

The European Group on Ethics of science and new technologies (EGE) Opinion on the ethics of synthetic biology

On May 28, 2008 President José Manuel Barroso asked the European Group on Ethics of science and new technologies (EGE) to issue an Opinion on the ethical, legal and social implications raised by synthetic biology. The EGE adopted its Opinion on November 18, 2009.

What is synthetic biology?

Synthetic biology is a new research field within which scientists and engineers seek to modify existing organisms by designing and synthesising artificial genes or proteins, metabolic or developmental pathways and complete biological systems in order to understand the basic molecular mechanisms of biological organisms and to perform new and useful functions. Synthetic biology might have an impact on the following sectors: biofuels, antipollutants, textiles, cosmetics, diagnostic and therapeutic tools, vaccines, drugs food and feed ingredients.

In its Opinion the EGE uses a definition definition of synthetic biology that includes: 1) the design of minimal cells/organisms (including minimal genomes); 2) the identification and use of biological 'parts' (toolkit); and 3) the construction of totally or partially artificial biological systems.

Why synthetic biology should be addressed from an ethical perspective?

In its Opinion the EGE identifies and addresses ethical concerns particularly but not exclusively from the point of view of safety and security. Beyond this, the ethical reflection addresses justice, governance, science and society dialogue, intellectual property and concepts of life. As for other new technologies, synthetic biology must respect the international framework on ethics and human rights and in particular the respect for human dignity, which is conceived as not only a fundamental right in itself but 'the real basis of fundamental rights'. Other ethics principles that have to also be taken into account include, inter alia, the principles of safety; sustainability, justice, precaution, freedom of research and proportionality.

The EGE Opinion:

In its Opinion the EGE proposes a number of specific recommendations on synthetic biology, namely, inter alia:

Safety

The EGE advocates that any use of synthetic biology products should be conditional on meeting safety requirements identified in the Opinion as needing further elaboration. The EGE recommends among other things that the EC initiates a survey on relevant risk assessment procedures in the EU and identify possible gaps in the current regulations and how identified gaps are to be filled; and that a Code of Conduct for research in synthetic biology should be prepared by the EC;

Environmental applications

The EGE recommends among other things that before an organism, fabricated or modified via synthetic biology, is released into the environment, ecological long term impact assessment must be carried out. The results of the study should be evaluated

taking into account the precautionary principle and EU legislation on the deliberate release into the environment of genetically modified organisms (2001/18/EC).

Energy and sustainable chemical industry

The Group proposes that the use of synthetic biology for alternative energy supply in EU Member States would be complementary to the EU renewable energy plan. The EGE also advocates that the protection of consumers' rights is a key factor. The EGE therefore stresses that labelling of specific synthetic biology products, such as cosmetics and textiles, should be explored.

Biomedicine and biopharmaceutical applications

The EGE recommends that further to the application of scientific and legal frameworks, specific ethics considerations have also to be addressed by the competent Authorities (such as EMEA) when drugs and medical products will result from synthetic biology protocols.

Biosecurity, prevention of bioterrorism and dual use

New tools may be derived from synthetic biology for the military sector such as biomaterials or bioweapons. Ethical analysis must assess the goal of security in relation to transparency. In addition, the EGE recommends control mechanisms such as licensing and registering of tools in order to prevent terrorist uses of synthetic biology. The Group also recommends that the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction should incorporate provisions on the limitation or prohibition of research in synthetic biology.

Governance

The existing fragmented regulatory framework may not be sufficient, and the EGE urges the EC to propose and put in place a robust framework for synthetic biology, identifying the relevant stakeholders and indicating their responsibilities. The EGE proposes that the EU takes up the question of governance of synthetic biology in relevant global fora.

Patenting and common heritage

The EGE proposes that debates on the most appropriate ways to ensure the public access to the results of synthetic biology is launched. The EGE stresses that general ethical issues raised by patent applications have to be addressed properly in the patent allocation system. The EU legal patent system defines the EGE as the body to assess ethical implications related to patents. The EGE urges the European Patent Organisation and national patent offices to take account of Article 7 in the EU patent directive 98/44 and implement this article.

Trade and global justice

The EGE recommends that when synthetic biology is discussed at international level, including the WTO, the ethical issues associated to the technology should be addressed. This should be taken into account in the Doha round negotiations. The EGE urges that EU Biosafety standards for synthetic biology products are adopted as minimal standards for EU import-export of synthetic biology products.

Science and society dialogue

The Group asks the EU and EU Member States to take actions to promote public debates and engagement amongst the stakeholders in order to identify main societal concerns in the different areas covered by synthetic biology.

Research

The Group invites the Commission to support basic research in the fields of biology, chemistry, energy, materials science, and engineering, as well as applied and interdisciplinary research, as identified in this Opinion. This should be reflected in the R&D EU research Framework Programmes budget. The Group notes that synthetic biology could lead, in the future, to a paradigm shift in understanding concepts of life. It therefore calls on the Commission to initiate an open intercultural forum to address the issues, to include philosophical and religious input.