EUROPEAN COMMISSION
DIRECTORATE-GENERAL
JOINT RESEARCH CENTRE
Directorate F - Health, Consumer & Reference Materials
Unit Head "Knowledge for Health & Consumer Safety"

1. JRC-ICGEB Joint Expert Meeting

2. Genome Editing and Related Technologies: Scientific and Regulatory Considerations

Background

"Genome editing" is a recent technology that can be considered as ultramodern microsurgery on genes. It is an innovative technology that is booming in molecular biology laboratories; in 2015 experts considered it the "breakthrough of the year" and, given its precision, low costs and ease of use, it has become the model of the "democratisation of science".

Genome editing helps us to understand complex biological processes and can - for example - be used to directly correct genetic disorders in affected tissues and cells to cure diseases that cannot be treated (easily) with traditional therapies.

Genome editing can also be used to modify, correct or add new and valuable traits in animals or plants, for example. These are the major providers of nutrition for the world population and any improvement in nutritional value and resilience would be welcome in many species. Successful proof of concept applications have already been reported in pig, goat and cattle as well as in several agricultural crops, such as mildew induced resistance in wheat.

The ease of use, accuracy and efficiency of genome-editing tools has led to their broad adoption in research, as well as to proof of concept applications in gene therapies involving non-reproductive (somatic) cells.

It is also possible to deploy genome editing in human germline cells (sperm and eggs) as well as in early embryos. Many stakeholder groups are debating this issue, which, for some, remains a line not to be crossed whereas for others it provides possibilities for improving the human condition through the repair of deleterious genetic mutations. The precise effects of genetic modification on an embryo may be unknown until after birth and this raises concern about unintended effects that may not surface for years.

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In general, there are serious concerns regarding the ethical and safety implications of human germline cell research. There is also concern on the negative impact this could have on important work involving the use of genome-editing techniques in non-reproductive cells and thus on genome-editing work in general.

When genome editing (and related technologies) is applied to living cells, the result often leads to the creation of a novel organism, capable of replicating. These organisms may be placed on the market as products, or as parts of products, that may be novel and are unknown to society.

It is standard practice, before these products are placed on the market, or before they are released into the environment, that a risk assessment is carried out.

The situation with regard to genome editing appears similar to the issue of genetically modified organisms where certain techniques applied to living, replicating organisms may result in genetically modified products that are risk assessed on a case-by-case basis before they are released into the environment or placed on the market.

However, there has been no decision yet as to whether products resulting from genome editing should be treated in the same manner as GMOs or whether another regulatory framework is to be applied.

Format

The proposed workshop aims to bring together stakeholders from academic, industrial and governmental organisations and will have the following format:

- Section one: The technology involved and its future developments;
- Section two: Present and future innovations and their potential impact on society (health, agriculture, industry, …);
- Section three: Ethical concerns;
- Section four: Possible role of the regulator.

A final, fifth section will be dedicated to formulating conclusions and recommendations.

Expected Outcome

- Anticipate the technology landscape and the associated expected innovations;
- Create a Directory of possible hazards associated with the application of the technology;
- Provide an evaluation of related ethical concerns;
- Establish a Catalogue of policy options;