IT'S IN OUR GENES

SEIZING THE OPPORTUNITIES OF GENETIC ENGINEERING IN AGRICULTURE

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CONSUMER CHOICE CENTER

Executive Summary

The global food supply presents us with many challenges. With a growing population, and the needs and standards of a constantly richer society increasing the demands towards farmers, we need to act smart. In fact, novel technology, such as genetic engineering allows doing more with less. It's a game changer.

This policy note seeks to explain the basics of 2021 standards of modern genetic technology in a comprehensive way, and lays out which smart policy changes can help achieve a just and reasoned way to work with the technology of the future.

Our Policy recommendations:

- Reform the 2001 EU Directive on GMOs
- Consider gene-edited seed without the introduction of foreign genes as conventionally bred seeds
- Consider gene-edited seed that has received foreign genes as a transgenic GMO
- The above mentioned changes would bring the EU in line with the Cartagena Protocol
- Fast-track the GMO approval process, favouring innovation

INTRODUCTION

The global food supply presents us with many challenges. With a growing population, and the needs and standards of a constantly richer society increasing the demands towards farmers, we need to act smart. Bigger isn't strictly better -- just because we are set to increase our population by 50% in a short amount of time (by historical comparison) does not mean we need to double the size of our farms, double the personnel, or double the costs for farmers, consumers, and the environment. In fact, novel technology allows doing more with less.

Genetic engineering is technology unlike any other. The precise genetic modification of crops has arisen not out of a need to interfere with nature, but out of necessity and thanks to human ingenuity. Early application of genetic engineering stood to solve the problems of complicated environments with challenging climates. As climate change progresses, these challenges will only grow larger.

Picture the state of human medicine prior to the development of certain advances. Ear or mouth infections or pneumonia led to the death of millions until penicillin came into widespread use. What is true in medicine, also applies for modern agriculture: high-yield farming has made our societies more advanced, provided us with a safer food supply, and has provided more food for fewer resources. The technologies of today are incomparable with those of 30 years ago. In fact, the invention of gene-editing has opened a new chapter for agriculture, allowing us to act precisely, with trusted experts. Pinpointed DNA-changes allow us to much more precisely target and understand the changes that we are making.

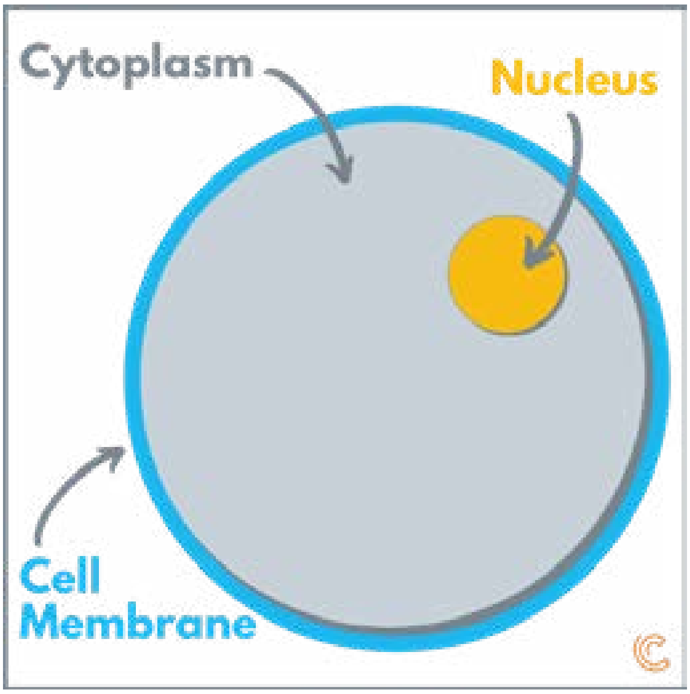
However, gene engineering has also troubled advocates of caution. While some will reject any technological advances, sometimes for the sake of signalling a stance against "consumerism". That is not the case for most consumers -- consumers expect safe food at socially acceptable prices.

This policy note seeks to explain the basics of 2021 standards of modern genetic technology in a comprehensive way, and lays out which smart policy changes can help achieve a just and reasoned way to work with the technology of the future. It is our mission to amplify the voices of scientists and policy-experts, and convince law-makers that Europe too can be at the forefront of this scientific revolution. European history shows that we thrive on innovation, and the belief that technology makes us healthier and more prosperous, for the benefit of all citizens.

It is, so to say, part of our DNA.

UNDERSTANDING GENETIC TRAITS

DNA (deoxyribonucleic acid) is the blueprint for the structure and function of our bodies, as well as any other existing living being. Amino acids, chemicals inside of our bodies, form proteins, which in turn form cells, which then form tissues, with tissues then forming organs. Amino acids follow the "instructions" of the DNA to align into the right proteins.



DNA is contained in the nucleus of a cell (the centre), while amino acids are in the cytoplasm. Chemicals contained in the nucleus make copies of the DNA strands -- called RNA (ribonucleic acid). RNA leaves the nucleus into the cytoplasm and "meets" ribosomes, molecular machines which use RNA information, combine it with the protein-building capacity of amino acids, to create proteins. Proteins, in turn, fulfil different functions, including building new cells.

Influencing DNA strands can influence the physical and functional traits of plants, but is in no way a mere human-induced phenomenon. **Mutagenesis** (a change in the genetic information leading to a mutation) and **transgenesis** (the introduction of foreign DNA traits) also occur naturally. The fact that transgenesis exists in nature is a relatively recent scientific discovery, with the example of sweet potato as a natural GMO making the round in media coverage. 2019 research now seems to confirm that 1 in 20 flowering plants are naturally transgenic[1].

When we mention plant breeding, we associate genetic engineering with complex

1. Matveeva, T.V., Otten, L. Widespread occurrence of natural genetic transformation of plants by Agrobacterium. Plant Mol Biol 101, 415–437 (2019). https://doi.org/10.1007/s11103-019-00913-y scientific procedures and laboratory-based work. However, the history of plant breeding does not start in lab coats.

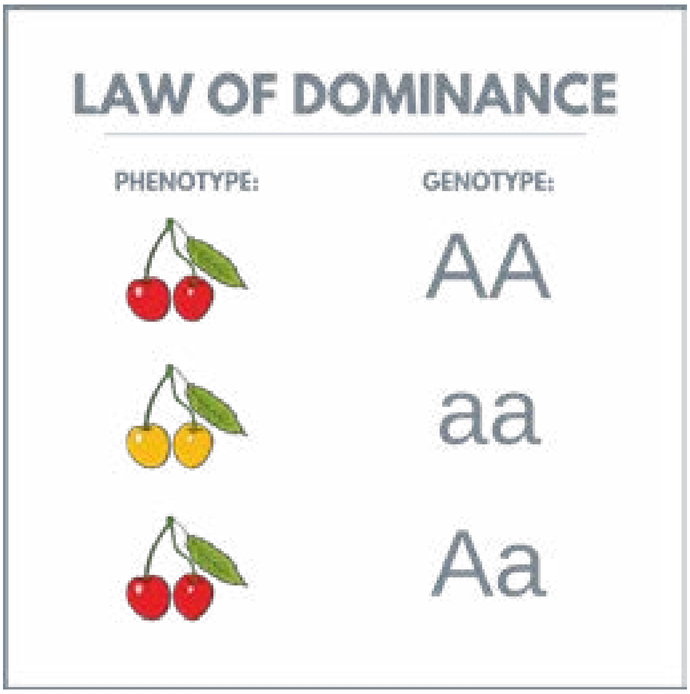
Dating back to the earliest existence of agriculture, farmers would select the best seeds to plant new crops. This process has structurally influenced the genetic variety of crops and has made agriculture more efficient over time. A practical application of this knowledge would be to compare wild apples to those that can be purchased in major retailers: wild apples are not sweet, are far smaller than retail apples, and are generally not advised for consumption.

Plant hybridisation, or crossbreeding, was revolutionised by the findings of Gregor Mendel. For centuries, farmers had already cross-fertilised plants in the effort of improving their genetic structure, but Mendel had achieved generalisations about hybridisation that would pave the way for understanding DNA. He crossbred pea plants (due to their diverse varieties), choosing opposites in his experiments: short with tall, those with green seeds with those with yellow seeds, and after an eight-year experiment analysing the peas resulting from his crossbreeding efforts, concluded three important laws about heredity:

1 **Law of Independent Assortment:** genes with different traits segregate independently of each other. In essence, we cannot assume that the inheritance of one genetic trait automatically implies the inheritance of another.

2 **Law of Segregation:** offspring receive one genetic trait - randomly selected - from each parent.

3 **Law of Dominance:** Mendel identified that genetic traits are either dominant or recessive, and that the dominant traits “win” when determining genetic characteristics such as colour. (see below)



The first cherries are homozygous, meaning they have two AA traits, thus making the cherry offspring red. The second cherries are also homozygous, with two aa traits, making their offspring yellow. The third cherry offspring is red, despite having an “A “and an “a” trait, which indicates that the “A” trait is dominant. These last cherries are heterozygous and clearly show that the colour red is a dominant trait.

N.B. This is a simplified approach to the Law of Dominance. It is important to note that some yellow cherry traits can be arrived at by crossing two red cherry varieties, thus illustrating the complexity of researching and understanding the characteristics of genetic traits.

For these establishing of these scientific laws, Mendel is considered the father of modern genetics.

APPLICATION OF GENETIC ENGINEERING

The application of genetic engineering in food production is numerous, representing a genuine revolution for consumer choice and the health of consumers. Virus-resistant tomato, disease-resistant rice, gluten-free wheat — these are just some of the many innovations made possible through gene-editing. But traditional GMO technology has already set the cornerstone of innovation, and provided a noteworthy yet tragic example: Golden Rice.

"The application of genetic engineering in food production is numerous, representing a genuine revolution"

As one of the creators of this rice variety, Ingo Potrikus, explains, the problem in developing countries is not only a lack of nutrition but also malnutrition. It was this scourge that he wanted to tackle, particularly vitamin A deficiency, by creating a genetically modified organism to prevent this deficiency. He therefore created a variety of rice enriched with beta carotene, a precursor of vitamin A, a standard still to be improved upon. Vitamin A deficiency is estimated to blind nearly 500,000 children and cause between 1 and 2 million deaths each year. This is due to the fact that in many developing regions, diets heavily rely on existing rice varieties, which do not provide the necessary diversity for a healthy lifestyle.

Former U.S president Bill Clinton, applauding the invention of Golden Rice, stated in 2000 that 40,000 lives a day could be saved through its distribution.

Golden Rice has been genetically improved: invented in the early 1990s, it is still not available for human consumption in an overwhelming majority of developing markets, although it was developed for humanitarian purposes. Since its conception, golden rice has been subjected to harsh criticism, but has never been shown to present the adverse effects that it was banned for. In order to counter criticism that the rice varieties were merely produced to generate a profit, the Golden Rice Project has made it available for free for humanitarian use. Despite this fact, the tragic reality is that the use of Golden Rice remains sparse.

Most of the currently used GMOs are herbicide tolerant and insect resistant crops, including soy, maize, oilseed rape and cotton.

Through new gene-editing technologies, the applications are even more vast and promising. Technologies such as CRISPR have the ability to reduce mycotoxin contamination or even fight locust plagues in developing regions by inducing targeted heritable mutagenesis to the migratory locust.

With endless possibilities for innovation should come endless will to expand the application of the technology in agriculture.

IS IT SAFE?

The European Union prides itself with its rigorous food safety testing, with European consumers expecting a high level of safety associated with the food they eat. To some extent, genetically engineering has implicitly been regarded with heightened scepticism, by comparison to conventional plant-breeding technologies. This has led to inconsistencies (including legal ones), which will be addressed in the next chapter. Meanwhile, the question of whether the "science is in" on existing GM technologies has been answered.

More than 280 food safety agencies (governmental and international) support the safety of genetic engineering to modify traits in plants. This fact does not equate with automatic approval of all GM crops, merely that the technology in itself does not constitute a human health risk. This list of agencies includes the World Health Organization (WHO), the Food and Agriculture Organization (FAO), the International Council for Science (111 National Academies of Science and 29 scientific unions), the French Academy of Medicine, the United States National Academy of Sciences, the American Medical Association, the American Dietetic Association, as well as the European Food Safety Authority (EFSA).

It is important to note that EFSA does not authorise GMOs in the European Union, it merely concludes risk assessments which are then forward for authorisation to the European Commission's Standing Committee on Plants, Animals, Food and Feed.

As Michigan State University researchers point out in a 2018 publication:

"With genetic engineering, usually only one gene from the donor, with a known role or coding for a known protein, is added or inserted into the current set of genes of a recipient plant. In contrast, traditional breeding methods mix many genes (from similar plants) in the mating process. Further, the resulting plants or offspring could have multiple and/or unpredictable outcomes, some of which can be undesirable (e.g., negative impact on yield, quality, or flavor).[2]"

Genetic engineering thus represents a safe breeding method, not just by virtue of comparing it to traditional breeding methods, but also on the characteristics of the technology itself. Examples such as Golden Rice have demonstrated that GMOs not only allow for safer food, but also healthier alternatives.

2."Understanding the biology behind GMOs can help consumers evaluate GMO safety", Michigan State University, MSU Extension Agriculture, December 21, 2018, https://www.canr.msu.edu/news/understanding-the-biology-behind-gmos-can-help-consumers-evaluate-gmo-safety

THE RADIOACTIVE SHOTGUN - RANDOM MUTAGENESIS: LEGAL INCONSISTENCIES

Conventional plant-breeding technologies include random mutagenesis. In the 20th century, plant-breeders significantly increased the number of naturally occurring mutations by inducing it through chemicals and radiation, achieving changes in the genome that aren't directed or which outcome is not certain.

Robert Hollingworth, professor emeritus of the Michigan State University (MSU) Department of Entomology and Institute for Integrative Toxicology has described the process as follows:

"More crops than you would imagine, in the supermarket today, were actually bred by mutagenesis. That is either treating the seeds with mutation-causing chemicals or blasting them with radiation. Ruby Red Grapefruit is an example and some of the barley strains that are used, even to produce organic beer, were produced in this way. It is quite common.

With mutagenesis, often the majority of things that happened were bad and so they would get thrown away, but once in a while something that was positive, like having no seeds or being shorter and therefore easier to harvest resulted and those were eventually released on the market, and without anybody asking a question."

In essence, GMOs, and in an even more direct way, gene-editing, are precise methods, while existing mutagenesis is imprecise. A coherent application of precautionary food safety policy would prioritise genetic engineering over random mutagenesis.

A list of thousands of mutant varieties created through radiation is available on the website of the International Atomic Energy Agency, making publicly accessible information. However, despite being publicly available, it most certainly isn't public knowledge, comparable to the way many consumers believe that organic food production does not involve pesticides. If food products were to be labelled with a "product created through radiation", could we expect a reasoned conversation about the pros and cons of this method, or rather a complete rejection of these products from the start? The answer is intuitive. This is not an attempt to discredit random mutagenesis as a plant-breeding technology, nor make a wider claim about mandatory labelling, yet it does open this question: having considerably more certainty over the effects produced by genetic engineering than for those effects created by random mutagenesis, why are mandatory GMO labels are more attractive political option?

Furthermore, the inconsistencies of public discourse have made their way into legislation at the European Union level. The directive on the use of GMOs (addressed in the next chapter) excludes random mutagenesis, as the European Court of Justice has confirmed: "The Court states, however, that it is apparent from the GMO Directive that it does not apply to organisms obtained by means of certain mutagenesis techniques, namely those which have conventionally been used in a number of applications and have a long safety record."

This is inconsistent with the scientific understanding of these procedures. In fact, human-induced transgenesis has a long safety record, while the results of random mutagenesis is, as previously explained, volatile.

NECESSARY CHANGES

The discovery of CRISPR-Cas9 by Emmanuelle Charpentier from the Max Planck Institute for Infection Biology in Berlin and Jenifer Doudna from the University of California, has far-reaching positive impacts for the work of medicine, but also for industry and consumers in the area of energy and agriculture. However, due to outdated EU-legislation dating back to the beginning of the century, genetic engineering is not legal to be used in food. A European discovery cannot be used to the benefit of Europeans.

It is necessary to reform 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. This legislation led to European Court of Justice ruling Case C-528/16, Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt, which found "techniques/methods of genetic modification conventionally used and deemed to be safe" and the "concept of 'genetically modified organism'" to necessitate banning the use of new breeding technologies in European agriculture.

The ECJ ruling is based on outdated legislation, which indiscriminately rules on the basis of a technology, as opposed to advocating for a case-by-case safety assessment, which would be more in line with a reasoned application of the precautionary principle. We endorse the joint statement of the German National Academy of Sciences Leopoldina, the Union of German Academies of Sciences, and the German Research Foundation, which in 2019 called for a "scientifically justified, differentiated regulation of genome edited plants in the EU".

In 2019, 85 scientific institutions signed a joint call for the use of gene-editing technology for sustainable agriculture and food production in the EU.

Overall, we identify a misapplication of the precautionary principle, as it - in this case - applies to a technology in itself, as opposed to a case-by-case analysis. In a scientific a regulatory analysis in 2016[3], Agnes E Ricroch (Associate Prof Plant Genetics AgroParisTech Paris PhD), Klaus Ammann (Emeritus Prof. Hon. from the Bern University, Switzerland, Plant Biotechnology: Biosafety, Gene Flow and Ecology of Transgenic Crops), Marcel Kuntz (PhD plant biotechnologist who is a Research Director Centre National de la Recherche Scientifique in Grenoble, France), explains that "Europe is politically locked in its misinterpreted Precautionary Principle and is unable to positively address the issue of new techniques (such as genome editing) and genetic engineering in general", and concludes that:

"We propose a simple and operational method, which focuses on the phenotype of a new variety instead of the method used to generate it. Our proposal involves a flexible and scalable system that is capable of adapting to the rapid evolution of new technologies such as genome editing. This system will need to assess actual risks and not overestimate perceived risks of new varieties simply because they fall into the EU "GMO" regulatory framework."

We believe that these suggested changes match the needed regulatory adaptation for agricultural innovation in Europe.

3. Ricroch, Ammann, Kuntz. Editing EU legislation to fit plant genome editing (2016). https://doi.org/10.15252/embr.201643099

CONCLUSION

In the absence of listening to its own scientists, the European Union is lagging behind the rest of the world. The Consumer Choice Center has, together with the Genetic Literacy Project, released the Gene Editing Regulation Index, which compares the regulatory leniency of governments in different regions of the world. The European Union does not score well. It is time for policymakers to stand up for science and innovation and let Europe remain a global powerhouse of breakthroughs.

To do so, the European Union needs to make targeted regulatory changes that have been outlined in this policy note. These changes are in line with existing scientific knowledge and are also consistent with high food safety standards.

We need to allow European scientists to participate in the gene-revolution and have them work together with farmers to release the innovations of the future. Recent gene-editing innovations allow us to produce more paper with fewer resources and make salmon less prone to disease and more affordable for consumers. Through genetic engineering, we can both fight the challenge of climate and that of increasing population.

Let us usher in a century of innovation in Europe, and let European scientists lead the charge.

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