



“Genome Editing: Scientific opportunities, public interests, and policy options in the EU”

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New EASAC report on genome editing advises European policy-makers on how to approach groundbreaking research on plants, animals, microbes and humans

A new report by the European Academies’ Science Advisory Council on genome editing gives advice to European policy-makers on groundbreaking research involving genome editing and plants, animals, microbes and patients. In this report, “Genome Editing: Scientific opportunities, public interests, and policy options in the EU”, EASAC emphasises that policy-makers must ensure that the regulation of applications is evidence-based, takes into account likely benefits as well as hypothetical risks, and is proportionate and sufficiently flexible to cope with future advances in the science.

Present knowledge gaps and uncertainties mean that more basic research will be necessary. EASAC expects that research advances will fill many of the current knowledge gaps and that progressive refinement of genome editing tools will further increase their efficiency and specificity, thereby reducing off-target effects. EASAC anticipates that the fast pace of change in research and innovation will continue.

EASAC’s new report addresses several areas in which genome editing occurs, including plants, animals, micro-organisms, human cell genome editing as well as gene drive applications for vector control. EASAC also makes recommendations regarding cross-cutting issues, including engaging with the public.

A few highlights from EASAC’s conclusions include:

- Regarding **plants**, EASAC advises EU regulators to regulate the specific agricultural trait/product rather than the technology by which it is produced.
- As genome editing pertains to **animals**, livestock breeding in agriculture should also be governed by the same principle as proposed for plant breeding – to regulate the trait rather than the technology and be open and explicit about what is being done.
- With regard to the modification of animals to serve as a source for **xenotransplantation**, EASAC urges European regulators to prepare for the new opportunities coming into range.
- For **gene drive** applications, for example to help in control of disease vectors, EASAC supports proposals for a phased approach to research that will enable responsible development and allow sufficient time to consider what changes might be needed in regulatory frameworks.
- Genome editing in **microbes** does not raise new issues for regulatory frameworks and is currently subject to the established rules for contained use and deliberate release of GMOs.

Given the wide range of potential applications, including pharmaceuticals and other high value chemicals, biofuels, biosensors, bioremediation and the food chain, it is important to consider these in the EU strategy for innovation in the bioeconomy.

- Regarding **human cell genome editing**, intensive basic and clinical research is needed and should proceed subject to appropriate legal and ethical rules and standardised practices. Clinical use of somatic cell gene editing should be rigorously evaluated within existing and evolving regulatory frameworks. Clinical use of germline interventions (that would be heritable) poses difficult issues and it would be irresponsible to proceed until and unless the relevant scientific, ethical, safety and efficacy issues have been resolved and there is broad societal consensus.

EASAC urges the policy community as well as scientists to continue their efforts to promote **public engagement** with the important research advances and their societal implications. It is important for both policy-makers and scientists to build trust with the public. Public engagement will also require greater investment in social science to better understand how to improve.

Global justice is also a crucial element to consider. There may be risk of increasing inequity and tension between those who have access to the benefits of genome editing applications and those who do not, although the widespread adoption of the technique might facilitate the sharing of benefits. It is also vital for EU policy-makers to appreciate the consequences, sometimes inadvertent, of EU policy decisions on those outside the EU.

EASAC is formed by the national science academies of the EU Member States, Norway and Switzerland, to collaborate in giving advice to European policy-makers. EASAC provides a means for the collective voice of European science to be heard. Through EASAC, the academies work together to provide independent, expert, evidence-based advice about the scientific aspects of European policies to those who make or influence policy within the European institutions.

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