EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES

Statement on Gene Editing

In 1975 an international conference (the Asilomar Conference) was convened to consider the implications of the new technologies that were then becoming available to modify the genome of organisms through the insertion or deletion of segments of DNA. At that time it was only possible to genetically modify microorganisms. That conference instigated a moratorium on the genetic modification of humans – germline modification – and the interpretation of the discussions led to significant regulation of all forms of genetic 'manipulation', whether the organisms were modified and used in containment, or (later) when released into the environment.

The technology has changed very significantly over the last 40 years as we have learned to understand more of the processes by which genetic material is altered in microorganisms, plants and animals and it is now possible to precisely insert or delete sequences of DNA in situ. This forty year old global consensus on prohibiting human germline gene modification has come under significant pressure in 2015.

In February of this year, the UK parliament voted to approve regulations, following a rigorous debate, that permit the clinical use of mitochondrial replacement techniques. While mitochondrial gene transfer does not involve gene editing techniques, it could be argued that the approval of this limited form of germline gene modification did cross a Rubicon. There has been a rapid development in gene editing technologies in the last five years, and the announcement in April 2015 of genome editing of non-viable human embryos using CRISPR-Cas9 demonstrated that human germline gene modification has moved out of the realm of the theoretical, and clinical applications are becoming feasible. Techniques such as CRISPR-Cas9 can modify genomes of living organisms at *precise* locations in more *specific* ways and more *cost-effectively* than previously possible. This is already challenging the international regulatory landscape for the modification of human cells in the near to medium term.

Gene editing of somatic cells is currently in clinical development for a variety of conditions. The editing of genomes in human somatic cells certainly raises ethical questions, but is distinct from germline gene modification, in that changes in the gene(s) do not persist beyond a single generation.

As to human germline editing, the EGE is of the view that there should be a moratorium on gene editing of human embryos or gametes which would result in the modification of the human genome.

Germline gene modification is still in its infancy and there are many significant technical hurdles to be overcome before clinical applications become a viable reality. The question of whether, if ever, germline engineering of human embryos would be precise enough to guarantee a successful outcome and would be acceptable to the public is still an open one.

The more pressing question for policy makers at this moment is whether germline genome editing technology research should be suspended, under which conditions it could proceed, and in this respect varying views have been articulated. The EGE is of the view that this question warrants careful consideration, given the profound potential consequences of this research for humanity. It has been suggested that research with a clinical application, as distinct from basic research, should be subject to a moratorium. We would be cautious in terms of whether such a clear-cut distinction can be made between basic and translational research. Likewise, the blurring of the lines between clinical applications in pursuit of therapeutic or enhancement goals (albeit the ethical issues pertaining to each may be different), must be considered.

The EGE considers that deliberation regarding the acceptability and desirability of gene editing will require inclusive debate which extends to civil society where diverse perspectives and those with different expertise and values can be heard. This cannot be left to select countries, social groups or disciplines alone. The EGE cautions against reducing the debate to safety issues and the potential health risks or health benefits of gene editing technologies. Other ethical principles such as human dignity, justice, equity, proportionality and autonomy are clearly at stake and should be part of this necessary reflection towards the international governance of gene editing. Moreover, ethical consideration needs to be given to all applications of gene editing, including the non-human applications. It is likely that many of the practical applications of gene editing will occur in the environmental sphere and will have significant implications for the biosphere.

For some members of the EGE, human germline gene modification for reproductive purposes cannot be ethically justified; they therefore call for upholding the prohibition that reflects, among others, Art. 3 of the European Charter of Fundamental Rights; because of the blurring lines between basic and applied research, some also call for a moratorium on any basic research involving human germline gene modification until the regulatory framework is adjusted to the new possibilities. For other members of the EGE, there may be positions worth considering which would justify continued research. As is the case in the scientific community at large, diverse views are represented in the group. We call for a broad public debate on these issues and are convinced that the EGE will make a useful contribution to these deliberations. In view of the above considerations, we urge the European Commission to request that the EGE succeeding the current group, as a matter of priority, consider the inextricably linked ethical, scientific and regulatory issues pertaining to germline and somatic cell gene modification.

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