Q&A on the New Breeding Technologies (NBT)

"There is still little knowledge and little reliable data on new genetic engineering methods such as Crispr."

- There is a broad scientific consensus on the safety of modern breeding methods.
- Modern breeding methods are much more precise than many of the classic approaches that have been used in Switzerland for a long time and also intervene in the plant's genome.
- For leading researchers in the field, one thing is clear: claiming that there is no corresponding data basis is simply wrong.

Research into genetic engineering has been going on for decades. The potential risks, also in relation to new processes, have been analysed time and again. Genetically modified plants pose no greater risk than conventional breeding. This was also confirmed in 2012 by the National Fund Project 59 (NRP 59). The scientific consensus is comparable to that on human-induced global warming. A survey of around 2,000 American scientists from the fields of biology and biochemistry in 2014 showed that 91 per cent of respondents consider the consumption of genetically modified foods to be completely harmless.

This also applies to the new, more precise breeding methods. Genome editing applications are more precise and demonstrably cause fewer so-called "off-target effects" (mutations in undesirable locations) than methods that are already authorised today, such as classical mutagenesis. The Swiss Academy of Sciences (SCNAT) has also pointed out on various occasions that the scientific basis can be regarded as sufficient to adapt the legal provisions to the current state of knowledge and that breeding techniques will no longer play a role in regulation in future, but only the product, i.e. the plant with its new properties.

This is also confirmed by Prof Wilhelm Gruissem from ETH Zurich, who was already significantly involved in NRP 59. In an interview, he points out that there are numerous studies that prove that the new breeding methods, just like conventional breeding methods, can be used with a manageable level of risk. In view of this, the assertion that there is no reliable data and only limited knowledge regarding the new genomic methods, as was also made during the debate in the National Council, is out of thin air.

Sources

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Nebelspalter (2021): Brennwald Ep. 9: Prof Wilhelm Gruissem (ETH) in conversation with Reto Brennwald

"Research remains permitted and now we need to collect data and findings for another four years so that we can make a fact-based decision on how to proceed in four years' time."

- The EU and the UK are working towards the authorisation of genome-edited plants. In both cases, this is done with reference to scientific findings.
- In Switzerland, research is to continue for another four years to clarify whether there are any risks associated with modern plant breeding. This question has long been clarified, as the processes in the EU and UK show.
- What's more, not only is there a wait-and-see approach, but the moratorium is even being tightened: some methods based on conventional mutation breeding are now also to be covered by the Genetic Engineering Act.

Breeding research for use in Switzerland will be frozen for another four years. This is incomprehensible. Especially now that the benefits of the new breeding methods are becoming clear. Research is not an end in itself. It should also be applied. The lack of prospects for utilising the results is detrimental to basic research at universities and blocks application-oriented developments in plant breeding. Switzerland was once a leader in the field of gene technology and biotechnology. The cultivation bans are diminishing its international status.

The scientific consensus regarding new plant breeding technologies is clear. This is also the reason why efforts are currently being made to amend genetic engineering legislation, not only in the EU but also in the UK. The sceptics deny that, from a scientific point of view, the facts are on the table. Against this background, the Chevalley postulate adopted by the National Council, which among other things calls for more clarification of the risks, should be seen as political skirmishing. It also implies that the numerous countries that already authorise genome-edited plants on a product basis or are on the way to such a regulation would do so in a scientific vacuum. A presumption. Only product-based authorisation is based on an evidence-based policy.

Switzerland is actually doing the opposite. The moratorium, which would be extended by four years, would also affect the further development of some applications of mutation breeding that are currently exempt from the Gene Technology Act, e.g. transposon mutagenesis. Eva Reinhard, Director of Agroscopoe, said in an interview: "*The methods that would then still be available to us would definitely be a step backwards into the past".* Why a naturally occurring process should suddenly become dangerous just because it is accelerated by humans is also incomprehensible from a scientific point of view.

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Postulate 20.4211. Genetic Engineering Act. Which scope of application?
Eva Reinhard, in an interview with CH Media on 22 September 2021

"Consumers in Switzerland don't want genetically modified food on their plates anyway."

- Swiss consumers are more open-minded towards genome-edited foods than is always claimed.
- The latest studies show that the Swiss are open to new breeding methods if they recognise a concrete benefit.
- According to a gfs.Bern survey conducted in summer 2021, a relative majority is against the new breeding methods being subject to the moratorium on genetic engineering.

Recent studies show a differentiated picture of the average Swiss consumer, as demonstrated, for example, by a recent ETH study. In this study, 643 consumers from German-speaking Switzerland were asked about late blight in potato plants. Specifically, the respondents were asked to indicate which type of treatment they would prefer if the plant was infected. The options were synthetic pesticides, natural pesticides such as copper, which are used in organic farming, the introduction of a resistance gene from a wild potato or the rewriting of certain genes using genome editing. The result: the study participants were most likely to agree with the introduction of a wild potato gene. And rewriting the genes was just as acceptable to the test subjects as the use of pesticides, whether natural or synthetic.

These findings are consistent with those of a gfs.Bern survey published in autumn 2021. This also showed that consumers are willing to accept genome-edited food if there is a tangible benefit behind it. Finally, the survey showed that a relative majority is against the Federal Council's plans to place the approaches to genome editing under the moratorium. The argument that Swiss consumers do not want genetically modified food on their plates therefore falls short of the mark. On the contrary, current surveys show that the opportunities offered by modern breeding methods are being recognised. Food produced using modern breeding methods would therefore also have a good chance of being widely accepted on Swiss plates - as is already the case abroad. To achieve this, however, we would have to stop denying scientific findings and instead sow doubts and fears.

Sources

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Gfs.Bern (2021): Study on "genome editing". Cautious initial assessment of genome editing, but high potential benefits are seen.

"A declaration is needed. Consumers want to know whether they are eating genetically modified products."

- To date, it is estimated that over 4000 crops have been created using classical mutagenesis. According to the European Court of Justice, interventions in the genome via irradiation and chemical treatment are genetic engineering.
- Nevertheless, there is still no mandatory declaration. Consequently, such a declaration should also be dispensed with for genome-edited plants without transgenic genetic material. After all, this type of breeding is less far-reaching and more targeted than classic mutagenesis.
- Transparency creates trust. For this reason, all methods used in the breeding of each crop plant could be reported when the variety is authorised.

For many decades, mutagenesis induced by nuclear radiation has been systematically used in conventional and organic plant breeding to obtain plants with new characteristics that are not possible using conventional plant breeding methods. Chemically induced mutagenesis is still used in plant breeding today. According to a list compiled by the International Atomic Energy Agency, over 3,200 new plant varieties developed using mutagenesis had come onto the market by 2017. According to a judgement by the European Court of Justice (ECJ, July 2018), organisms resulting from this conventional, undirected mutation breeding are "genetically modified organisms" (GMOs). If the ECJ were to be consistent, most common fruit and vegetables would have to be labelled as GMOs. This would also apply to organically grown products.

A distinction makes no scientific sense in relation to the product. One of the outstanding properties of genome editing is precisely that modifications in the genome of a plant bring about changes that could also occur naturally. *"For example, the disease resistance of its original predecessor can be transferred to a high-yielding crop plant - and does not have to be painstakingly crossed over the years,"* says Urs Niggli, former Director of the Research Institute of Organic Agriculture (FiBL). Jörg Hacker, President of the German Academy of Sciences Leopoldina, said in 2018: *"This means that certain forms of genome editing using tools such as Crispr could be exempt from regulation in future if the result is 'nature-identical'."*

A one-sided declaration for genome-edited plants without transgenic genetic material would not only be inconsistent, but its incompleteness would even be misleading for the consumer. If anything, there should be a general obligation to declare the breeding methods used for all crops and products derived from them. It is questionable whether this would really bring any added value for consumers, as the majority of products would probably have to carry a GMO label. A declaration of every breeding method used in the variety authorisation procedure would serve to build trust and transparency.

Sources

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"Before genome-edited plants are authorised, the legal basis for the coexistence of natural and genetically modified plants must be ensured. The question of liability has also not yet been clarified."

- Hundreds, if not thousands, of crops are already being cultivated today that have been bred using classical mutagenesis. The idea of "mutation-free" Swiss agriculture is a mirage.
- In view of this, it makes little sense to demand coexistence regulations for genome-edited plants without transgenic genetic material. One would be regulating the coexistence of plants bred using directed and undirected mutagenesis, which are indistinguishable in the field. This lacks any scientific logic.

Genomutated plants have been growing in Swiss fields for decades: Many plants have been created using breeding methods that intervene in the genome. However, this was done in a much less targeted manner than if it had been done using the new breeding methods.

If the circles that insist on a regulation on coexistence were honest, they would explain to their supporters that genetically modified seeds are already being cultivated on large areas today. Even in organic farming! Consequently, we should already be working today to ensure that all plants created by means of classical, untargeted mutagenesis disappear from the fields. This would affect thousands of crops. After all, only a very small number of today's crop plants have developed entirely without this breeding method.

In view of this, it also makes no sense to subject the cultivation of seeds created by targeted mutagenesis (genome editing) to coexistence requirements. This would regulate the coexistence of identical products, which is absurd. A separate coexistence regulation for genome-edited plants without transgenic DNA is also unnecessary with regard to crops that have been bred without mutagenesis. For decades, these have also been exposed to the supposed negative influences of mutagenesis-bred and therefore genome-edited plants. This apparently without negative effects for the affected varieties, the environment and humans.

The same applies to the question of liability: in all facets of economic life, liability issues have been clarified or mechanisms are in place to clarify them. It is exactly the same with the cultivation of plants. It is absurd to assume that fundamentally new, insoluble liability issues would arise here. Instead, plant varieties obtained using new breeding technologies should be subject to exactly the same legal obligations as a conventional farmer already has when planting new seeds.

More and more countries are deciding to authorise the cultivation of genome-edited plants without transgenic genetic material as "GMO-free". Where there are no differences in the end product, there should be no differences in regulation - neither in the declaration of the products nor in the regulations governing the cultivation of the plants. If transgenically bred worries were to be authorised one day, we would have to think about a coexistence regulation, as plants are being bred that could not have developed naturally in this way.

Sources

Swiss Academy of Sciences (SCNAT) (2020): Plant breeding – from cross breeding to genome editing
Crispr is not always genetic engineering, Tagesspiegel 18 January 2018

"Robustness and climate resilience are based on a large number of coordinated genes and their epigenome. CRISPR/Cas interventions on individual genes do not offer a solution."

- In many cases, a trait is mainly caused by a single gene. In these cases, the claim does not apply at all.
- There are indeed traits that are based on a variety of genetic and epigenetic factors. However, the presence of several factors does not mean that all factors have the same share in the trait. Often 1-2 factors are mainly responsible. This already allows a partial improvement of the traits to be achieved.

In practice, it is easy to determine whether a deliberately introduced mutation produces a particular trait: a plant can be observed in the laboratory and later in the field and compared with an unmodified plant. If there are constant and replicable changes in a growth trait, it can be assumed that this is due to the genetic mutation. Interventions in individual genes using new breeding technologies can be observed in exactly the same way as random mutations caused by mutagenesis in conventional breeding.

In many cases, a trait is mainly caused by a single gene. In such cases, interventions on a single gene are effective: the breeding goal can be achieved completely or almost completely by a single intervention.
For example, Prof Soyk from EPFL has bred a more robust tomato with a targeted point mutation. In contrast to conventional tomato plants, the fruit-bearing branches are not kinked. As a result, the plant sags less and ripe tomatoes are less likely to break off. This small modification can significantly reduce food loss, especially at harvest time.

However, as rightly claimed, there are also traits that are based on a variety of factors, including epigenetics. Certain breeding goals are complex to achieve and progress may not be expected quickly, as further research is still needed. In most cases, however, a breeding goal can still be partially achieved. This is because the presence of several factors does not mean that all factors have the same share in the trait. However, there are often one or two factors that are by far the most responsible. In these cases, too, interventions on individual genes are therefore expedient, although it is not assumed that the breeding objective will be achieved in full, but rather a partial improvement. Even small improvements in terms of climate resilience (such as drought tolerance) and robustness can make a major contribution to more sustainable agriculture.

Sources

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"There is not yet a single product on the market that would be of interest to Swiss farmers. Authorisation for genome-edited food is therefore not mandatory."

- Genome-edited plants are also of interest to Swiss farmers - especially with a view to reducing the use of pesticides and climate change
- The Swiss Academy of Sciences has compiled a list of examples of applications of genome-edited plants in Swiss agriculture.
- Various varieties are already well advanced in their development - for example fire blight-resistant Gala apples or higher-yielding rapeseed pods.

It is not least the current policy of prevention that contributes to the fact that the product range is not yet as broad as it could be today. The potential of new breeding methods is far from exhausted. Internationally, development is proceeding at a rapid pace. It is not without reason that the Swiss Academies of Arts and Sciences (a+) write: "It *can be assumed that varieties with characteristics that are also of interest to Swiss agriculture will come onto the market in the near future."* Various varieties are already well advanced in their development - for example mildew-resistant tomatoes or fire blight-resistant Gala apples. SCNAT has also published a report on examples of applications of genome-edited crops for Swiss agriculture (see sources).

Not least the pesticide initiatives in 2021 have shown that local producers will have no choice but to reduce their use of plant protection products. And this is precisely where new breeding technologies could become interesting for Swiss farmers sooner than many think: *"The new genomic processes and genome editing in particular could make an important contribution to the breeding of varieties for sustainable agriculture in rapidly changing cultivation conditions (e.g. plant and pest resistance, drought tolerance). Not using such varieties would make it impossible to utilise existing potential for more environmentally friendly food and fodder plants,*" continues a+.

The first genome-edited tomatoes have recently been launched on the market in Japan. The fruits have been modified using CRISPR/Cas9 precision breeding so that they have improved characteristics such as higher amino acid production. Parts of the farming community also recognise the opportunities. This is demonstrated not least by the vote of SVP National Councillor Martin Haab during the Council debate on the Genetic Engineering Act. The President of the Zurich Farmers' Association insisted that the report on the Chevalley postulate should not only focus on the risks, but above all on the opportunities of genome editing. The request to speak is an important signal: the agricultural sector is also aware that modern plant breeding is a great opportunity for local producers.

Sources

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National Councillor Martin Haab (2021): Vote as part of the National Council debate on the Genetic Engineering Act

La technologie CRISPR utilisée au Japon pour booster des tomates: RTS, 28 September 2021

"Green genetic engineering has so far failed to fulfil its promises. Why should it be any different with genome editing?"

- Outside Europe, the benefits of genetic engineering are recognised by farmers. In the USA, GM crops are grown on >60% of the land.
- A meta-analysis by the University of Göttingen, which took 147 studies from various countries into account, concluded in 2014 that GMO technology has reduced the use of pesticides by 37 per cent on average, increased crop yields by 22 per cent and boosted farmers' profits by 68 per cent.
- Examples such as Bt aubergines have also proved successful in small-scale farming.

Genetic engineering is now used in agriculture worldwide. The main areas of cultivation for genetically modified plants are the USA, Brazil, Argentina, Canada and India. In the USA, genetically modified plants are grown on >60% of the land. The advantages of genetic engineering are therefore recognised by farmers.

However, there are also numerous examples that demonstrate the diverse and clear ecological and humanitarian benefits of green genetic engineering to date - beyond golden rice. In Bangladesh, farmers produce Bt-modified eggplants (Bt Brinjal). The aubergines are spared pest infestation, the fruit and also the harvests are larger and more plentiful. Previously, farmers had lost 40 per cent of their harvest due to pest infestation - the genetically modified aubergines thus contribute to the food security of rural communities. Thanks to built-in insect resistance, small farmers also have to spray their aubergines less.

A meta-analysis by the University of Göttingen, which took 147 studies from various countries into account, concluded in 2014 that GMO technology has reduced the use of pesticides by 37 per cent on average, increased crop yields by 22 per cent and boosted farmers' profits by 68 per cent. The increases in yields and profits are higher in developing countries than in industrialised countries. And this despite higher prices for the new seeds.

A broad-based study from 2018 concludes that genetically modified corn is a success story: on average, it achieves 10 per cent higher yields than conventional varieties. This is due to the significantly reduced infestation with pests. In addition, the cultivated maize contains around a third less of the plant's own toxins, such as carcinogenic mycotoxins. And a genetically improved maize variety from Syngenta has been shown to increase the feed efficiency of cattle by 5 per cent, thereby reducing emissions of climate-damaging methane.

It is good to see that researchers from Swiss colleges and universities are not discouraged and are continuing Ingo Potrykus' research against all odds: Navreet Bhullar and her team at ETH Zurich, for example, have developed transgenic rice varieties that not only produce beta-carotene as a precursor of vitamin A in their grains, but also enrich iron and zinc. The research group is leading the way with its multi-nutrient rice.

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Nature study on GM corn: Elisa Pellegrino, Stefano Bedini, Marco Nuti & Laura Ercoli (2018): Impact of genetically engineered maize on agronomic, environmental and toxicological traits: a meta-analysis of 21 years of field data. Nature.
Corn variety from Syngenta: Enogen corn for feed delivers potential 5% increase in feed efficiency
ETH Globe article (2021): "Optimising nature"

"Companies and research centres always apply for patents on their inventions straight away. This will only increase with the new genetic breeding methods. Patents on plant varieties are blocking traditional breeding."

- Researchers and companies can only protect their inventions worldwide with patents. The new technologies are leading to an increasing "democratisation" of plant breeding. When inventors apply for patents as a result, this is evidence of innovation and not a threat to traditional breeders.
- Patents are not granted on plant varieties in either Switzerland or the EU. Moreover, plant characteristics cannot be patented if they are the result of traditional breeding methods.
- Only properties or technical processes that are truly novel, such as a certain clearly defined inventive application of new breeding technologies, can be patented.
- Under Swiss law, breeders are always permitted to continue breeding using traditional methods, even if patents already exist. However, it may only be marketed without a licence if the new variety no longer contains the patented material.

It is nothing new for researchers or research-based industries to patent their inventions. After all, patents are a strong incentive to invest in research and development. Especially for highly specialised companies in our small country, it is incredibly important that they can protect their inventions worldwide.

Contrary to the slogans of NGOs, there are no patents on entire plant varieties in Switzerland or the EU. Patents always relate to clearly defined characteristics of plants or plant breeding techniques, which must also be new and innovative. This is because patents are examined individually by experts (so-called patent examiners, Alber Einstein worked as such in Bern) to determine whether the invention is truly novel compared to the state of the art and whether an inventive step has taken place. This state of the art changes over the years.

In Europe and Switzerland, patents are not granted on characteristics of conventionally bred plants and animals (so-called "essentially biological processes") and on characteristics that already occur in nature (so-called "natural traits"). NGOs are still using older patents to scandalise, as the European Patent Office only applies the new regulations to patents applied for after 2017. But the fact remains: These would no longer be granted today. However, patents can be asserted on properties of plants and animals that were achieved using a novel technical method, such as an inventive application of genome editing.

However, this does not restrict breeding. This is because there are special rights for breeders in Switzerland and the EU: both the Patent Act (Art. 9 para. 1 let. e PatA, SR 232.14) and the Plant Variety Protection Act (Art. 6 let. c Plant Variety Protection Act, SR 232.16) recognise a breeder's privilege. This means that they are permitted to continue breeding a variety without obtaining authorisation from the patent holder. Even patented biological material may be used for the development of new varieties using traditional breeding methods.
The new variety may then be marketed completely licence-free, provided it no longer contains the patented material. If the new variety contains the patented trait or technology and benefits from it, a corresponding licence must be negotiated with the patent holder. This ensures that traditional breeders have access to the greatest possible genetic diversity.

There are no known cases in which the commercialisation of new plant varieties in Switzerland has been made impossible due to patented properties.

For many researchers in Switzerland, one thing is certain: a liberalisation of the approval process for new breeding methods will also lead to new providers entering the market in this country. Start-ups from universities and colleges such as ETH or EPFL are likely to increase and with them the range of products on offer. One thing is clear: in contrast to traditional breeding methods, the new methods are cheaper and faster. In future, it will no longer just be the big multinationals that succeed in bringing new varieties to the market. Until now, only they have been able to finance the lengthy developments at all.

More providers also mean more moderate prices in the medium term. Unfortunately, the policy of prevention in Switzerland and Europe has meant that supply is still limited. However, countries such as the UK are now looking forward to a change in authorisation practice, which should lead to numerous new products in the medium term. If the EU and Switzerland follow suit one day, a lively market is likely to be established.

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"A few corporations divide more than 60 per cent of the global seed market, including genetically modified varieties, among themselves. The concentration of power in the seed market rips off small farmers."

- Figures on market concentration cited in the public debate "give a misleading picture and are not helpful for policy makers given the wide differences between different cultures and countries." (OECD, 2018)
- The situation varies greatly depending on the crop (broccoli vs. wheat or rice) and country (USA vs. India).
- The market concentration for seeds with genetically modified traits is indeed very high. For small companies, the regulatory hurdle of genetic engineering requirements and authorisation studies prior to market entry is almost insurmountable.

In its 2018 report "Concentration in Seed Markets", the OECD analysed the potential impact of major company takeovers on prices, product selection and innovation in the seed sector and made policy recommendations to protect and promote competition and innovation in plant breeding. It concludes that there are considerable differences between the various crops and countries and that it is not possible to speak of concentration across the board.

The market concentration for seeds with genetically modified traits is much higher and the market is almost exclusively dominated by large multinational companies due to the high regulatory costs. For small companies, the regulatory hurdle of genetic engineering requirements and authorisation studies prior to market entry is almost insurmountable.

On the other hand, according to the OECD, the data on patents for CRISPR/Cas9 indicate that this new technology is mainly dominated by academic institutes. Policy makers should therefore avoid unnecessary regulatory barriers to market access. This is particularly important given the emergence of new plant breeding techniques, which should also be accessible to smaller companies. Policy makers should also ensure that plant breeders have access to genetic material through efficient procedures and facilitate efficient licensing of intellectual property.

In order to accelerate innovation, the OECD advises that the public sector should focus on basic research and leave applied research and commercialisation to the private sector in view of increasing investment. Political decision-makers could also promote private research and development through public-private partnerships. The conclusion of the introduction to the study is noteworthy: "This study also emphasises the importance of accurate data to address issues of market concentration. Highly aggregated estimates of market concentration, which have been cited in the public debate, provide a misleading picture and are not helpful to policy makers given the wide variation across crops and countries."

The "Access to Seeds Index 2019", which compares how well companies make their seeds available to smallholder farmers, also contradicts the common narrative: companies such as Syngenta and Bayer are among the best-placed in this index. Access to safe, certified seeds is important because the necessary increase in productivity must primarily be achieved by smallholder farmers in developing countries so that they can make a greater and more stable contribution to food security in their countries and to their own better lives. And because, for example, according to Dr Marja Thijssen of

Wageningen University, farmers in Africa lose up to 50 per cent of their harvests due to poor or counterfeit seed.

Sources

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"The new technologies are actually mainly used today where the development of herbicide-resistant plants is concerned."

- Herbicide tolerance research is only a small part of modern breeding methods
- It is to be expected that the increased authorisation of genome-edited plants in various countries will improve and broaden the product range
- The ban policy in many countries has meant that only a few new varieties have been introduced.

A study commissioned by the Federal Office for the Environment in 2020 shows that 63 plant projects are in the development pipeline. Only 11 of these are concerned with herbicide tolerance. The majority of commercial research therefore has other objectives, such as improving drought or heat tolerance or increasing yields. Nevertheless, the 11 ongoing projects show that further progress can also be expected in the area of herbicide tolerance. In spring 2021, the EU presented a comprehensive study that provides an overview of the global development pipeline of genome-edited organisms. It described 426 applications in plants on their way to the market. The most important areas of genome editing in plant breeding are currently optimised plant composition (nutrients, starch, oil, vitamins, allergens, etc.) with 115 projects and improved disease resistance (against fungi, viruses, bacteria, parasites, etc.) with 113 projects. 88 projects aim to increase yields. Improved resistance to environmental factors such as heat, drought, etc. is being pursued in 38 research projects. Other breeding objectives, each accounting for less than 10 percent, are technical improvements for variety development, herbicide tolerance, improved storage properties and changes in colour and odour. The implicit assertion that existing research has not delivered what was promised does not take into account the fact that research is continuing to make progress.

Ironically, opponents of genetic engineering repeatedly claim that the promises once made by the technology have not been realised. However, the same circles ensure that research and the commercial application of genetically modified food is prevented in many countries. In view of this prohibition policy in many countries, it is clear that the full potential of genetic engineering methods has never been realised.

Genome editing, which enables more precise and cost-effective breeding, will act as a kind of catalyst here. Research will be accelerated and products are likely to improve accordingly. In addition, many countries are currently in the process of liberalising their approval practices. This market liberalisation should help to unleash the full potential of new breeding methods.

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