

# **Minutes of the 16<sup>th</sup> plenary meeting of the European Group on Ethics in Science and New Technologies**

Brussels, 27-28 June 2019

## **1. Approval of the agenda and minutes**

## **2. Nature of the meeting: non-public**

## **3. List of points discussed:**

- Updates from the Commission and EGE members
- Discussion on Gene Editing Opinion (draft chapters on humans, animals, plants and gene drives)
- Discussion on Gene Editing Opinion (draft texts on decision-making and risk; communicating science)
- Statement on Ethics
- IDBEST 2019 and EGE Roundtable on Gene Editing
- AOB

## **DAY 1: 27 June 2019**

### **Updates from the Commission and EGE members**

- An update was provided on the political transition underway following the European elections, including forthcoming decisions concerning the new leadership of the Commission, Council and Parliament.
- An update was provided concerning the development of an EU framework on AI governance. A broader discussion followed on wider trends surrounding the development of AI ethics globally, touching on funding, stakeholders and structural conditions influencing this work.

The discussion then moved on to the presentation of the preliminary Opinion structure including the drafting inputs circulated by email ahead of the meeting.

The meeting was chaired and moderated by Christiane Woopen, Chair of the EGE.

### **Discussion on Gene Editing Opinion**

#### **➤ Chapter on gene editing in humans**

Discussion took place on the Chapter on Human Gene Editing.

Feedback was given on the draft introductory text as well as on key points to discuss within the chapter more broadly. Comments included:

- Clarifying scientific descriptions and adapting language;
- The need to highlight more clearly in the introduction the ethical risks and epistemic uncertainties of the technology.
- The possibility to distinguish more clearly between somatic and germline gene editing, and the ethical issues associated with both (e.g. enhancement and justice issues linked to somatic gene editing and safety and dignity issues linked to germline).
- The relative usefulness of mitochondrial transfer as an example in this context.
- The need to introduce more clarity over the issue of safety and the notion of ‘safe enough’.
- Issues surrounding research on embryos (including the usefulness/purpose of such research when there is no prospect of implantation).
- The existence of ‘alternatives’ as a core question for this chapter.

A set of exchanges were held on the specific EGE contribution to the debate on human gene editing and touched on:

- The European regulatory framework (with reference to the distinction accorded to medicines based on gene/cell therapy in the Clinical Trials Directive and in protocols of the European Medicines Agency).
- On germline gene editing, the ‘safe enough’ criteria (while taking into account the complex and often context-dependent nature of this question).
- On somatic gene editing, issues associated self-administration.
- The distinct features of gene editing that distinguish it from other technologies (e.g. low threshold - cheap, more targeted) as a lens for examining the ethical implications of gene editing.

#### ➤ **Discussion on Gene Editing Opinion – Chapter on gene editing in animals**

During discussion on the Chapter on Gene Editing in Animals, feedback was given on the draft text on the ‘3Rs’ principle underpinning the use of animals in scientific research. Comments touched on:

- Whether the ‘3Rs’ principle would or should be reconfigured as applied to gene editing.
- The impact of gene editing research on the implementation of the 3Rs principle (possibility to refine experiments, less wastage, welfare compliant techniques, potential use of organoids as alternative models, yet also an anticipated growth in animal experiments involving CRISPR).
- The thought experiment of applying the 3Rs principle to humans in medical research (conclusion that inapplicable due to very different configurations of human and animal research experiments).
- The question of which animal species warrant special ethical attention or occupy distinct moral categories. E.g. pigs, which will be overwhelmingly affected by xenotransplantation. It was highlighted that the special focus on primates draws upon several factors indicating proximity to humans, including brain research and scientific studies which indicate strong similarities to the functioning of human brains.

➤ **Discussion on Gene Editing Opinion – Chapter on gene editing in plants**

Discussion took place on the draft chapter on Gene Editing in Plants. Feedback given on the draft text included:

- The need to distinguish between the precautionary principle and a precautionary approach.
- The need to lay the ground for conclusions and recommendations relating to EU legislation on GMOs.
- The need to nuance language on biodiversity (and highlight the limits of human knowledge of biodiversity).

➤ **Discussion on Gene Editing Opinion – Chapter on gene drives**

Discussion took place on the draft chapter on gene drives. Feedback given on the draft text centred on the need to clarify the table classifying gene drive levels of human intervention and discussions on issues of terminology.

The conclusions at the end of the day indicated that **Chapters 3 and 4** were more advanced and in very good shape already, that **Chapter 2** was in the pipeline with very promising elements discussed, and that particular effort and attention were necessary for **Chapter 1**.

**DAY 2 – 28 June 2019**

**Discussion on Gene Editing Opinion (texts on decision-making and risk; communicating science)**

Discussion took place on the draft texts on ‘decision-making and risk’, and ‘communicating science.’ It was highlighted that these texts were not for direct inclusion in the opinion, but rather as elements to feed the reflection in relation to cross-cutting issues or other sections of the Opinion.

Exchanges on the first text touched on issues including the precautionary principle, on processes of weighing risk, and on expertise versus the knowledge of lay people (including ‘lay experts’ living with a hazard).

Discussion on the second text focused on questions of deliberative democracy, science communication and trust (communication not only as providing information but as contextual sense-making and part of regulatory approaches).

**Statement on Ethics**

A discussion was held on the Statement on the role of Ethics in policymaking and international governance. In order to further develop and refine the draft outline, members

were asked to suggest the most important question/issue/argument that they believe should feature in the statement. Contributions included:

- The privatisation of research agenda setting and the increasing influence of corporate and quasi-monopolistic actors in shaping ethics and research.
- Epistemic questions in relation to ethics: how do we handle the knowledge we have and the knowledge we lack.
- Geopolitical pressures and the need to rationalise, justify and promote the European value system.
- Avoiding ethics elitism (not about who gets to do ethics but about how ethics is done) while addressing questions of legitimacy and expertise.
- A European and international ethics mapping (role of different institutions e.g. European Court of Justice and protection of EU values).
- Interplay between ethics, science, law and politics.
- The need for new institutions and communications methods (and implications for the EGE).

### **IDBEST and the EGE Roundtable on Gene Editing**

A discussion was held on the EGE public roundtable and International Dialogue on Bioethics and Ethics in Science and Technologies (IDBEST) scheduled for 16 & 17 October 2019. The rationale of these events was recalled and the format presented, and the Group appreciated and approved. Suggestions for speakers and participants were put forward by members.

### **AOB**

- The EGE presence at ESOF 2020 was discussed with agreement that Anne Cambon Thomsen will put together a panel proposal on gene editing with the involvement of EGE members and Christiane Woopen and Jeroen van den Hoven will put together a session proposal on the role of ethics.
- It was proposed to invite Dr. Markus Frischhut to speak with the group.

## **4. Conclusions/recommendations/opinions**

The following allocation of drafting tasks were discussed and confirmed:

### **Humans:**

1.1 Introduction : Christiane will work on the introduction and Carlos & Herman on the legislative framework

1.2 Specific issues :

- Christiane will work on *Distinction between prevention therapy, enhancement / Status of “materials” / Enhancement, disenchantment*
- It was asked if Siobhan might prepare 2 paragraphs for the *Distinction between basic, preclinical and clinical research*

- Emmanuel will work on *Justice Issues*
- Ana on *Safety*

**Animals:**

2.1 Introduction : Anne will prepare it and Herman will prepare the legislative framework part

2.2 Specific issues : will be prepared by Anne & Jeroen (adding elements on organoids); Ana will work on the 3Rs part

**Plants:**

Nils-Eric will go through the text

**Gene drives:**

Barbara will revise on basis of the comments, send to Nils-Eric and then share with everybody

**Zooming out/cross-cutting questions of ethics and governance building on the above:**

All are invited to identify, from the chapters above, the key cross-cutting issues

**5. Next steps**

- Members to send the drafting inputs to the whole group by 17<sup>th</sup>-19<sup>th</sup> July 2019. This will be shared in a consolidated document for the working session.

**6. Next meeting**

Working session on 24-25 July 2019, Brussels

Plenary meeting on 11-12 September 2019, Brussels

**7. List of participants**

**Day 1:** Emmanuel Agius, Anne Cambon-Thomsen, Ana Sofia Carvalho, Carlos Casabona, Eugenijus Gefenas, Julian Kinderlerer, Herman Nys, Barbara Prainsack, Laura Palazzani, Nils-Eric Sahlin, Marcel Jeroen Van den Hoven, Christiane Wopen; Florence Dose, Jim Dratwa, Johannes Klumpers, Joanna Parkin.

**Day 2:** Emmanuel Agius, Anne Cambon-Thomsen, Ana Sofia Carvalho, Carlos Casabona, Eugenijus Gefenas, Julian Kinderlerer, Herman Nys, Laura Palazzani, Barbara Prainsack, Nils-Eric Sahlin, Marcel Jeroen Van den Hoven, Christiane Wopen; Florence Dose, Jim Dratwa, Joanna Parkin.