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EFB GM STATEMENT

EUROPEAN FEDERATION OF BIOTECHNOLOGY'S VIEW ON BENEFITS OF GENE EDITING

Below descriptions and explanations are intended as information around the latest ruling of the European Court of Justice (CJEU) in Case C-528/16 on gene editing technologies and the impact it will have on innovation in the space of biotechnology in Europe. Our hope is that the information can be used in rallying support from researchers around Europe and to explain to politicians why the legislation on which the ruling is based will need revision and exemption for forms of gene editing technologies that do not change the inherent genetic traits of an organism.

On July 25 the Court of Justice of the European Union issued a judgement in Case C-528/16 on new breeding techniques. Per this ruling the use of any gene editing on an organism puts the organism in scope of GM regulation. Furthermore, it was stipulated that any changes resulting from classical breeding and mutagenesis techniques e.g. irradiation or chemical induced spontaneous mutations also result in making an organism GMO, but they are in effect exempted from the regulation.

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GENE EDITING

Gene editing is a term used for precision mutagenesis of an organism. Gene editing generally comes in one of two forms:

"Gene editing is a term used for precision mutagenesis of an organism."

1. Directed cuts in the genome resulting in mutation through the cells repair system (known as SDN1):

The gene editing components cuts the DNA in a very specific place but leaves it to the cells native repair system to repair the DNA and introduce a random mutation similar to the process in nature.

2. Transgene:

A designed DNA sequence is inserted at a very specific locus in the genome after the cut through the gene editing system.

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GENE EDITING VS CLASSICAL MUTAGENESIS

As SDN1 does not result in in any transgenic DNA insertion but rather result in spontaneous changes through the DNA repair system it is indistinguishable from other techniques introducing spontaneous mutations and thus have the same features and should be regulated in the same manner, i.e. exempted from being GMO. Otherwise, the possibility of two identical organisms being regulated differently exists. Both of these processes occur naturally in all living organisms where DNA damage happens frequently. Gene editing is a tool to reach the UN Sustainable Development Goals (SDGs). Below are some concreate examples where SDN1 gene edited organisms have significant positive impact on the UN sustainability goals:

> "Gene editing and classical mutagenesis occur naturally in all living organisms where DNA damage happens frequently."

1. Efficient utilization of land for food is important to end hunger, achieve food security, reduce environmental footprint and promote sustainable agriculture. By using improved plants and microorganisms in the agricultural field a number of improvements can be made, including a higher yield and a lower environmental footprint (lower fertilizer) of the production and a significantly lowered use of pesticides where the biological alternatives fully degradable in nature can help prevent chemicals in the ground water and in food products. More draught resilient and flooding tolerant agricultural practices can be established using gene edited plants and microorganisms.

While some gains are possible with naturally occurring organisms, significant improvements could be obtained with the use of gene editing. More food with less land can become the prime contributor to reduce net CO_2 emissions. FAO report in its 2018 edition says that: "New evidence in this year's report highlights that beside conflicts, climate variability and extremes are also a key force behind the recent rise in global hunger. They are also one of the leading causes of severe food crises. The number of extreme climate-related disasters, including extreme heat, droughts, floods and storms, has doubled since the early 1990s ("The State of Food Security and Nutrition in the World", FAO). This development is not just relevant for developing counties but also for Europe.

2. Reduced environmental impact from meat production and reduced use of antibiotics in farming can be obtained using gene edited microorganisms. Animal probiotics provide an opportunity to increase health status of animals, such as poultry and pigs, resulting in higher weight gain on the feed and lower use of antibiotics. Naturally occurring microorganisms with effects as probiotics sometimes carry antibiotic resistance genes which is not intended and needed, for effects such as antibiotics resistance can be easily removed by SDN1 and performance of microorganisms and safety of their use improved.

"Gene editing is a tool to reach the UN Sustainable Development Goals (SDGs)."

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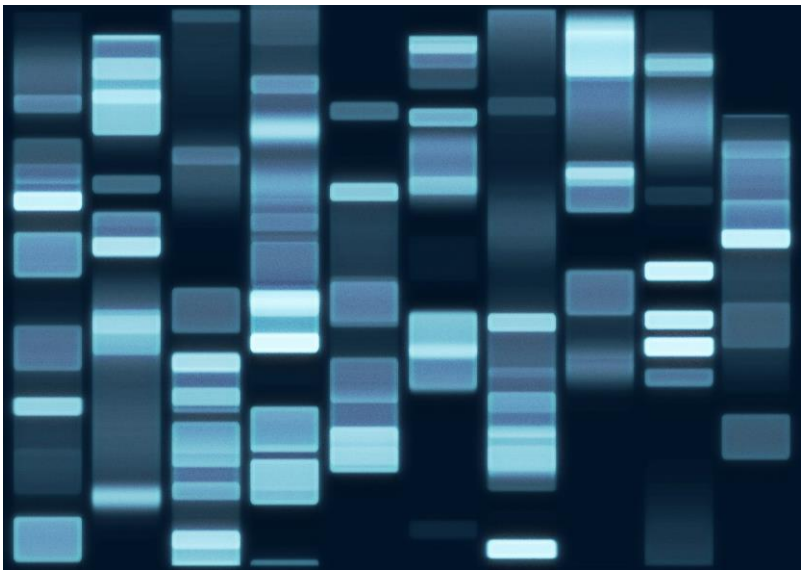
THE ADVANTAGES DISAPPEAR WITH THE RULING OF THE CJEU

The ruling is based on the GMO directive on deliberate release. While the directive is soundly based on the precautionary principle, the ruling equates SDN1 and transgenic gene editing. It was never the intention of the directive to regulate SDN1 or other technologies resulting in mutations that could occur naturally, according to the technical experts involved in the originally drafting of the directive. Obtaining regulatory approval of a GMO organism to be released to the environment is extremely difficult in the EU system, with only very few approvals granted since 2001. Mutations of an (micro)-organism obtained by SDN1 could have occurred in nature as well, and equating SDN1 with transgenic organisms effectively means that Europe cannot benefit from the sustainability, safety, health and economic benefits of this technology.

"With CJEU's ruling, Europe cannot benefit from the sustainability, safety, health and economic benefits of this technology."



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