Deliverable 2.2

Position Statement and Recommendations on Governance

Work Package 2: Governance and Society

Austrian Research Promotion Agency (FFG)

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Description of Work of Work Package 2 / Deliverable 2.2

Until now synthetic biology research is approved by a considerable part of the public as long as it is regulated by strict laws. Europeans consider synthetic biology a sensitive technology that demands precaution and special laws and regulations (Gaskell et al. 2010). Certain aspects and features of synthetic biology call for strict regulatory approaches and governance concepts: synthetic biology touches fundamental philosophical and ethical aspects including the very definition and perception of life and living systems. The complexity of living systems and the inherent unpredictability of their behavior demand safety, security as well as ethical considerations (Description of Work – WP2 of ERASynBio, p. 12).

Work Package 2 (Governance and Society) of the Synthetic Biology ERA-NET (ERASynBio) addresses the challenges stated above by introducing social science perspectives and by constantly tracing and integrating ethical, legal, economic, and societal considerations relevant for synthetic biology. The contributors to WP2 elaborate recommendations on governance, public dialogue, and intellectual property rights and convey them to policy makers and empowered authorities.

Deliverable 2.2 (Position statement and recommendations on governance of synthetic biology) focuses on the governance aspects of synthetic biology and is one of the central tasks of WP2. The WP-leader together with governance experts has examined, analyzed and evaluated past and existing frameworks and national regulations. Furthermore, central questions of governance were discussed in a dedicated workshop with invited experts in Vienna, on March 14-15, 2013. This document contains the distilled outcomes of the workshop, and presents central ideas and recommendations from relevant reports by bioethics councils and commissions at European and international level.

Recommendations on Governance from the ERASynBio Expert Meeting in Vienna

The ERASynBio "Workshop on Public Dialogue and Governance of Synthetic Biology" was an expert meeting that focused on societal, ethical, and regulatory issues of synthetic biology in Europe.[1] The experts attending the workshop[2] discussed central aspects of governance, public engagement, and the integration of social science perspectives in future transnational funding activities that will emerge within ERASynBio. The meeting was organized in altering phases of presentations by governance experts and bioethicists and in discussion phases in the plenary or in breakout sessions with smaller working groups composed of three to five people.

The central discussions within the workshop revolved around the following questions:

- How can the legal, ethical, and social aspects of synthetic biology be addressed and reflected in governance and regulation?

[1] The workshop was organized by the Austrian Research Promotion Agency (FFG) in its function as leader of WP2. It took place in the BMWF function rooms, Palais Harrach, Freyung, Stairs 3/2nd floor, 1010 Vienna, Austria.

[2] A list of the workshop participants, affiliations, and contacts appears in the final section of this report (Annex).

- How can issues of equality, justice, fairness, etc., be taken into account in governance regimes? How can distributional issues (patenting, access) be brought into governance?
- Who should regulate synthetic biology research and applications? What is the role of national governments? Should there be regulation at a European or at a transnational level? What is the role of scientists/researchers? Should there be global standards for governance of synthetic biology? What is the role of public/society? Of expert commissions? Are current regulatory frameworks adequate?
- How can policies and strategies take into account the anxieties and concerns towards synthetic biology, such as bioterrorism, biohazards, unknown risks, and uncontrollability?
- How can policies meet the expectations and demands for a responsible regulation of synthetic biology (transparency, information, control, labeling, safety, security, proactive and precautious use, etc.)?
- Are there new, proactive regimes of governance emerging? How do we move from risk management to the management of equality and solidarity?

These questions were discussed in depth, and recommendations on governance developed out of such discussions. The following section lists the distilled outcomes of the expert meeting. These recommendations are not associated to singular participants, but represent the agreements of the group. They are a summary of the original statements by the participants and do not represent the personal opinions of the writers of this document.

Recommendation No. 1

Governance of synthetic biology should be based on a set of principles, in particular **participation**, **transparency**, **accountability**, and contribution to the global **common good**. These principles should permeate all levels of the ERA-NET – from the strategic down to individual projects.

Recommendation No. 2

Transparency, participation, and accountability should be emphasized in the preparation of calls and also in the selection processes by the project boards. Funding should depend on the applications being able to demonstrate that these principles will be put into practice in research.

Recommendation No. 3

Research projects could meet the principle of **transparency** by publishing summaries of their content, and of their possible impacts in open-access journals, and by communicating via web 2.0 tools. Synthetic biology research projects could have their own websites or blogs where clear, accessible, and candid information is offered to the public.

Recommendation No. 4

The principle of **accountability** could be put into practice by guaranteeing and making evident that the research projects are within the law. For this purpose, an authority should be created that supervises the compliance of research projects with legal and ethical standards and frameworks.

Recommendation No. 5

The principle of **participation** can be met by setting up effective and bold public dialogue activities. Such a public dialogue should include the participation of a wide range of stakeholders, who might be lay citizens, scientists, affected groups, representatives of industry, policy makers, advisory board members of science fund councils, and so on.

Recommendation No. 6

Before any scientific research project is funded, transparent, participative, and accountable processes should be developed in order to deliberate crucial questions, such as the following: Is synthetic biology needed? For whom / for which group? What are the risks and benefits? What are the alternatives? How will uncertainties (as opposed to risk) be dealt with? Other crucial questions may be posed. Nevertheless, restrictions should be used sparingly, keeping in mind that innovation should not be stifled. For instance, research should not be restricted on the ground of "dual use" alone (possibly malevolent in addition to clearly beneficial use).

Recommendation No. 7

Policy recommendations for the very broad field of synthetic biology may be too vague or too difficult to apply. Recommendations on governance and governance itself should aim at specific areas of application or specific objects created by synthetic biology. For example, in the field of drug development, normative claims by affected groups should be included, as well as more distant views by other groups/publics.

Recommendation No. 8

Recommendations on governance should not only be made on paper, but there should be an authority or control mechanism that guarantees that these recommendations are implemented, and implemented in an adequate manner.

Recommendation No. 9

Buzzwords and ethical concepts may be avoided or used in a reasonable manner because they are typically normatively loaded. If buzzwords like "transparency" are used, it should also be defined what this notion exactly means, because it might be understood in very different ways by different people.

Recommendation No. 10

Scientists and researchers themselves should reflect on what they are doing and be responsible for their research and consider its outcomes. The old approach of "we are only producing tools and whatever people do with these tools we are not responsible for" – the old idea that science is innocent – should not be accepted.

Recommendation No. 11

The great variety of existing reports on ethical, legal, and social implications of synthetic biology and the recommendations therein should be considered. For example, the EGE Opinion No. 25, or recent reports from the Nuffield Council on Bioethics or from the U.S. Presidential Commission for the Study of Bioethical Issues could be a point of reference when discussing governance issues in the context of synthetic biology.

Overview of Reports and Recommendations on Governance

When talking about recommendations for the governance of synthetic biology, the great variety of existing reports by bioethics councils and commissions at European and international levels should be taken into account (e.g. acatech - National Academy of Science and Engineering 2012; European Academies Science Advisory Council 2010; European Commission's Directorate-General for Health & Consumers 2010; Nuffield Council on Bioethics 2012; OECD Royal Society 2010; Presidential Commission for the Study of Bioethical Issues 2010; The European Group on Ethics 2009). A selection of relevant documents and reports on ethical, legal, and social aspects of synthetic biology and the recommendations on governance within those documents are listed in the following section.

Report from the Nuffield Council on Bioethics

The report "Emerging Biotechnologies: Technology, Choice and the Public Good" released in December 2012 by the Nuffield Council on Bioethics considers how a socially and ethically responsible innovation can be fostered in biotechnologies. The Nuffield Council suggests a "public ethics" approach (Nuffield Council on Bioethics 2012). This "public ethics" should be applicable in different sites where biotechnologies emerge and permeate different contexts and levels, such as regulation, policy, research, and business. The central aim is to develop a form of governance that maximizes social benefit and democratic accountability. This aim can be reached by following a set of recommendations, which can be summarized as follows:

Public engagement and social benefit

The "public ethics" approach suggests that different publics should be engaged together with experts and scientists from the field in order to generate "plural and conditional" (Nuffield Council on Bioethics 2012, 176) perspectives and advice. The sole reliance on experts should be avoided in order to guarantee that not only costs and benefits in economic terms are identified, or technical solutions are sought for problems with social dimensions, but that social solutions prevail over technical ones when challenges with social implications are faced (Nuffield Council on Bioethics 2012, 176). Through the engagement of different stakeholders and social interests a "public frame for research policy decisions" (Nuffield Council on Bioethics 2012, 178) can be constructed. Finally, all innovation should have a social value (Nuffield Council on Bioethics 2012, 178).

Information and alternatives

The information provided in public dialogue activities must be accurate and complete. The experts that engage with the public are also responsible for the appropriate further proliferation of the information they have given (Nuffield Council on Bioethics 2012, 176). Furthermore, alternative technological pathways should be examined and taken into account before a particular pathway is chosen, in order to "illuminate obscured assumptions, constraints and mechanisms of the innovation system" and to "identify sites and opportunities for more constructive governance, prioritization and control" (Nuffield Council on Bioethics 2012, 175).

Authorities and regulation

In order to guarantee that research does not merely reflect the objectives of a particular government department, a senior minister who is free from the responsibilities of one specific department, should be put in place. The role of this senior minister is to coordinate and bring funding bodies and

government research policy under one roof. Furthermore, a clearly written governmental research policy should be published that should be the point of reference for other public research policies (Nuffield Council on Bioethics 2012, 178). Also, past research policies of individual public funding bodies of government as a whole should be evaluated and assessed. With this strategy it will be possible to understand the conditions under which selective biotechnological research support is plausible (Nuffield Council on Bioethics 2012, 177). The state should intervene in the biotechnology market in order to guarantee that innovations generate social benefits. And "innovation should be included in corporate social responsibility reports as a separate, specific issue" (Nuffield Council on Bioethics 2012, 178).

Report from the Presidential Commission for the Study of Bioethical Issues

In 2010 U.S. President Barack Obama asked the Presidential Commission for the Study of Bioethical Issues to engage in the research field of synthetic biology, in order to investigate the risks and benefits of synthetic biology and to identify key ethical aspects that should accompany further development of the new technologies. The Commission met this demand by setting up public meetings and engaging deliberately and in an open environment with various stakeholders, among them scientists, ethicists, and engineers (Presidential Commission for the Study of Bioethical Issues 2010, 2-3). A set of recommendations were elaborated, which rely on five basic ethical principles identified by the Presidential Commission and which should guide public policy making. The five principles and the recommendations arising thereupon are as follows:

Public beneficence

The principle of "public beneficence" is tied to the idea that funding in synthetic biology research should be evaluated by a central body and that the results be made public. In addition to the funding for synthetic biology activities as such, research on risk assessment and risk reduction and on social and ethical implications of synthetic biology should be evaluated. The most promising research in synthetic biology should be supported and innovation should be encouraged after evaluation of risks and benefits of synthetic biology research. Effective evaluation could be guaranteed through peer-review mechanisms and the inclusion of National Institutes of Health and federal agencies in the evaluation (Presidential Commission for the Study of Bioethical Issues 2010, 6-7).

Responsible stewardship

The Commission recommends that research in synthetic biology should embrace a middle ground – this means that until all risks and benefits are identified, there should neither be a moratorium on research nor absolute freedom of research. Harms, developments, and opportunities should be identified and monitored by oversight authorities that are also responsible for informing the government about novel developments, risks, and benefits in the growing field of synthetic biology. The principle of responsible stewardship can best be met by guaranteeing that coordination, clarity, and accountability are in place across the government. Furthermore, international cooperation and dialogue is necessary to ensure safety and security of research in synthetic biology. The Commission also recommends that researchers working in the field of synthetic biology should receive an ethics education similar to that received by medical and clinical researchers. Appropriate training models should be identified and questions about moral objections should be discussed periodically in a deliberative process. The implications that synthetic biology has or could have on nature,

environment, humans, and other species should constantly be reassessed (Presidential Commission for the Study of Bioethical Issues 2010, 8-12).

Intellectual freedom and responsibility

The freedom of research in synthetic biology should be limited only when the perceived risks are too high and when public safety and security are endangered. Restrictions on research should be made carefully in order to not hamper research efforts in synthetic biology by overregulation. Accountability should be fostered at all levels – from the individual scientist up to governmental agencies. A culture of self-regulation and corporate and individual responsibility should be supported, and specific safety and security risks in institutional and non-institutional settings (including the "do-it-yourself" community) should be assessed by the government. Finally, export controls could be set up, but only after consulting academic, scientific, and research communities and relevant regulatory and science agencies (Presidential Commission for the Study of Bioethical Issues 2010, 12-14).

Democratic deliberation

An ongoing discussion about synthetic biology and an exchange of views between different stakeholders and publics should be promoted to ensure that progress in synthetic biology is understood and that policy issues reflect public perceptions and demands. When public engagement activities are set up, the language used should be accurate and clear. Sensationalist buzzwords such as "playing God" or "creating life" should be avoided, because they impede understanding of ethical and scientific issues related to synthetic biology. Furthermore, educational activities at all levels and age groups should be set up and supported by various actors, be they governmental or non-governmental (Presidential Commission for the Study of Bioethical Issues 2010, 14-16).

Justice and fairness

Risks and benefits of research in synthetic biology should be fairly distributed and not be apportioned to certain populations, subgroups or individuals. This holds true on the one hand for the risks associated to the research, and on the other for the products and manufacturing processes resulting from successful research. The benefits and advances from research in synthetic biology, especially in the pharmaceutical and medical sector, should also reach the populations and individuals that are most in need, but cannot afford to buy them at a high price (Presidential Commission for the Study of Bioethical Issues 2010, 16-18).

EGE Opinion No. 25

The European Group on Ethics in Science and New Technologies to the European Commission (EGE) was approached in 2008 by President José Manuel Barroso, who asked its members to investigate ethical, legal, and social questions related to the newly emerging field of synthetic biology. He argued that "the debate about the legitimacy of engineering new life forms has mainly focused on safety issues and a work on the ethical, legal and social implications that may derive from this specific use of biotechnology is still missing" (Barroso cited in: The European Group on Ethics 2009, 11).

About a year later, in November 2009, the EGE presented Opinion No. 25, a document discussing relevant issues concerning the governance of synthetic biology and making recommendations. A broad range of principles, which are connected to aspects of intellectual property, justice, science

and society dialogue, and ethical and philosophical discussions about life, is presented. According to these principles, the recommendations within EGE Opinion No. 25 can be summarized as follows:

Safety

In order to identify possible gaps in current risk assessment procedures in the EU, a study of the existing bio-safety procedures should be initiated and mechanisms indicated to fill possible gaps. The competent authorities within the EU and national authorities should carry out the identified risk assessment procedures. The completion of such bio-safety procedures should be a precondition for research funding and marketing of products. As soon as effective rules for biosafety are defined, an international dialogue should be promoted and a standardized approach for funding and adequate monitoring instruments should be facilitated.

The Commission should prepare a Code of Conduct for research on synthetic microorganisms that for example foresees cases of accidental release. Studies on long-term risks should be a precondition for the release of modified organisms into the environment. The precautionary principle must be taken into account for the data resulting from the studies, and the "Directive on the deliberate release into the environment of genetically modified organisms" should be applied.

Concerning energy and sustainable chemical industrial applications of synthetic biology, an international approach of promoting and co-financing of projects should be followed. Competent authorities should monitor authorization procedures and ensure that the safety of workers and of the environment is guaranteed and that risks are assessed. Consumers' rights should always be protected, and products made with synthetic biology always labeled.

Concerning biomedical and biopharmaceutical applications, not only legal and scientific frameworks should be applied, but also ethical issues be addressed. Data on medical applications should be made available on an international scale (The European Group on Ethics 2009, 49-51).

Biosecurity, prevention of bioterrorism, and dual uses

The "Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction" should be further elaborated to incorporate synthetic biology applications. Together with the EGE, the Commission should define a comprehensive framework for security and ethical issues in regard to synthetic biology. Databases should be available to all their users, suspicious sequences should be identified and reported, while at the same time privacy must be guaranteed. A competent authority to which users and companies can report suspicious and harmful sequences should be put in place (The European Group on Ethics 2009, 52).

Governance

A robust framework on governance should be put in place on the EU level by the Commission. Relevant stakeholders and their responsibilities should be addressed, be they industry, scientists, military, political, or administrative agents. Furthermore, ethical guidelines for the conduct of researchers and institutions should be established, and questions of governance should in general be discussed on a global level (The European Group on Ethics 2009, 53).

Intellectual property

Open public access to the products and results of synthetic biology should be discussed, as well as the limits of patenting. Besides, questions of global justice and trade should be further discussed in order to avoid gaps between EU member states, and between developing countries and the EU. Bi- and multilateral science programs could be established, and minimal standards for import and export of synthetic biology products be adopted (The European Group on Ethics 2009, 54).

Science and society dialogue

Public engagements and dialogue should be encouraged on both national and EU levels, and responsible reporting on synthetic biology should be promoted. Implications of synthetic biology should be addressed in the media, seminars and courses could be organized, and fora for exchange created (The European Group on Ethics 2009, 55).

Research

Basic research in chemistry, biology, engineering, energy, and materials science should be supported and reflected in the budget of EU and national Research and Development programs. Interdisciplinary research on the following aspects should be funded: "risk assessment and safety; security uses of synthetic biology; ethical, legal and social implications; governance; science and society (including media and the public)" (The European Group on Ethics 2009, 56).

EASAC Policy Report No. 13

In the European Academies Science Advisory Council (EASAC), the national science academies of the EU member states should work together in order to provide evidence-based, independent, expert advice about scientific issues of public policies to policy makers within the European institutions (http://www.easac.eu/about-easac/what-is-easac.html).

In December 2010, the EASAC published the policy report "Realizing European Potential in Synthetic Biology: Scientific Opportunities and Good Governance (European Academies Science Advisory Council 2010). The central aim of the report is to support the development of a coherent strategy for regulation, research, and innovation in synthetic biology at the EU level. The recommendations of the EASAC for the EU are intended to assist member states in which synthetic biology research already takes place, and support countries with less activity to become involved in synthetic biology research. The EASAC identifies six critical points:

Research capacity

Transnational research should be supported at the EU and member state levels, and new initiatives should be funded to promote networks between smaller laboratories across states. The scientific disciplines involved in synthetic biology should be strengthened, and interdisciplinary centers of excellence be developed. In addition to the directly involved disciplines, social science perspectives should also be integrated and funded (European Academies Science Advisory Council 2010, 1).

Training

The integration and combination of disciplines such as biology, engineering, physics, chemistry, and informatics should be promoted and enter training at all levels – from undergraduate to post-doctoral programs (European Academies Science Advisory Council 2010, 1).

EU competitiveness

Current strategic funding and investment of EU Structural Funds and Programs for innovation must continue and should include research in synthetic biology. Research and development in synthetic biology will be critical for the industrial sector and will also have implications for smaller companies. Therefore the competitiveness of the European Union must be preserved and steel itself for growing international competitiveness (European Academies Science Advisory Council 2010, 2).

Research governance

EU regulators need the support of the scientific community, which has the duty of informing them accurately about challenges and opportunities of synthetic biology. In particular, the issues of biosecurity and biosafety are crucial for the governance of research, and the precautionary principle should prevail until the harmlessness of products and organisms created with synthetic biology is shown. Codes of conducts could be formulated at the global level, or for individual institutions and researchers. Training and education programs should be supported, and the necessary infrastructure should be provided. Regulation should not compromise research or intimidate communication to be transparent. Patenting should be implemented in a reasonable manner so that it neither stifles competition nor slows the translation of research achievements into product development (European Academies Science Advisory Council 2010, 2).

Product regulation

Products and organisms created with synthetic biology (e.g., fuels, chemicals, medicinal products, environmental products) should be treated as products from other sources when it comes to the approval of new products (European Academies Science Advisory Council 2010, 2).

Societal engagement

Accurate and accessible information in lay language should be provided to the broader public in a pro-active manner. It could also be helpful to generate forecasts on the benefits that synthetic biology might bring and on the impact that different regulatory approaches might have. Furthermore, ethical issues should be debated (European Academies Science Advisory Council 2010, 2).

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Annex: List of Participants at the ERASynBio "Workshop on Public Dialogue and Governance of Synthetic Biology"

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