

Minutes of the Meeting of the European Group on Ethics in Science and New Technologies

Brussels, 19-20 March 2019

- 1. Approval of the agenda:** yes
- 2. Nature of the meeting:** non-public
- 3. List of points discussed:**
 - Ethics of AI
 - Hearings on gene editing
 - Timing for the upcoming Opinion and Statement
 - Statement on ethics
 - Opinion on Gene Editing and working methods
 - AOB

DAY 1: 19 March 2019

Ethics of AI

The group was updated on the progress towards the AI guidelines and the forthcoming Commission communication on AI. In sum, the text of the revised guidelines is better anchored in the EU Charter and reflects a clear will to respond to the EGE's comments; the current draft Commission communication on AI also incorporates clear acknowledgement of the EGE. Both the Communication and revised guidelines are due to be issued on 8-9 April 2019.

Hearings with Peter Dabrock, German Ethics Council

Peter Dabrock spoke on the governance aspects of gene editing. He explained the links between science and society, for example the impact of the precautionary principle on civil society, trust etc. Making reference to the precautionary principle (Article 191 TFEU), he argued that the application of this principle to CRISPR in an EU context is not contentious. However, wider applications might still be ambiguous. European Environment Agency has widened the precautionary principle from a cost-benefit analysis to a more culturally sensitive approach, including aspects like scientific complexity, uncertainty and ignorance, as well as taking into account the effects of action, as well as inaction.

The speaker referred to recent experiments with monkeys, and explained that these do not pose complex questions from the scientific point of view, and can be addressed within the legal framework governing animal experimentation ethics and the 3Rs (reduce, replace and refine), as the experiments were contained in the lab. However, these experiments raise political interest, as very different fields of application merge.

Referring to the recent moratorium on human germline editing advocated by a number of scientists in Nature, he reminded that in 2017 the German Ethics Council had issued an

opinion calling on the German bundestag and government to set up an international conference on this topic. He stated that international standards are needed and should be monitored by an international agency.

Hearings with George Gaskell, London School of Economics

With the fast pace that the gene editing technologies are developing, there is a wide debate on the appropriate legal and regulatory mechanisms to govern the use of different techniques. George Gaskell referred to the decision of European Court of Justice which has ruled that products of mutagenesis should be treated as GMOs. This understanding was consequently used in the interpretation of the Directive 2001/18/EC. This also implies that the new CRISPR-CAS9 technology should be considered as genetic engineering, falling under the European GMO regulation. He informed that a majority of NGOs welcomed this ECJ ruling. He highlighted the public opinion dimension, and its due consideration in the formulation of a regulatory framework for gene editing. Currently, information shedding light on public views on gene editing is limited. He referred to existing surveys indicating that public acceptance tends to depend on the *use* of the technology in question rather than the technology itself (e.g. whether for adult or pre-natal application, or for therapeutic or enhancement purposes). The risk that the precautionary principle be used as a political tool and not a scientific principle was highlighted.

DAY 2 – 20 March 2019

Timing for the upcoming Opinion and the Statement

There was a discussion and reflection on the optimal timeline for the delivery of the Opinion on Gene Editing, taking into account the forthcoming end of the current Commission mandate, and the process of institutional renewal in the autumn. The risks of delivering an Opinion during the hiatus in the Commission's activities (from June to end September-October) was discussed, underscoring the risk of 'damp squib' if issued before the institutional renewal. The question in essence: should the EGE deliver its Opinion before the summer or to the incoming Commission in the autumn. The latter option was seen to have the advantage of eliciting buy-in of the new Commission. To take into account: this timing would also refine the scheduling of the roundtable and would dovetail well with the development of an EGE Statement pertaining to the role of ethics in the EU.

Statement on ethics

Further discussion took place on the proposal put forward during the February EGE meeting for the Group to develop a short reflection on issues surrounding the role of ethics in the EU. This was discussed again and extensively supported at the March meeting. It was agreed that this was a high and timely priority, that it could address the place of ethics in a European context, how it is integrated into policy-making and innovation-making, as well as reflections on what it means to 'do ethics' in this context (e.g. the nature of ethical expertise). It should be both accessible and contain substantive elements on the nature of ethics for policymaking. If this statement is developed in parallel to the Opinion on Gene Editing, with delivery for the autumn, the timing would be particularly felicitous to feed into the process of institutional renewal of the Commission.

Opinion on Gene Editing and working methods

The work was built on the ‘working groups’ dynamic initiated at the previous EGE meeting. The morning of the second day was spent in a ‘break out’ session, with three working groups (on gene drives; human gene editing; and gene editing of non-human primates) working in parallel in order to delve deeper into those specific issue areas: identifying key sub-themes, potential open questions, and conceptual considerations. The three groups reported back during the afternoon session. It was agreed that this working methodology has been very successful and merits being repeated during future meetings. Each working group will produce a half-page summary of its discussions ahead of the April EGE meeting.

AOB

- The Group shortly discussed the frequency of the Plenary meetings, with the importance – and difficulty – for members to fully attend all meetings, and it was agreed to learn from and assess this year’s arrangement going forward.
- The Group was informed about ESOF 2020 – it will take place on 5-9 July 2019 in Trieste, Italy. The potential participation of the EGE was considered. The call for proposals for sessions is open from 13 March to 15 June 2019. The slogan for ESOF 2020 will be ‘Freedom for Science, Science for Freedom’.

4. Conclusions/recommendations/opinions

- The following working Groups were established:
 - Gene editing in non-human primates: Anne Cambon-Thomsen (convener), Jeroen van den Hoven, Andreas Kurtz
 - Gene editing in plants: Julian Kinderlerer (convener), Andreas Kurtz, Herman Nys
 - Somatic human gene editing: Eugenijus Gefenas (convener), Ana Sofia Carvalho, Carlos Casabona
 - Germline gene editing in humans: Nils-Eric Sahlin (convener), Andreas Kurtz, Carlos Casabona, Laura Palazzani, Anne Cambon-Thomsen, Emmanuel Agius
 - Gene drives: Barbara Prainsack, Nils-Eric Sahlin, Julian Kinderlerer

It was highlighted that the working groups remain open for other members to join, and other groups may still be created as the process evolves. The role of convener was clarified (i.e. distinct from that of rapporteur, a coordinating role rather than about single-handed drafting).

5. Next steps

- Each of the working groups will prepare a short first input for the Opinion based on the discussion (half-page summary) and the secretariat will outline the cross-cutting issues based on the working groups (half-page summary).
- Jeroen van den Hoven and Jim Dratwa will prepare a first outline for discussion for the upcoming Statement on the role of ethics.

6. Next meeting

10-11 April 2019, Brussels

7. List of participants

Day 1: Emmanuel Agius, Anne Cambon-Thomsen, Ana Sofia Carvalho, Eugenijus Gefenas, Julian Kinderlerer, Andreas Kurtz, Herman Nys, Laura Palazzani, Barbara Prainsack, Carlos Maria Romeo Casabona, Nils-Eric Sahlin, Marcel Jeroen Van den Hoven ; Peter Dabrock, George Gaskell ; Florence Dose, Jim Dratwa, Louiza Kalokairinou, Johannes Klumpers, Maija Locane, Joanna Parkin.

Day 2: Emmanuel Agius, Anne Cambon-Thomsen, Eugenijus Gefenas, Julian Kinderlerer, Herman Nys, Barbara Prainsack, Carlos Maria Romeo Casabona, Marcel Jeroen Van den Hoven ; Florence Dose, Jim Dratwa, Louiza Kalokairinou, Maija Locane, Joanna Parkin.