Minutes of the 15th Plenary meeting of the European Group on Ethics in Science and New Technologies

Brussels, 22-23 May 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 structure
- Work in Working Groups
- Reporting from the Working Groups
- Discussion on revised structure and allocation of work
- Statement on Ethics
- AOB

DAY 1: 22 May 2019

Updates from the Commission and EGE members

- An update was provided concerning the development of an EU framework on AI
 governance, including the launch by the European Commission of a piloting phase
 involving stakeholders to test the key requirements developed by the AI High
 Level Expert Group. Attention was also drawn to the wider panorama of different
 sectoral groups and mechanisms working on AI.
- The Group was informed of the current political transition affecting the EU institutions underway following the European elections. A new political leadership of the European Commission is expected (though not guaranteed) to be in place by the autumn of 2019.
- Members were informed of the upcoming renewal of EGE membership. They were reminded that while the legal basis of the Group provides for a 5 year mandate, individual members are appointed for a 2.5 year mandate. Membership of the EGE is limited to three terms and members who are not eligible for renewal cannot be renewed but will form part of a wider EGE alumni network.

Discussion on Gene Editing Opinion structure

The Secretariat shared a draft preliminary structure, put together on the basis of the written summaries of working groups and plenary discussions. The discussion on the preliminary structure covered the following points:

• Ethics should be woven throughout the opinion, with key ethical stakes highlighted from the outset, specific ethics issues highlighted in each 'issues' chapter and cross-

- cutting ethical questions explored at the end. This overarching ethics chapter should not be drafted until the 'issues' chapters are developed.
- How to deal with the legislative framework? It was agreed that legislation should be touched upon as part of each 'issues' chapter. This should not constitute a mapping but rather make use of examples to highlight the state-of-play and in particular existing gaps or inconsistencies.
- Modifications to the structure, in particular merging sections to create one issues chapter on 'animals'. It was agreed that 'animals' warrant a self-standing chapter (e.g. encompassing aspects of xenotransplantation, and specific regulatory developments FDA's decision to regulate animal gene editing under GMO legislation).
- What added-value does this group bring to the topic: the bigger picture perspective, the EU angle (through focusing mainly on those areas where the EU has competence) and through capturing new, little explored issues (e.g. enhancement but also disenhancement, biodiversity but also human diversity). By examining both the key questions for policymaking but also re-visiting the concepts, key reference points which frame this debate.
- Use of 'key message' boxes and chapter summaries at the end of each section to guide readers through the report.
- The need to acknowledge and name the potential tensions of a 'human-centred' approach, tendency towards speciesism.
- Elements missing from the existing structure, e.g. issue of disenhancement, human diversity.

Work in Working Groups

The Group then split into the following working groups for a breakout session:

- o Human germline and somatic gene editing;
- o Gene editing in plants

The Working Groups were tasked to identify the key ethics issues under the heading of their group; the key ethical questions at stake; structuring considerations for the Opinion; and issues that link to other areas of the opinion (cross-cutting themes).

Reporting from the Working Groups

Members reported on the key outcomes of working group discussions (refer to written summaries on human germline and somatic gene editing and gene editing in plants circulated 29 May 2019).

DAY 2 - 23 May 2019

Work in Working Groups

The Group split into the following working groups for a breakout session:

- o Gene editing in animals (including non-human primates);
- o Gene drives and biodiversity

The Working Groups were tasked to identify the key ethics issues under the heading of their group; the key ethical questions at stake; structuring considerations for the Opinion; and issues that link to other areas of the opinion (cross-cutting themes).

Reporting from the Working Groups

Members reported on the key outcomes of working group discussions (refer to written summaries on gene editing in animals and on gene drives circulated 29 May 2019).

Discussion on revised structure and allocation of work

A new preliminary structure, integrating revisions proposed by the group, was presented and discussed.

Discussion focused on the structuring of the 'issue' chapters (Humans, animals, plants, gene drives). It was underlined that these should include the following elements:

- What are we talking about
- What is happening in this field
- Summary of current ethical debates
- Reference to relevant legislative framework (gaps, fit-for-purpose?)
- What are we interested in, what is our distinctive approach, EGE angle

An exchange then took place of cross-cutting themes identified during the working group discussions, highlighting issues of: safety, justice, biodiversity, humanness, autonomy.

A first set of drafting components were allocated to individual members.

Statement on Ethics

The group discussed the rationale, conceptual boundaries of the upcoming Statement, as well as the timeline and context in which it will be published. A preliminary outline developed by the Secretariat and Jeroen van den Hoven was presented.

The subsequent discussion highlighted the following important elements to be taken into account in the Statement:

- Evolution of ethics in Europe (becoming increasingly proceduralised, focusing on technical, legal violations).
- Programmatic rather than retrospective, focus on current cross-roads and how to go forward (forward-looking).
- EU as a moral laboratory, ethics experiment, including the approach to dealing with value conflicts.

- Need to avoid ethics elitism (not about who gets to do ethics but about how ethics is done).
- Increased need, relevance of ethics (crisis of values).
- Ethics inflation, questions of legitimacy and expertise.
- Public engagement and acceptance, 'ethics by the people for the people'?

A discussion on the timing of the statement's release highlighted the 10th anniversary of the EU Charter of Fundamental Rights and the beginning of the new Commission mandate in late 2019.

AOB

- The Secretariat requested members to carefully check their reimbursement of travel and accommodation expenses for errors.
- The calendar for 2019 and 2020 was discussed. The need for an additional writing meeting (focused on working sessions) was highlighted and confirmed for July.

4. Conclusions/recommendations/opinions

The following allocation of drafting tasks were assigned:

- Section 1.1. Introduction to Humans: Andreas Kurtz (Siobhan O'Sullivan providing input on the EGE angle, approach to classic categories and distinctions)
- Section 2.1. Introduction to Animals: Anne Cambon Thomsen (excluding legal aspects)
- Section 3.1. Introduction to Plants: Julian Kinderlerer
- Section 4.1. Introduction to Gene Drives: Barbara Prainsack with input from Nils Eric Sahlin
- Julian Kinderlerer will produce a succinct draft of the plants chapter, building on the working group elements.
- Herman Nys will look at legal aspects for the introductory sections, drafting what is necessary in that regard for the Animals chapter, also drawing on Louiza's previously prepared legal analysis paper.
- Jeroen van den Hoven will draft text for section 2.2. (Specific issues on animals) on humanness, humanisation and its limits, etc. with particular reference to NHPs.
- Ana Sofia Carvalho will draft the "3Rs+" section for the Animals chapter.
- Nils Eric will draft a section on general aspects of risk and safety to be inserted eventually into the relevant chapters (possibly/probably the cross-cutting issues chapter).

5. Next steps

- Members to send drafting inputs to the EGE Secretariat and EGE Chair by 14th June 2019
- Secretariat to compile and circulate collated inputs ahead of the June EGE meeting.

6. Next meeting

27-28 June 2019, Brussels

7. List of participants

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

Day 2: Emmanuel Agius, Anne Cambon-Thomsen, Ana Sofia Carvalho, Carlos Casabona, Eugenijus Gefenas, Julian Kinderlerer, Andreas Kurtz, Herman Nys, Siobhan O'Sullivan, Laura Palazzani, Barbara Prainsack, Nils-Eric Sahlin, Marcel Jeroen Van den Hoven, Christiane Woopen; Jeremy Bray, Florence Dose, Jim Dratwa, Louiza Kalokairinou, Joanna Parkin.