic biology (2007-2008), TARPOL on industrial and environmental applications of synthetic biology (2008-2010), or ST-FLOW on standardization for robust bio engineering of new-to-nature biological properties (2011-2015). He served as an advisor to the European Group on Ethics (EGE) of the European Commission, the US Presidential Commission for the Study of Bioethical Issues, the J Craig Venter Institute, the Alfred P. Sloan Foundation, the Bioethics Council of the German Parliament and the EC's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) working group on synthetic biology. He is the author of several peer-reviewed articles, edited a special issue and two books about synthetic biology and its societal ramifications, and produced several documentary films. He is an external expert of the working group on synthetic biology of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the European Commission.

10:30 - 10:45

Though present risk assessment methodologies are appropriate for assessing potential risks of synthetic biology activities and products, the Scientific Committees suggest several improvements including:

1) the support for the characterisation of the function of biological parts and the development of computational tools to predict emergent properties of synthetic biology organisms,
2) streamline and standardise the methods for submitting genetic modification data and genetic parts information to risk assessors,
3) encourage the use of GMOs with a proven safety record as acceptable comparators for risk assessment,
4) aim to ensure that risk assessment methods advance in parallel with synthetic biology advances,
5) support the sharing of relevant information about specific parts, devices and systems with risk assessors.
Currently available safety locks used in genetic engineering such as genetic safeguards (e.g. auxotrophy and kill switches) are not yet sufficiently reliable for synthetic biology, because of mutation and positive selection pressure for mutants.

The Scientific Committees recommend 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.

Synthetic biology Opinion III: Research Priorities

SPEAKER: **Michelle Epstein,**
Member of the SCENIHR working group on synthetic biology

Michelle Epstein is from Montreal, Canada. After finishing a degree in biochemistry, Dr. Epstein began graduate studies in organic chemistry at The University of Alberta in Edmonton, Canada. She then went to medical school at this university, which was followed by an internship and residency in Internal Medicine at the University of British Columbia, Vancouver, Canada. She then went to Yale University in New Haven, Connecticut, USA where she completed a fellowship in Allergy and Clinical Immunology and a post doctoral fellowship in Immunobiology at the Howard Hughes Medical Institute. She then joined a laboratory at the National Institutes of Health in Bethesda, Maryland, USA for continued post-doctoral studies in Basic Immunology. She is currently working at the Laboratory of Experimental Allergy in the Department of Dermatology, Division of Immunology, Allergy and Infectious Diseases at the Medical University of Vienna, Vienna, Austria where she investigates allergies and immunology and participates in several EC funded projects. She is a member of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of the European Commission and a member of the SCENIHR working group on synthetic biology.

10:45 - 11:00

This presentation will focus on three questions from the synthetic biology Mandate:

asking the Scientific Committees to review the state of the scientific knowledge concerning specific risks to the environment and synthesise it following the procedure and the requirements mentioned in the Decision XI/11 of the Convention of Biodiversity (COP Decision XI/11) and include the synthesis in its Opinion;

to define the major gaps in knowledge to be filled for performing a reliable risk assessment in the areas of concern;

and to provide research recommendations on the main scientific gaps identified which also include 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.

Six novel synthetic biology developments will be addressed:

1) Genetic part libraries and methods;
2) Minimal cells and designer chassis;
3) Protocells and artificial cells;
4) Xenobiology:
5) DNA synthesis and genome editing;
6) Citizen science (e.g., Do-It-Yourself Biology (DIYBio).

Synthetic biology and GMOs

SPEAKER: Dorothée André,
Head of Unit, Biotechnology, DG Health and Food Safety, European Commission

Dorothée André is Head of Unit Biotechnology, DG Health and Food Safety, European Commission. The unit is dealing with legislation on genetically modified food, feed and seeds and co existence of GM crops with conventional and organic farming.

Previously, she was Head of Unit Biotechnology and Plant Health dealing with seeds and plant propagating material, plant variety rights, plant health and biotechnology from March 2009 to August 2010. She also served as a Deputy Head of the same unit from December 2005 to February 2009.

Dorothée André joined the Commission in 1993 where she was dealing with legislation on animal nutrition.

Prior to her career in the Commission, she worked with Smith Kline Beecham Animal Health as a regulatory manager for veterinary medicines.

Dorothée André is an agronomical engineer with a PhD in molecular biology, and she held an assistant position at university.

11:45 - 12:00

The operational definition of synthetic biology proposed by the Scientific Committees, i.e. *the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms*, is also applicable to a number of genetically modified organisms as they are defined under Directive 2001/18/EC on the deliberate release into the environment of GMOs. The Scientific Committees recognised the difficulty to define the relationship between genetic modification and synthetic biology on the basis of quantifiable and measurable inclusion and exclusion criteria.

Future applications of synthetic biology may raise questions on whether certain organisms produced with the use of synthetic biology fall under the scope of the existing legislation on GMOs. The Commission is currently addressing the same question for a number of new breeding techniques and is therefore engaged in a legal interpretation of Directive 2001/18/EC in this respect. The Commission 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 synthetic biology.

Potential impacts of synthetic biology on the conservation and sustainable use of biological diversity

SPEAKER: Anne Teller,
Policy Officer, DG Environment, European Commission

Anne Teller is Senior Expert in the Directorate-General Environment of the European Commission. She is Belgian and graduated as a Forest Engineer at the University of Brussels; she is also Master of Science in Forest and its relation to Land Management from the University of Oxford. Anne has nearly thirty years of experience in European environmental policy. She has worked at regional, national and European level. Her specific domain of interest is the improvement of the knowledge and evidence base for environment policy at EU and global level.

12:00 - 12:15

Synthetic biology has the potential to provide for opportunities for new benefits for health, the environment, resources management and the economy. At the same time, 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. This is a very complex issue with socio-economic impact that needs to be addressed consistently within the Convention on Biological Diversity (CBD) and its Protocols (Cartagena and Nagoya).

In 2014, the 12th Conference of the Parties decided to establish an Ad Hoc Technical Expert Group on synthetic biology and to convene a moderated open-ended online forum to support its work. The Secretariat of the Convention was also requested to prepare an updated report on relevant information on components, organisms and products resulting from synthetic biology techniques that may impact the conservation and sustainable use of biological diversity. The Conference of the Parties will consider a draft decision on synthetic biology at the 13th meeting in December 2016 in Mexico on this basis.

Synthetic biology from the perspective of the European Research and Innovation policy

SPEAKER: Carmen de Vicente Coll,
Programme Officer, DG Research and Innovation, European Commission

Carmen de Vicente Coll is a national from Spain. She has had scientific, managerial and leadership responsibilities in the public sector in Spain, the private sector in France, and the international public sector. Carmen has worldwide international research and development experience as a program leader and project manager. She has lived and worked in Europe, the Middle East, North and South America. Her special interest has been the delivery of research outputs, in particular through public and private collaboration. She joined the European Commission, where she works as a programme officer in DG Research and Innovation, Directorate D – Key Enabling Technologies –, in Advanced Manufacturing Systems and Biotechnologies, focusing on projects in the area of "Cutting-edge Biotechnologies". Her responsibilities include the preparation of the Work Programme, project management and KET Biotechnology policy development.

12:15 - 12:30

Europe is a world leader in the area of Biotechnology. Under Horizon 2020, Biotechnology is placed under the Leadership in Enabling and Industrial Technologies (LEITs) activities with an indicative EU budget of €360 million. Biotechnology is considered a key enabling technology (KET) driving European innovation and competitiveness in different sectors. 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.

This pillar encompasses the development of emerging tools such as those of synthetic biology. Already in the Work Programme 2014-2015, there was a topic on synthetic biology and as a result three projects were selected to carry out their work. It is expected that new technologies will respond to societal needs, that they will take into account public concerns and that they are developed with transparency, openness and responsibility.

Alternative Feedstock for the Chemical Industry – Carbon Utilization

SPEAKER: Achim Boenke,
Policy Officer, DG Internal Market, Industry, Entrepreneurship and SMEs, European Commission

With a PhD-thesis completed with the title Dr. rer. nat. at the University Ulm – Topic "Analytik und Chemie der Carbonylverbindungen als Spurenstoffe der unvollständigen Verbrennung", Achim Boenke is a Principle Administrator and a Policy Officer in the Chemicals Unit D.2; Directorate D - Consumer, Environmental and Health Technologies within the Directorate General Internal Market, Industry, Entrepreneurship and SMEs. His policy areas include, amongst others, industrial safety; emission of chemical installations; bio-based products and bioeconomy; sustainable chemistry; energy as well as renewable raw materials as feedstock and innovation. He is also an active member of various European Commission interservice groups and European Technology Platforms (i.e. Sustainable Chemistry (SusChem) and Industrial Safety (ETPIS)). Moreover, he is co-chairing the Steering Group on Environmental Sustainability within the OECD-Working Party on Manufactured Nanomaterials.

12:30 - 12:45

The Energy Union Package Communication «A Framework Strategy for a Resilient Energy Union with a Forward-Looking Climate Change Policy»[1] calls for «A forward-looking approach to carbon capture and storage (CCS) and carbon capture and utilization (CCU) for the power and industrial sectors, which will be critical to reaching the 2050 climate objectives in a cost-effective way». The new Strategic Energy Technology (SET) Plan[2] that was does include CCU allowing for financial support. As reported by Christophe McGlade and Paul Ekins (2015) in Nature[3], at global level a third of oil reserves, half of gas reserves and over 80% of current coal reserves should remain unused from 2010 to 2050 in order to meet the target of 2°C and this would allow for an at least 50% chance of keeping global warming below 2°C throughout the twenty-first century, however, the cumulative carbon emissions between 2011 and 2050 need to be limited to around 1,100 gigatonnes of carbon dioxide (Gt CO2). Carbon Utilization (CU) is not a technology but various approaches and should also not to be mixed up with Carbon Capture and Storage (CCS). CCS is defined in the Directive 2009/31/EC on the geological storage of carbon dioxide as the «'geological storage of CO2' means injection accompanied by storage of CO2 streams in underground geological formations». Hence, Carbon Utilization means the use & re-use of CO2 as: (a) An alternative feedstock for the chemical industry as an alternative carbon source, through repetitive recycling CO2 may be stored and generated CO2 emissions during recycling could serve as a secondary raw material; (b) An intermediate substance generating of NH3, CH4, synthetic fuels including methanol, ethanol that could serve as substance based energy including fuel carriers or substance energy storage; and (c) Mineralization – recycled CO2 is included in construction materials. Detailed realistic estimations on what could be the ecologic and economic impact of the CU for the European economy do not exist yet. Artificial photosynthesis as one approach of CU is in the research phase, encompasses design and assembly of devices including their components for the direct production of solar fuels, photo-electrochemistry and its application in fuel cells, engineering of enzymes and photoautotropic microorganisms for microbial biofuels, synthetic fuels and bio-hydrogen production using it lateron for manufacturing of syngas generating other building blocks. There is a need building on national, regional activities and different types of projects in NL, NO, FR, BE and DE for new CU activities. Technology providers facilitate gases/substances transfer into other chemical building blocks on industrial sites where additional infrastructure such as pipelines are not feasible. In this respect, it is expected that various projects and the scheduled research, innovation, pilot and demonstration activities will deliver more technical solutions including ecological and economic information.

1 European Commission, Energy Union Package - A Framework Strategy for a Resilient Energy Union with a Forward-Looking Climate Change Policy, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, the Committee of the Regions and the European Investment Bank, COM(2015) 80 final, Brussels, 25.2.2015.

2 European Strategic Energy Technology Plan (SET-Plan) aims to accelerate the development and deployment of low-carbon technologies – see https://ec.europa.eu/energy/en/topics/technology-and-innovation/strategic-energy-technology-plan.

3 Christophe McGlade & Paul Ekins (2015), The geographical distribution of fossil fuels unused when limiting global warming to 2 °C, Nature, 517, 187–190 – see see http://www.nature.com/nature/journal/v517/n7533/full/nature14016.html.

The European Commission's Scientific Advice Mechanism

SPEAKER: **Sigrid Weiland,**
Policy Officer, Scientific Advice Mechanism, European Commission

Dr Sigrid Weiland is currently working as policy officer in the new Scientific Advice Mechanism of the European Commission, hosted by the Directorate-General for Research and Innovation (DG RTD).

Having graduated in biology she obtained her PhD for her work on genetic causes of human hereditary epilepsies.

Before joining the European Commission, she was business-developer in the start-up phase of a biotech company and was patent examiner in the area of biotechnology at the European Patent Office in Munich. Since 2005, she has dealt with different biotech-related issues in several services of the European Commission, including the Joint Research Centre, DG Agriculture and most recently in the foresight team of the unit, Science policy, foresight and data' at DG RTD.

13:00 - 13:15

As announced by President Juncker on 13 May 2015, the European Commission has set up the EC Scientific Advice Mechanism («SAM»). Its objective is to support the Commission with high quality, timely and independent scientific advice for its policy-making activities. This will contribute to the quality of EU legislation, in line with the Better Regulation agenda.

SAM will aim at better matching the demand for and supply of scientific advice. For this purpose it will bring together evidence and insights from different disciplines and sources while taking into consideration the specificities of EU policy making. It will draw on the wide range of scientific expertise in Europe through a close relationship with national academies and other bodies, as well as the expertise of a High-Level Group (HLG) of independent scientific advisors.

The HLG is the core of SAM and was established by the Commission Decision of 16 October 2015. The group is composed of seven highly qualified, specialised, independent experts, appointed in their personal capacity, acting independently and in the public interest. The seven members proposed by an independent Identification Committee were appointed by Carlos Moedas, the Commissioner for Research, Innovation and Science, on 10 November 2015.

Synthetic biology – viewpoint of Austrian Federal Ministry of Health

SPEAKER: Sanda Pasc,
Ministry of Health, Austria

Sanda Pasc works at the Department for Genetic Engineering of the Federal Ministry of Health in Vienna. Her area of activities covers Contained Use of Genetically Modified Organisms, Molecular Genetic Testing on humans and Scientific evaluations and Inspections. Ms Pasc studied Molecular Biology at the University of Vienna with specialisation in Genetics, Microbiology and Neuroscience. She received a Master's degree and graduated with distinction. Ms Pasc did her diploma thesis in Microbiology on Selective translation of leaderless mRNAs under different stress conditions at the Max F. Perutz Laboratories in Vienna at the department of Microbiology and Immunology.

Furthermore, Ms Pasc graduated with distinction at the secondary College of Chemistry with specialisation in Biochemistry, Biotechnology and Genetic Engineering in Vienna. This education qualified her for working in the laboratory of companies, where she gained experience in analytical chemistry, cell biology, microbiology as well as molecular biology.

14:15 - 14:45

National actions on synthetic biology are in the early stages of development at the Austrian Federal Ministry of Health.

The challenges of synthetic biology to risk assessment and risk management were analysed as well as recommendations set for actions based on the findings in a study funded by the Austrian Federal Ministry of Health. Synthetic biology raises issues concerning, e.g., technical, biosafety, security, regulatory and ethical standards. The establishment of a clear, unambiguous definition commonly agreed-upon for synthetic biology and its products would facilitate the monitoring of relevant developments. New risks may arise as new organisms with novel properties are developed, which have to be assessed. By adequate risk research, control measures have to be established to protect human and animal health as well as the environment from exposure to synthetic biology organisms. Consequently, the current regulatory framework has to be analysed for its applicability and adapted if required. Efforts should be strengthened to setting internationally agreed high standards for regulations with a focus on synthetic biology.

The Scientific committees for Contained Use as well as for Deliberate Release and Placing on the Market of the Austrian Federal Ministry of Health have discussed these analyses and specified an undisclosed opinion regarding inter alia synthetic biology.

In search of synthetic biology-policy fit for purpose and future proof

SPEAKER: Julie Ng-A-Tham,
Ministry of Infrastructure and Environment, The Netherlands

Dr. Julie Ng-A-Tham currently works as a policy coordinator on biotechnology at the Ministry of Infrastructure and Environment.
Trained as a psychologist, she worked at the University of Amsterdam and the Tilburg University in the areas of strategic decision making, work and health and organizational change. Then she moved on to become a human resource manager and subsequently shifted to policy making and became the programme manager of the Dutch Environment and Health programme. She was also the programme manager of the Atlas for the living Environment, a website, assembling, displaying and explaining information on the environment with maps (http://www.atlasleefomgeving.nl). She was engaged in both the EU and WHO Environment and Health processes and contributed to the UNECE/WHO Pan European Programme on Transport, Health and Environment, both as a chair and a member state representative.

14:15 - 14:45

• Biotechnology develops swiftly. These developments, often referred to as synthetic biology, are innovative and potentially beneficial for societal needs.

• Increasingly, new biotechnological applications tend to fall outside the scope of current regulatory frameworks for GMO's, thereby raising questions about uncertainties in risk assessments, data and knowledge gaps and methodological gaps.

• For authorities, these developments raise questions about the adequacy and comprehensiveness of existing policies and regulatory frameworks covering the safe and secure use of biotechnology.

• The Netherlands is therefore assessing how well its regulatory and policy frameworks meet the scientific and policy making challenges. Since most of the legal framework on biosafety is set up in a global and European context, collaboration among EU Member States and the Commission is indispensable.

• Thus we call for an European policy agenda aimed at a shared understanding of synthetic biology and ensuring its safe and secure use while at the same time contributing to health and sustainability.

• We invite Member States and the EU Commission to join forces in making synthetic biology-policy fit for purpose and future proof.

More information on our activities:

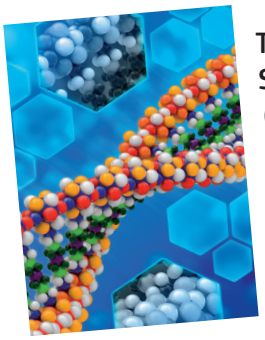
Non-Food Scientific Committees of the European Commission:
http://ec.europa.eu/health/scientific_committees/

Public Health website:
http://ec.europa.eu/health

Health-EU e-newsletter:
http://ec.europa.eu/health/newsletter/newsletter_en.htm

European Commission

Synthetic biology



The field of Synthetic Biology (SynBio) is full of exciting possibilities, from adapting crops to thrive in barren lands to growing new organs to save the lives of transplant recipients.

And yet all unexplored scientific territories may pose potential risks, which is why the Scientific Committees have scientific Opinions on SynBio from definition to potential risks to public health and to determining the type of risk-related research that needs to be done in this field.

→ WHAT IS SYNBIO?

SynBio, as defined in Opinion I, is 'the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms.' In other words, SynBio uses faster and easier methods for producing genetically modified organisms (GMOs) by adding or removing genes from an organism, or assembling modular genetic elements and creating one from scratch. The principal purpose of defining SynBio is to assist the identification of processes or products that might require a substantial change from current risk assessment and safety procedures.

→ WHAT ARE THE APPLICATIONS OF SYNBIO?

SynBio aims to design biological systems that do not exist in nature, or to re-design existing principles to better understand or improve life processes. There are SynBio applications already in use, such as yeasts that produce insulin or the malaria drug, artemisinin.

SynBio is still a young field, having emerged at the dawn of the 21st century, and applications for the pharmaceutical, chemical, agricultural, and energy sectors are growing.

→ ARE THE HAZARDS AND RISKS RELATED TO SYNBIO ACTIVITIES WELL EVALUATED?

The scope of the Opinions is for the foreseeable future (10 years) and currently, the existing methods of risk assessment for GMOs and chemicals are applicable; however, new SynBio developments may require adapting existing methods for risk and safety assessment.

→ ARE THERE ISSUES SPECIFIC TO SYNBIO THAT COULD EMERGE?

Challenges in assessing SynBio risks are foreseeable and include the integration of modified cells into/with living organisms; future developments of autonomous modified cells; use of non-standard biochemical systems in living cells; increased speed of modifications by new technologies and an evolving 'Do-it-Yourself Biology' among the citizen science community. However, these can be managed by combinations of strict safety approaches including SynBio safety locks, like genetic firewalls and genetic kill switches to ensure biosafety risks.

This fact sheet is based on the following opinions of the independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), on Health and Environmental Risks (SCHER), and on Consumer Safety (SCCS): 'Opinion on Synthetic Biology I - Definition" and "Opinion on Synthetic Biology II - Risk assessment methodologies and safety aspects". June, 2015

These opinions are available at: http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en.htm

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