ACHIEVING THE POTENTIAL OF GENOME EDITING

The perspective of the European Biotech Industry

EuropaBio®

The European Association for Bioindustries

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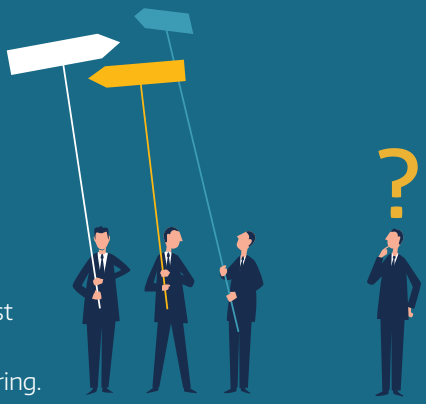
The European Union faces an opportunity to create headroom for innovation and continued investment for the future by fostering and guiding forward a major scientific breakthrough - genome editing.

Genome editing is an umbrella term for a range of tools[1] that enable precise changes to the genome of an organism. Applied worldwide by researchers in academia, governmental research institutions and industry, these innovations represent a promising next step in research towards beneficial uses in medicine, agriculture and the bio-economy aimed at addressing some of society's grand challenges.

While researchers, academia, industry and regulatory authorities have in-depth understanding of genome editing in terms of the underlying science and resulting benefits and challenges, this knowledge has not yet been fully passed on to the general public.

To help respond to this need, EuropaBio, the voice of the biotech industry, has developed this paper to bring the latest views from the developers and users of genome editing tools and applications.
This paper seeks to support the ongoing discussion about how to increase the public understanding of these tools and the solutions that come with them, as well as how to best develop any needed regulatory policies to enable their potential.



Public engagement and regulatory clarity will help ensure that Europe, together with the rest of the world, can reap the great societal and economic benefits that genome editing can bring.

[1] Genome editing methods allow for precise changes at targeted sites and include inter alia ODM (oligonucleotide directed mutagenesis), and a range of site directed nucleases (SDNs) such as CRISPR-Cas (clustered regularly interspaced short palindromic repeats) and TALEN (transcription activator-like effector nucleases) and ZFN (Zinc Finger Nucleases).

HOW TO ACHIEVE GENOME EDITING'S POTENTIAL

EuropaBio calls upon European decision-makers to create platforms to ensure consumer confidence and to provide regulatory clarity to enable innovation for developing products by genome editing methods.

To this end, EuropaBio calls for:

- an inclusive, fact-based platform for dialogue, information sharing and trust building to be set up by the European Commission that brings together the EU Member States, industry, public researchers, academia and civil society;
- a risk-proportionate, predictable, science-based and non-discriminatory application of existing policy approaches allowing innovation to benefit European society and the environment.

We stand ready to contribute to these efforts with our broad expertise in genome editing as it applies to healthcare, bio-economy and agriculture.

1

CURRENT AND FUTURE DEVELOPMENTS ENABLED BY GENOME EDITING

Researchers in public and private institutions across Europe and the globe have embraced genome editing because it is precise, efficient, versatile and provides ample opportunities to develop new and improve existing processes and products in a range of applications including:

- Healthcare and medicines;
- The bioeconomy;
- Plant and livestock breeding.

All these will bring great benefits to society and the natural environment. In certain cases, genome editing makes it possible to obtain products comparable or indistinguishable from those produced by natural processes and conventional techniques, such as mutagenesis.

Genome editing presents many potential fields of application, such as:

- The development and production of medicines, therapies, and diagnostic agents;
- Vaccines that can treat many harmful diseases;
- Bio-based chemicals that can substitute for non-renewable inputs;
- Bio-energy that can reduce environmental impacts;
- Nutrient-enriched and stress-resilient crops that help in the fight against food waste and food shortages.

Genome editing has already been beneficially applied in:

- The design of therapeutic tools for recognising specific viral DNA and eradicating HIV proviruses;
- The production of bio-based chemicals, like lactic acid and succinic acid;
- Substituting many of the traditional petrochemical building blocks (bio-refining);
- The cultivation of non-bruising potatoes – improving yields and reducing food waste.

2

REGULATORY CLARITY ESSENTIAL TO SECURE TRUST, INNOVATION, JOBS, INVESTMENT AND TRADE

Over the past decade, the European Commission[2] and EU Member States' regulatory[3] and scientific[4] bodies have been following and closely analysing the development of genome editing tools and applications. In particular, whether the EU framework regulating the use of existing methods for genetic modification[5] applies to products produced by means of genome editing, has been a subject of continuous assessment, albeit without coming to a conclusion on policy.

Regulatory clarity on genome editing is increasingly being established across the globe. In Europe, the decision-makers are being urged to step up their discussion to allow for innovation to happen in all relevant areas of application.

[2] New techniques in Agricultural Biotechnology, High Level Group of Scientific Advisors. Explanatory Note 02/2017, European Commission Scientific Advice Mechanism (SAM),

[3] New Techniques Working Group: Final Report, 2012

[4] EFSA Scientific Opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function (2012) EFSA Journal 10(10):2943

[5] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms.

3

CONSIDERATIONS FOR DEFINING THE BEST PATH FORWARD FOR EU SCIENTISTS, BUSINESSES, PATIENTS, AND CONSUMERS

Guided by the needs of society and supported by the science, EU decision-makers should engage with public and private researchers in communicating to their citizens on the uses of these tools hence raising societal awareness of the benefits. It should be recognised that with needed medical breakthroughs, improved food and feedstuffs and industrial production methods, and products that are environmentally beneficial, genome editing is a vital part of securing Europe's place as a global leader in science, innovation and competitiveness.

Only a proportionate, predictable, fit-for-purpose and science-based policy approach, providing equal regulatory treatment to equivalent products, will enable the tremendous potential of genome editing to benefit citizens, the economy and the environment.

Finally, both public and private ventures applying genome editing in various areas should continue working towards enhancing the precision and efficiency of these tools by strictly abiding by ethical codes for conducting responsible research.

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