Q&A on New Breeding Technologies (NBT)

"With regard to the new genetic engineering methods, such as CRISPR, there is still little knowledge and little reliable data."

- The scientific consensus on the safety of modern breeding methods is strong.
- The modern breeding methods are much more accurate than many of the classical approaches that have been used in Switzerland for a long time and also interfere with the genome of the plant.
- For leading researchers in the field, it is clear: It is simply wrong to claim that there is no data base.

Research has been conducted on genetic engineering for decades. The potential risks, including those relating to new procedures, have been investigated over and over again. Genetically modified plants pose no greater risk than conventional plants. This was also confirmed in 2012 by the National Fund Project 59 (NFP 59). The scientific consensus is comparable to that on human-induced global warming. A survey of around 2000 American scientists from the fields of biology and biochemistry showed in 2014 that 91 percent of the respondents considered the consumption of genetically modified foods to be completely harmless.

This also applies to the new more precise breeding methods. Applications of genome editing are more accurate and have been shown to cause fewer so-called "off-target effects" (mutations at unwanted places) than methods already approved today, such as classical mutagenesis. The Swiss Academy of natural Sciences (SCNAT) points out on several occasions that the scientific basis can be considered sufficient to adapt the legal provisions to the current state of knowledge and that breeding techniques will no longer play a role in regulation, 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 a major participant in the NFP 59. In an interview, he points out that there are numerous studies that show that the new breeding methods, just like conventional breeding methods, can also be used at a manageable risk. In view of this, the claim that there are no reliable data and only a small amount of information on the new genomic procedures, as also made in the context of the debate in the National Council, has been made out of thin air.

Sources

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"Robustness and climate resilience are based on a variety of matched genes and their epigenome. CRISPR/CAS interventions on individual genes do not offer a solution for this."

- In many cases, a characteristic is mainly caused by a single gene. For these cases, the claim is not at all effective.
- There are actually characteristics that are based on a variety of genetic and epigenetic factors. However, the presence of several factors does not mean that all factors share the same proportion of the characteristic. Often, 1 or 2 factors will be the main cause. This can already achieve a partial improvement of the characteristics.

In practice, it is easy to determine whether a specifically introduced mutation produces a specific characteristic: A plant can be observed in the laboratory and later in the field and can be compared to an unchanged plant. In the case of constant and replicable changes in a growth property, it can be assumed that this is due to the genetic mutation caused. Interventions on individual genes with new breeding technologies can be observed exactly the same as for example random mutations caused by mutagenesis in conventional breeding.

In many cases, a characteristic 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 of the 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. The small modification can significantly reduce the food loss, especially during harvest time.

However, as rightly claimed, there are also features that are based on a variety of factors, including epigenetics. Certain breeding objectives are complex to achieve and there may be no rapid progress to be expected, as further research is still needed. However, in most cases, a breeding goal can still be partially achieved. Because the presence of several factors does not mean that all factors have the same share of the characteristic. However, there are often one or two factors that are by far the main cause. In these cases too, interventions on individual genes are thus effective, although it is not assumed that the breeding objective has been fully achieved, but that the aim is to be partially improved. Even small improvements in climate resilience (such as drought tolerance) and robustness can contribute much to a more sustainable agriculture.

Sources

NZZ (2021): More robust tomato plant from Switzerland, interview with EPFL Prof. Soik
Brenner's Encyclopedia of Genetics (2013): Entry to quantitative trait of G.J.M. Rosa, p. 22-24

"Research remains allowed and now we are to collect data and findings for another four years, so that we can then decide on the next course of action in four years on the basis of facts."

- In the EU and in the UK, work is under way for the approval of genome-edited plants. In both cases, this is done with reference to scientific findings.
- In Switzerland, a further four years of research will be conducted to determine whether there are risks in modern plant varieties. This issue has long been resolved, as the EU and UK events show.
- In addition: Not only are we waiting for it, but the moratorium is being tightened up: In addition, some methods based on conventional mutation breeding are to be covered by the genetic engineering law.

Breeding research for an application in Switzerland will be frozen for a further four years. That is incomprehensible. Especially now, when the benefits of the new breeding methods are clearly evident. Research is not conducted for the sake of its own ends. It should also be applied. The lack of prospects for the exploitation of the results is harmful to basic research at universities and blocks application-oriented developments in plant breeding. Switzerland was once a leader in the field of gene and biotechnology. Their international status is being lost due to the ban on cultivation.

The scientific consensus on the new technologies of plant breeding is clear. This is also the reason why the aim is currently to adapt genetic engineering legislation not only in the EU, but also in the UK. Skeptics deny that from a scientific point of view, the facts are on the table. The Chevalley motion, adopted by the National Council, which calls for more clarification of the risks among other things, is to be seen as political wrangling against this background. It is also implied that the numerous countries that already permit a product-based system of genome-edited plants or are on the way to doing so would do so in the absence of science. A presumption. Only product-based approval is based on an evidence-based policy.

Switzerland is doing the opposite. The moratorium, which has been extended by four years, would also affect the further development of some applications of mutation breeding previously excluded from the genetic engineering law, for example Transposon mutagenesis. Eva Reinhard, director of Agroscope, said in an interview: "*The methods that are still available to us are definitely a step backwards into the past."* From a scientific point of view, it is not understandable why a naturally occurring process should suddenly become dangerous just because it is accelerated by humans.

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Postulate 20.4211. Genetic Engineering Law. What Scope?
Eva Reinhard, in an interview with CH Media on September 22, 2021

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

- Genome-edited plants are also of interest to Swiss farmers – especially with regard to reduced pesticide application and climate change
- Various varieties are already well advanced in their development – for example, fire-resistant gala apples or higher yielding rapeseed pods.
- According to the Swiss Academies of Sciences, a large number of new plants will be launched in the coming years, which will also be helpful for Swiss farmers.

It is not least the current prevention policy that contributes to the fact that the product range is not yet as broad as it could actually already be today. The potential of the new breeding methods has not yet been exhausted. Internationally, the development is rapid. Not without reason, the SCNAT writes: *"It can be assumed that varieties with interesting characteristics also for Swiss agriculture will be introduced on the market in the near future."* Various varieties are already well advanced in development – for example, mildew-resistant tomatoes or fire-resistant gala apples.

Last but not least, the pesticide initiatives have shown that local producers will not be able to reduce their use of plant protection products. After all, the issue is unlikely to go away anytime soon even after the votes. And this is exactly where it could become interesting for Swiss farmers sooner than many people think: *«The new genomic processes, and in particular genome editing, could make an important contribution to the breeding of varieties for sustainable agriculture in rapidly changing growing conditions (e.g. plant and pest resistance, drought tolerance). The abandonment of such varieties makes it impossible to exploit existing potentials for environmentally-friendly produced food and feed plants,"*adds SCNAT.

In Japan, the first genome-edited tomatoes have recently been on the market. They were modified with the precision cultivation CRISPR/Cas9 in such a way that they have improved properties such as higher amino acid production. Parts of the farming community also recognize the opportunities. This is demonstrated not least by the vote of SVP National Council Martin Haab in the context of the Council debate on the genetic engineering law. The president of the Zurich farmers' Association insisted that the report, which must now be drawn up by the Federal Council because of the Chevalley motion, should focus not only on the risks, but above all on the opportunities presented by genome editing. The request for a speech is an important signal: Agriculture is also aware that modern plant breeding is a great opportunity for local producers.

Sources

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CRISPR technology used in Japan to boost tomatoes: RTS, September 28, 2021

"Consumers in Switzerland do not want genetically modified food on their plates anyway."

- Swiss consumers are more open to genetically-edited foods than is always claimed.
- Recent research shows that the Swiss are open to the new breeding methods if they see a concrete benefit in them.
- According to a gfs.Bern survey conducted in summer 2021, a relative majority is opposed to the new breeding methods being subject to the genetic engineering moratorium.

Recent studies show a differentiated picture of the average Swiss consumer, as is demonstrated by recent research by ETH Zurich. In this survey, 643 consumers from German Switzerland were asked about the topic of herb and tuber rot in potato plants. Specifically, the respondents were asked to indicate which type of treatment they would prefer to use in the event of an attack on the plant. The selection included synthetic pesticides, natural pesticides such as copper used in organic farming, the introduction of a resistance gene from a wild potato or the transcription of certain genes by means of genome editing. The Result: The study participants were most likely to agree to the introduction of a wild potato gene. And the rewriting of the genes was just as acceptable to the test subjects as the use of plant protection products, whether natural or synthetic.

These findings coincide with those of a gfs.Bern survey, which was published in autumn 2021. It also showed that consumers are willing to accept genome-edited foods, if a concrete benefit becomes apparent. Finally, the survey showed that a relative majority is against the Federal Council's plans to subject the approaches of genome editing to the moratorium. The argument that Swiss consumers did not want genetically modified food on their plates therefore falls short. On the contrary, current surveys show that the opportunities of modern breeding methods are recognized. Food produced by means of modern breeding would therefore also have good chances to find widespread acceptance on the local plates - as is already the case abroad. To do so, however, one would have to stop denying scientific knowledge and instead consider doubts and fears.

Sources

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"It needs a declaration. Consumers want to know if they eat genetically modified products."

- To date, more than 4000 crops are likely to have been produced by 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 obligation to declare. Consequently, this should also be avoided in genome-edited plants without transgenic genetic material. After all, this type of breeding is less far-reaching and more targeted than classical mutagenesis.
- Transparency creates trust. Therefore, for each crop, all the processes used in its breeding could be reported in the approval of the variety.

For many decades, the mutagenesis caused by atomic radiation has been systematically used in conventional and organic plant breeding to preserve plants with new properties that are not possible with the methods of classical plant breeding. The chemically induced mutagenesis is still used in plant breeding today. According to a statement by the International Atomic Energy Agency, more than 3200 new plant varieties developed with mutagenesis have been launched on the market by 2017. According to a ruling of the European Court of Justice (ECJ, July 2018), organisms resulting from this conventional, uncontrolled mutation breed are "genetically modified organisms" (GMOs). If one were consistent in the spirit of the ECJ, most of the common vegetables or fruits would probably have to be declared as GMOs. This also relates to organically grown products.

A distinction based on the product makes no scientific sense. One of the outstanding features of genome editing is that modifications in a plant's genome cause changes that could occur naturally. *"In this way, the disease resistance of its original precursor can be transferred to a high-performance crop – and it does not have to be hybridized over years with great effort,"*says Urs Niggli, former director of the Institute for Biological Agriculture (FiBL). Jörg Hacker, President of the German National Academy of Sciences Leopoldina, said in 2018: *"This means that certain forms of genome editing with tools such as CRISPR could be exempted from regulation in the future if their result is 'nature-identical'*.

A unilateral declaration for genome-edited plants without transgenic genetic material would not only be inconsistent, but in their incompleteness even misleading for the consumer. If so, then there would be a general obligation to declare the breeding methods for all crops and products produced from them. It is questionable whether such a product would really add value to consumers, since the majority of products would probably have to bear a GMO label. The declaration of any cultivation method used in the variety approval procedure would serve to create confidence-building transparency.

Sources

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

- Already today, hundreds, if not thousands, of crops are grown using classical mutagenesis. The idea of a "mutation-free" Swiss agriculture is a mirage.
- In view of this, it makes little sense to demand co-existence regulations for genome-edited plants without transgenic genetic material. One would regulate the coexistence of plants bred by directed and undirected mutagenesis, which are indistinguishable in the field. This lacks any scientific logic.

For decades, genome-mutated plants have been in Swiss fields: Many plants have been created using breeding techniques that interfere with the genome. But this has happened much less purposefully than if it had happened with the new breeding methods.

So if the circles that insist on a co-existence regulation were honest, they would explain to their supporters that already today, genetically modified seed is grown on large areas. And in organic farming! Consequently, we should already work to ensure that all those plants that were created by the classical, untargeted mutagenesis disappear from the fields. This would affect thousands of crops. After all, only a tiny number of today's crops have been created entirely without this breeding method.

In view of this, it also makes no sense to subject the cultivation of seeds, which resulted from targeted mutagenesis (genome editing), to co-existence requirements. It would regulate the coexistence of identical products, which is absurd. A separate co-existence regulation for genome-edited plants without transgenic DNA is also unnecessary with regard to crops grown without mutagenesis. For these too have been exposed for decades to the supposed negative influences of mutagenesis-bred and therefore genome-mutated plants. This appears to have no negative impact on the affected varieties, the environment and people.

The same applies to the question of liability: In all facets of economic life, liability issues have been clarified or there are mechanisms in place to clarify them. Exactly the same is the case with the cultivation of plants. It is absurd to assume that there are fundamentally new unsolvable questions of liability. Instead, plant varieties obtained with new breeding technologies can be assumed to have exactly the same legal obligations as a conventional farmer already has when planting new seeds.

More and more countries are choosing to allow genome-edited plants without transgenic genetic material as "genetic engineering free" for cultivation. Where there are no differences in the final product, there should be none in the regulation either – neither in the declaration of products nor in the regulations governing the cultivation of plants. If transgenically bred varieties were ever allowed, one would have to think about a co-existence regulation, because here plants are bred that could not have been created naturally. .

Sources

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CRISPR is not always genetic engineering, Tagesspiegel January 18, 2018

"Companies and research centers always apply for a patent on their inventions. This means that the breeders who want to benefit from the new varieties are coming out of the frying pan and into the fire. As long as these patent issues are unresolved and the new genetic engineering breeding methods will make them even bigger, it will not be possible for breeders in Switzerland to obtain only this seed."

- Globally, approval requirements for genome-edited crops are being relaxed in more and more countries. The research activity is correspondingly strong.
- This opens up a market opportunity for many players. There is an increasing 'democratization' of plant breeding.
- Today, the large agricultural multinationals have a quasi-monopoly on innovative new plant varieties, because new crops are a lengthy and expensive business. Small operators are not able to keep up due to these regulatory hurdles.
- Neither Switzerland nor the EU grants patents on plant varieties. Nor can properties of a plant be patented, provided that they are the result of traditional breeding methods.
- Further breeding with traditional methods remains allowed for breeders under Swiss and EU law in any case, even if patents already exist. However, it may only be marketed without a license, provided that the new variety no longer contains the material protected by the patent.

The fact that researchers or research industries can patent their inventions is nothing new. After all, patents are a strong incentive to invest in research and development. However, this is a little more complicated when it comes to patents on animals and plants. In Europe, for example, patents on conventionally bred plants and animals may not be granted. This also applies to Switzerland. However, this does not apply to properties of plants and animals that have been achieved by a new method, such as genome-editing. Then patents can be asserted. The use would therefore entail the purchase of a license.

It is important to know that special rights for breeders already exist in Switzerland and the EU: Both the Patent Act (Art. 9 para. 1 e) of the Patent Act, SR 232.14) as well as the plant variety Protection Act (Art. 6 c) plant variety Protection Act, SR 232.16) recognize a breeder's privilege. This allows them to continue to breed any variety without obtaining a permit. Even patent-protected biological material may be used freely for the development of new varieties using traditional breeding methods. This ensures that breeders can fall back on the highest possible genetic diversity.
If a breeder wishes to continue breeding a variety for whose properties patents already exist using traditional methods, he may do so. The new variety may then be freely marketed without any license, provided that it no longer contains the material protected by the patent. If the new variety contains the patented feature or technique and profits from it, a corresponding license must be negotiated with the patent owner.
There are no known cases in which the marketing of new plant varieties in Switzerland would have been impossible due to patented properties.

For many researchers in Switzerland, the following is certain: A liberalization of the authorization practice for the new cultivation methods will also lead to new suppliers 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 supply. Because it is clear: In contrast to the classical cultivation procedures, the new methods are more favorable and faster. In the future, it will

no longer be only the big multinationals that will succeed in bringing new varieties to the market. So far, only these could finance the lengthy developments at all.

More suppliers mean more moderate prices in the medium term. Unfortunately, the prevention policy in Switzerland and Europe has led to a limited supply to this day. However, countries such as the United Kingdom are now looking forward to a change in approvals, which should lead to numerous new products in the medium term. Should the EU and Switzerland ever follow suit, a lively market should be established.

Sources

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"The new technologies are actually used today, especially 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 approval of genome-edited plants in different countries will improve and widen the range of products
- The prohibition policy in many countries has led to the fact that only few new varieties could be planted.

A study commissioned by the Federal Office of the Environment in 2020 shows that 63 plant projects are in the development pipeline. Only 11 of them deal with herbicide tolerance. A large part of commercial research therefore has other objectives, such as improved dryness or heat tolerance or yield increases. Nevertheless, the 11 ongoing projects show that further progress can also be expected in terms of herbicide tolerance. In spring 2021, the EU presented a comprehensive study to provide an overview of the global development pipeline of genome-edited organisms. It described 426 applications for plants on their way to the market. The most important areas of genome editing in plant breeding are currently optimized 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 pursued in 38 research approaches. Further breeding goals, each with a share of less than 10 percent, are technical improvements for variety development, herbicide tolerance, improved storage properties as well as changes in color and odor. The implicit claim that existing research did not keep what was promised does not take into account the fact that research is continuing to make progress.

Ironically, some of the opponents of genetic engineering have repeatedly argued that the promises that technology once made were not honored. However, the same circles ensure that research and the commercial application of genetically modified foods are prevented in many countries. Given this prohibition policy in many countries, it is clear that the full potential of genetic engineering has never been fully exploited.

Genome-editing, which enables more precise and cost-effective breeding, will act as a kind of catalyst here. Research is being accelerated and products are likely to improve accordingly. In addition, many countries are currently in the process of liberalizing their authorization practice. This market opening should only help to unleash the full potential of the new breeding methods.

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