TESTBIOTECH Background 25-1-2023

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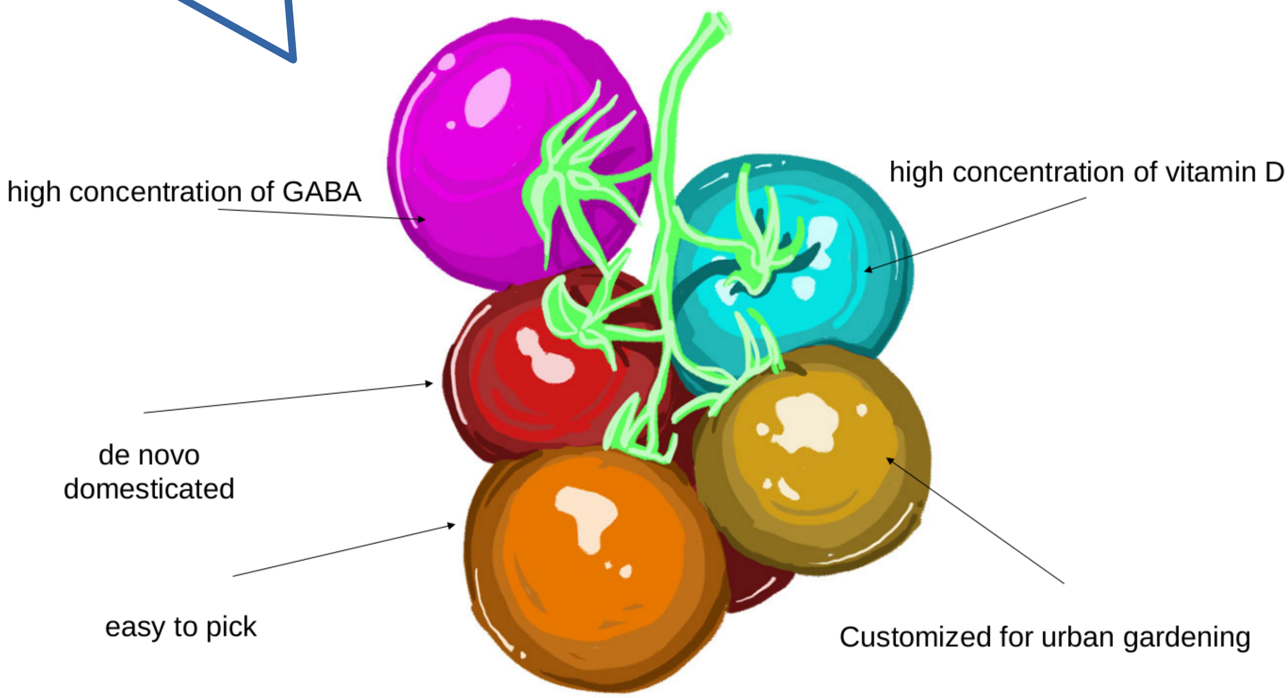
GE tomatoes on the march

What about the changing future of tomato salad?

Dozens of different New GE tomatoes could be grown and consumed in the future. The respective tomato varieties could also be crossed with other varieties or used in food products and salads.



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Summary

Over time, conventional breeding has changed the composition of nutrients and compounds in tomatoes. Very many new and old varieties are bred on the basis of a broad selection from natural biodiversity; and there are, in general, no health concerns about the consumption of ripe tomatoes. Longstanding breeding experience and cultivation over lengthy periods of time mean that tomatoes can be randomly and arbitrarily combined, and consumed in many food products. The use of genetic engineering could soon change this.

CRISPR/Cas ‘gene scissors’, in particular, make the genome available for changes to a greater extent compared to previous methods of breeding. The processes of new genetic engineering (also known as New GE or new genomic techniques, NGT) can cause genetic changes that are unlikely to occur with conventional breeding or random mutations: both the location of the mutation and the resulting gene combination can differ significantly from the results of conventional breeding. This applies to both intended and unintended genetic changes.

New genetic engineering can be used to achieve traits that are much more extreme, many of which can be associated with considerable side effects and risks for the engineered plants, animals and the environment. Such side effects ('trade-offs') can, for example, disrupt the interaction of plants with the environment, endanger food safety or make plants more susceptible to climate stress and diseases. It remains to be shown whether New GE can actually be used to produce plants that, e. g. are more resistant to environmental stress, such as climate change and plant diseases. New GE has great potential for changes in the genome, but it is not easy to translate this potential into actual benefits.

Both intended and unintended genetic changes as well as any effects resulting from the New GE organisms need to be risk assessed during the approval process, as there can be delayed negative consequences or effects that are amplified by combinatorial effects. The differences between New GE and previous breeding can easily be overlooked without a mandatory risk assessment, but can have serious consequences for health and the environment.

New GE applications often target tomatoes. The processes used in the new technology can produce traits that go beyond anything that has been achieved with previous breeding. We have included five examples in this background paper where the biological characteristics of tomatoes have been profoundly altered by the use of gene scissors, even without the insertion of additional genes. Amongst other things, nutrients in the tomatoes are supposedly enriched to lower blood pressure or enhanced for a higher vitamin content. Other New GE applications focus on traits for the cultivation and harvesting of tomatoes. The selected examples show that the results of the New GE processes must be thoroughly examined for risks:

'Easy to pick tomatoes': Genes that are otherwise always inherited in combination have been separated, making the tomatoes easier to pick. The dissection of gene linkage can cause new interactions between genes that cannot be predicted. It must, therefore, be examined whether the ‘gene scissors’ intervention also unintentionally causes changes in other plant characteristics.

'GABA tomatoes': The level of GABA content in these tomatoes is higher than in conventionally-bred tomatoes. GABA is thought to potentially reduce blood pressure. However, GABA has diverse functions in plant metabolism and it can, therefore, be assumed that the intervention in the genome will impact the metabolism of the tomatoes on several levels. For example, the plants may have altered responses to environmental factors, which in turn can influence other nutrients and compounds in the tomato fruit, and thus impact food quality. The tomatoes were not examined in detail before being approved in Japan; neither with regard to the claimed positive effects nor health risks.

'De-novo-domesticated tomatoes': CRISPR/Cas has made it possible to simultaneously alter several genes of the wild form of the tomato. In a 2022 report, the European Food Safety Authority (EFSA) comes to the conclusion that in this case, the current methods of risk assessment are not sufficient to examine the safety of the fruit. Ultimately, the domestication was not replicated, and a completely new tomato variant was generated that had never before been achieved with conventional breeding.

'Small bushy tomatoes’: The small bushy tomato plant is supposed to be particularly suitable for 'urban gardening'. For this purpose, the functions of three different regulatory genes were 'knocked out'. However, these genes influence each other in their functions, which can, amongst other things, lead to severe disturbance of plant growth.

'Vitamin D tomatoes': This tomato has an increased vitamin D content. One side effect is a reduction in the concentration of compounds essential for the natural defence mechanisms of the tomato plants. Environmental risks in this respect may include, e. g. sensitivity to environmental stress, interactions with pollinators and soil organisms or food safety. It should also be remembered that vitamin D can accumulate in the human body and an overdose can cause vitamin D toxicity (hypervitaminosis D).

Dozens of different New GE tomato varieties could be grown and consumed in the future. The respective tomato varieties could also be crossed with each other or their fruits mixed into many food products, including salads.

For example, tomatoes with a higher vitamin content which are consumed in combination with other vitamin-containing foods or food supplements could cause problems. New questions, particularly in regard to long-term effects, could arise if different varieties of genetically engineered tomatoes are mixed together and have, e. g. a higher content of GABA, vitamin D and anthocyanins. In addition, the processes of new genetic engineering also cause unintended effects.

Even if individual tomato varieties are considered to be safe, new uncertainties and risks may arise from the combination of their traits. Thus, a risk assessment of each of the individual New GE tomatoes is necessary, also to assess their cumulative effects and possible interactions with the environment or other New GE organisms. This also applies to other plant species (such as rice, wheat, canola and camelina), animals and microorganisms.

It is therefore important to keep control of the releases of New GE organisms and the marketing of the food products derived thereof. Otherwise, considerable damage could be caused to agriculture and in ecosystems, and many more risks could accumulate and go unnoticed in the production of food. Similar to environmental pollution with plastics and chemicals, it does not always have to be a specific genetically engineered organism that causes the problems; rather, it is the entirety of the effects of New GE organisms that can be decisive.

Against this backdrop, Testbiotech is not per se against further research, but it does see the need for strict control and limitation of the type and quantity of organisms released into the environment or used to produce food. To this end, also in the future, all genetically engineered organisms must be subject to mandatory risk assessment and be traceable after they are brought to market.

1. Introduction

Tomatoes (*Solanum lycopersicum*) are popular fruits that can be eaten raw, cooked or processed into products such as ketchup. Unlike the products of transgenic plants currently imported into the EU (maize, soya, rapeseed, beets and cotton), which are mainly used as animal feed, tomatoes are foodstuffs primarily intended for direct human consumption.

Tomatoes are considered to be healthy. They produce vitamins and secondary nutrients, such as carotenoids, which are said to have a positive effect on human health, but they also produce substances classified as toxic, such as tomatidine (a glycol alkaloid). However, the secondary ingredients in plants and their fruits are not only important for human nutrition, they are also important for the plant itself as a defence against pathogens and pests as well as for interactions with soil organisms and insects, such as bumblebees, which are among the most important pollinators.

Furthermore, gene expression and ingredients change considerably during the ripening process of tomatoes, and the colourants formed during this process have a major influence on the tomato's resistance to pests (see e. g. Jobson & Roberts, 2020). However, not all gene functions and metabolic processes are understood in detail (see e. g. Choi et al., 2022).

Over centuries, conventional breeding has changed the complex nature of the biologically active nutrients and compounds in tomatoes. Natural biological diversity thus provides great potential for breeding different tomato varieties. If, in the course of the long period of conventional breeding, variants have also appeared that were unsuitable for human consumption, these errors have been corrected. The tomato fruits currently on the market can be randomly and arbitrarily combined and consumed in food products, as this based on longstanding experience gained from breeding and cultivation. But does this also apply to genetically engineered tomatoes?

2. Transgenic tomatoes (old GE)

The first genetically engineered tomato plant to be approved in the USA in 1994 was the so-called Flavr-Savr tomato. It was approved for marketing in some European countries as tinned tomatoes. The aim of the genetic engineering was to block the production of a plant enzyme responsible for breaking down the cell walls - the tomato thus remained "in shape" for longer. This tomato variety was an economic flop, as it was difficult to harvest and its taste was not convincing either. It was quickly withdrawn from the market.

In 2022, another GM tomato was tested by the authorities in the USA: the USDA approved the release of the tomatoes with increased levels of anthocyanins, which are considered health-promoting substances.[1] However, further testing could be conducted by environmental and health authorities before commercial cultivation is started. The tomato contains genes from other plants (snapdragon) and also a resistance gene against antibiotics (Butelli et al., 2008). The tomato was developed in the UK in 2008 at the John Innes Centre, which is also involved in the development of New GE tomatoes (Li et al., 2022).

3. New GE Tomatoes

New GE can be used to bring about genetic changes that go beyond anything that can be achieved with conventional breeding, even without having to insert additional genes. Unlike conventional breeding (including random mutagenesis), New GE techniques can overcome the limitations of naturally evolved genome organisation. CRISPR/Cas ‘gene scissors, in particular, make the genome available for changes to a much greater extent compared to previous methods of breeding (Kawall, 2019).

This higher availability of the genome makes it possible:

- to make fundamental changes in the biological properties of organisms, even if no additional genes are inserted;
- to overcome the limitations of natural genome organisation such as repair mechanisms (or other protective factors, e. g. gene duplications), thus generating new genotypes beyond what can be achieved with conventional breeding;
- to achieve more extreme versions of known phenotypes or even new phenotypes (traits), which are often associated with side effects ('trade-offs').

In addition, the technical capacity of tools, such as CRISPR/Cas, also have immense potential to generate unintended genetic changes that are hardly possible using conventional breeding.

There are currently many projects using New GE to generate new traits that cannot be achieved with conventional breeding. Against this backdrop, five well-known examples were selected for this report. Many of the projects involve intervening in the metabolism of the tomatoes to change the composition of the nutrients and compounds so that the tomatoes become 'even healthier'. Others target properties that affect the cultivation and harvesting of tomatoes. In all cases, the properties of tomatoes are profoundly altered by the use of genetic scissors, even though no additional genes are introduced.

Table 1 gives an overview of some selected projects. This is followed by a characterisation of the tomatoes and what is known so far about the risks.

1 https://iflscience.com/genetically-modified-purple-tomatoes-will-be-popping-up-on-us-plates-by-next-spring-65283

Table 1: Selected examples of tomatoes derived from New GE

Trait	Stage of development / regulation	Sources
Easy to pick	Deregulated by USDA	USDA, 2020
Increased content of GABA (γ-Aminobutyric acid)	Authorised in Japan for cultivation in domestic gardens and for consumption	Nonaka et al., 2017
De-novo domesticated tomato	Basic research	Zsögön et al., 2018
Small bushy tomato (‘Urban Gardening’)	Deregulated by USDA	Kwon et al., 2019
Increased content in Vitamin D	Field trials planned in UK	Li et al., 2022

3.1 Easy to pick tomatoes

The tomato genome contains a high percentage of traits that are always inherited in combination (Lin et al., 2014). This is referred to as ‘genetic linkage’. The respective genes determining the traits are often close to each other in the genome. Gene combinations in which a desired trait is linked to an undesired trait is often problematic for breeders. One example is a trait that facilitates harvesting: the fruit can be picked from the plant without the stalk sticking to it. This 'easier harvesting' trait is, however, always inherited in combination with a less desirable tomato shape. With the help of New GE, it was possible to decouple the desired genetic trait ('easier harvesting') from the undesirable trait. This has resulted in tomatoes that are easy to detach from the stalk and have the desired fruit shape. It is, however, a combination of traits that is different from what could be achieved with previously-used breeding methods. The structure of the genome was changed in such a way that new gene combinations were created, which could not otherwise have been expected. The US Department of Agriculture (USDA, 2020) classified the tomatoes as not requiring approval. However, no cultivation appears to be taking place as yet.

Important for risk assessment: Current research shows that the structure of the genome, especially in tomatoes, has a considerable influence on the growth and response of the plants to environmental factors. It also influences nutrients and compounds in the tomato fruit (see point 4.2). Genetic linkage is important for the structure of the genome and the interactions between genes (Soyk et al., 2019). It is therefore important to investigate whether other properties, such as the composition of the nutrients and response to stress factors, are also unintentionally changed as a result of the intervention with the gene scissors.

3.2 GABA tomatoes

In Japan, the first 'CRISPR tomato' was released for consumption in January 2021, the same one which had also previously been deregulated by the US Department of Agriculture. The GABA content in the tomatoes is many times higher than in tomato fruits obtained from conventional breeding. GABA (γ-aminobutyric acid) can inhibit the transmission of certain stimuli in the central nervous system, which is why it has, amongst other things, a blood pressure-lowering effect (Nonaka et al., 2017). Accordingly, the fruits are promoted as a modern lifestyle product. However, at the same time, GABA influences many different functions in tomato plants: amongst other things, it influences growth, resistance to pests, plant diseases and other metabolic functions. The content of GABA in tomato plants increases naturally when, for example, it is attacked by pests. In contrast, attempts to permanently increase the GABA content by means of conventional breeding have so far been unsuccessful.

Important for the risk assessment: Due to the diverse functions of GABA in the metabolism of the plants, it can be assumed that the intervention in the genome will impact the metabolism of the tomatoes on several levels. For example, the plants can show altered responses to environmental factors, which can in turn have an influence on the nutrients and compounds in the tomato fruit and, therefore, on food quality (see also point 4). The tomatoes were not examined in detail before being approved in Japan; neither with regard to the claimed positive effects nor health risks.

3.3 De-novo domesticated tomatoes

In 2018, CRISPR/Cas 'gene scissors' were used to successfully and simultaneously change several genes in the wild form of the tomato plant. 'Cuts' to six genes turned small fruits growing on bushy plants into tomatoes that looked similar to the tomato fruits currently on the market (Zsögön et al., 2018). New genetic engineering can in a short space of time replicate the results of decades of conventional breeding. When several genes are altered at the same time, this is referred to as "multiplexing". Although no additional genes are inserted, the results are astonishing: the number of fruits, their size and shape, ingredients and growth habit were changed in a few steps and within a short time. No application for approval has yet been submitted for these tomatoes.

Important for risk assessment: As current research results show, the structure of the genome of the different tomato varieties has a considerable influence on the growth and response of the plants to environmental factors (see point 4). In fact, a 2022 European Food Safety Authority (EFSA) report came to the conclusion that the previous risk assessment methods were not sufficient to assess the safety of the fruit in this case. The reason: the composition of the nutrients and compounds in the tomato were so different to those in commercially grown tomatoes that the usual comparison with conventionally-bred plants would not produce meaningful results (EFSA, 2022). Ultimately, therefore, domestication was not replicated, but a new tomato variant was generated which would in all likelihood not have been achieved with conventional breeding.

3.4 Small bushy tomatoes

In 2020, a paper was published on a small bushy tomato plant that was supposed to be particularly suitable for 'urban gardening' in limited spaces; earlier flowering was also a feature (Kwon et al., 2020). In this case, CRISPR/Cas was used to knock out the function of three different regulatory genes that influence the growth of tomatoes. A patent is pending for these tomatoes (WO2021108272) and they have been deregulated by the US Department of Agriculture (USDA)[2]. However, the tomatoes are apparently not yet being cultivated. As the regulatory genes affect many traits of the plants simultaneously, some variants of CRISPR tomatoes exhibited severe growth disorders. Other variants showed sufficient vigour in the greenhouse, but bore very small fruits.

Important for the risk assessment: As mentioned, current research has proven that the structure of the genome of different tomato varieties exerts considerable influence on the growth and response of the plants to environmental factors (see point 4.2). In the present case, it was shown that the target genes also influence each other in their regulation and expression (epistasis), which can lead, amongst other things, to severe growth disorders in the plants.

2 www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/Regulated_Article_Letters_of_Inquiry

3.5 Vitamin D tomatoes

According to a paper published in 2022, it is possible to increase the content of vitamin D in tomatoes with the help of New GE (Li et al., 2022). However, depending on the tomato variety and environmental conditions, the concentration of vitamin D in the fruit can vary greatly. Precise dosage, e. g. using tablets, is hardly possible. In addition, the gene that was 'switched off' with the help of CRISPR/Cas also affects the synthesis of natural defence substances (such as α-tomatin), which are important for the plants. The tomato plant could, therefore, be more susceptible to pests or even climate change. In order to check the risks and possible benefits, a variant of the tomato will be tested in field trials in England. No application for approval has been submitted as yet.

Important for the risk assessment: Whether or not the genetically engineered tomatoes create new problems instead of the hoped-for benefits is completely open. There are risks to both the environment and food safety, e. g. sensitivity to environmental stress, interactions with pollinators and soil organisms. It should also be remembered that vitamin D can accumulate in the human body and an overdose can cause vitamin D toxicity (hypervitaminosis D).

4. What are the causes of risks?

As explained above, New GE can be used to achieve new genotypes and biological traits in a different way and with different results compared to previously used genetic engineering techniques or conventional breeding methods (including random mutagenesis). There are risks and side effects associated with the use of tools such as CRISPR/Cas. Tomato plants are a useful example in this respect.

4.1 Intended and unintended changes

Although New GE has great potential to induce changes in the genome, it is not easy to translate this potential into actual benefits. The reason is that the traits obtained with New GE are often extreme expressions of biological traits that would hardly be expected from conventional breeding. This depth of intervention can lead to side effects ('trade-offs') in the metabolism of the organisms, which, for example, disrupt the interaction of plants with the environment, cause animal welfare issues or endanger food safety. Such side effects can occur even if the intervention in the genome is targeted and precise, and must, therefore, be taken into account in risk assessment. The side effects also have a considerable influence on the length of time it takes for New GE plants or animals to actually make it from the laboratory to market maturity, and also call into question whether this can be achieved at all.

In addition, although New GE and its most important tool, CRISPR/Cas ‘gene scissors’, is more precise and faster than previous genetic engineering methods, it is by no means error-free. Whilst unintended genetic changes (mutations) also occurred with previous breeding methods, these changes could have occurred spontaneously (naturally) over longer periods of time.

In contrast, New GE processes are accompanied by genetic changes that would in all likelihood not happen in conventional breeding or random mutagenesis: both the location of the mutation and the resulting gene combination can differ significantly from the results of conventional breeding and from natural processes. This applies to both intended and unintended genetic changes. Accordingly, the risks can also differ significantly from those of conventionally-bred plants or animals. If unintended genetic changes are overlooked, they can spread rapidly in larger populations.

In this context, it is important to note that the processes of new genetic engineering involve several steps, all of which are associated with risks. For example, the use of CRISPR/Cas ‘gene scissors’ in plants (also in the case of tomatoes) typically starts with the non-targeted procedures of 'old genetic engineering' to introduce the DNA that forms the gene scissors into the cells. Therefore, the result of the first step of CRISPR/Cas technolgy in plants is, in most cases, a transgenic organism that may have a broad range of unintended genetic changes. The transgenes are only removed from the genome at the end of the multi-step process with the application of conventional breeding (segregation breeding).

An overview of risk issues related to the intended and unintended genetic changes caused by New GE can be found, for example, in Kawall et al. (2020) and Kawall (2021).

As a result, at each stage of the process - (i) the insertions of DNA for gene scissors, (ii) the recognition and alteration of the target region and (iii) the repair processes in the cells - specific unintended changes can occur that are associated with risks.

4.2 New gene combinations and changes in the structure of the genome

Genetic specificity must be taken into account when intervening in the genome of our crops, such as tomatoes: it has been shown in recent years that there is a large (natural) genetic variance between varieties, especially in the genome of tomatoes, which is not only reflected in specific gene variants, but also in the structure and composition of the genome. The effect of a gene depends, in general, on its location in the genome. If the structure changes, the effect of a gene can also be changed.

Major deviations in the structure of the genome are called 'structural variations'. They can arise, for example, from gene duplications or major deletions in the genome (Alonge et al., 2020). Structural variations can cause major differences in the structure of the genome between varieties. In tomato plants, these differences can have a great influence on the size and taste of the fruit, but also on their response to environmental stress (Alonge et al., 2020).

As mentioned above, the effect of individual genes in a plant also depends on the structure of the genome and the interaction with other genes. It is known that the interactions between genes can often have unpredictable and also extremely negative consequences (Rodríguez-Leal et al., 2017; Soyk et al., 2019; Alonge et al., 2020). In this context, the presence or absence of mutations in other genes can strongly influence the effects. For example, two positive traits can actually have negative effects in combination, this effect is called epistasis (Soyk et al., 2019; Alonge et al., 2020; Jobson & Roberts, 2020). In addition, some of the structural variations are initially ‘silent’, i. e. have little or no influence on the development of the plant. However, such variations, which are referred to as 'cryptic gene variants', can become apparent when they are recombined with other genes or after exposure to environmental influences.

Since the use of 'gene scissors' often leads to the creation of new gene combinations that would otherwise not be possible or expected, the effect of 'cryptic gene variants' and potential changes to the structure of the genome must be given special consideration.

In this context, it is often difficult to estimate the effect of a new variation inserted by the gene scissors. For new gene combinations, interactions with other mutations as well as effects caused by the structure of the genome and different environmental conditions must be included and tested (Kawall, 2021).

Table 2: Selected examples of New GE tomatoes, side effects and risks*

Trait	Differences compared to conventional breeding	Relevance for risk assessment
Easy to pick	Separation of genetic linkage causes new gene combination not previously achieved.	The tomatoes have to be examined to exclude risks caused by the structural changes in their genome.
Increased content in GABA (γ-Aminobutyric acid)	New gene combination not previously achieved results in higher GABA content.	Impacts on health? Changed response of the plants to environmental stressors?
De-novo domesticated tomato	Simultaneous knock-out of six genes results in new gene combination not previously achieved as well as major changes in plant composition.	According to EFSA, the changes in plant composition need to undergo detailed risk assessment.
Small bushy tomato (‘urban gardening’)	Simultaneous knock-out of three genes results in new gene combination not previously achieved.	Interactions between the genes cause unintended effects on growth and result in smaller tomato fruit.
Increased Vitamin D content	New gene combination not previously achieved results in higher Vitamin D3 content and a reduction in the natural defence substances in the plants.	Impacts on health? Changes in plant fitness and weakened tolerance of the plants to environmental stressors?

* see references in the body of the text

4.3 Interactions and cumulative risks

New GE organisms across many species with a wide range of different traits may soon be released into the environment. Cumulative damage resulting from these releases may be more or less likely, depending on the intended or unintended traits. Large-scale releases may increase the likelihood of such effects. Interactions may occur between species or between different traits within a species. These interactions may be direct or indirect, immediate, delayed or even cumulative.

In general, interactions resulting from additive, antagonistic or synergistic effects are difficult to predict. Both intended and unintended effects must be considered. Even if individual New GE organisms are considered to be safe, new uncertainties and risks may arise from the combination of their properties. Thus, individual New GE organisms must be risk assessed, including their cumulative effects and their possible interactions with the environment or other New GE organisms.

This also applies to New GE tomatoes. Up until now, different tomato varieties can be mixed into in all types of food, e. g. tomato salad, or combined with other foods or food supplements. They can be consumed raw in large quantities without any specific health risks. However, in the future, dozens of New GE tomato varieties could be grown and sold for consumption. In addition, there may also be other transgenic tomatoes derived from 'old genetic engineering' on offer. The respective tomato varieties could also be crossed with each other, mixed into other food products or used, e. g. in salads.

Tomatoes with increased vitamin content that are consumed in combination with other vitamin-containing foods or food supplements could lead to future problems. New questions, particularly in regard to long-term effects, could arise if different varieties of genetically engineered tomatoes are mixed and consumed together and have, e.g. a higher content of GABA, vitamin D and anthocyanins. In addition, there are other unintentional changes in the tomato fruit nutrients and compounds, some of which are so complex that their overall effect is difficult to assess (see e. g. EFSA, 2022).

So far, the EU authorisation approval process has held back from examining the interactions of products from different GM plants that could be mixed into food products and/or feed. Apparently, EFSA does not have a sufficient methodology. Chronic and indirect health effects, which can arise, for example, through changes in the microbiome (the composition of the intestinal bacteria), have not yet been taken into account. In addition, analytical methods that can measure changes at the metabolic level (so-called 'omics') have also not yet been used (see also Testbiotech, 2021).

Against this backdrop, it is obvious that the approval process for the genetically engineered tomatoes, which is used here as an example, would present the EU food authority with considerable difficulties. At the same time, deregulation, i. e. approval of the tomatoes without thorough risk assessment, would not be justifiable. Similar conclusions can be drawn from the evaluation of other NGT projects, e. g. wheat plant (see Testbiotech, 2022).

Conclusions

The differences between New GE and previous breeding may easily be overlooked without a mandatory risk assessment, but can have serious consequences for health and the environment.

It is therefore important to keep control of both releases of New GE organisms and the marketing of any derived food products. Otherwise, considerable damage could be caused to agriculture and in ecosystems. In addition, many more risks could be introduced and go unnoticed in food production processes.

Even if individual tomato varieties are considered to be safe, new uncertainties and risks may arise from the combination of their traits. What is needed is a risk assessment of the individual New GE tomatoes, in addition to risk assessment of their cumulative effects and their possible interactions with the environment or other New GE organisms. This also applies to other plant species (such as rice, wheat, rapeseed, camelina), animals and other life forms, such as microorganisms.

Similar to environmental pollution with plastics and chemicals, it does not always have to be a specific genetically engineered organism that causes the problems; rather, the sum of the effects of genetically engineered organisms can be decisive.

This also applies to New GE tomatoes. At present, different tomato varieties can all be mixed into, e. g. tomato salad, or combined with other food products or food supplements. Raw consumption, even in large quantities, is not associated with specific health risks.

In future, the consumption tomatoes with increased vitamin content in combination with other vitamin-containing foods or food supplements could lead to problems. New questions, particularly in regard to long-term effects, could arise if different varieties of genetically engineered tomatoes are mixed together and have, e.g. a higher content of GABA, vitamin D and anthocyanins. In addition, there are unintended effects caused by the processes of new genetic engineering.

Against this backdrop, Testbiotech is not per se against further research, but does see the need for strict control and limitation of the type and quantity of organisms released into the environment or used to produce food. To this end, all genetically engineered organisms, also in future, must be subject to mandatory risk assessment and traceable after being placed on the market.

Clearly, the New GE tomatoes and also all other New GE plants must undergo mandatory approval assessment before they can be released and/or marketed. The risk assessment must identify (as currently required by EU legislation) the intended and unintended genetic alterations caused by the process of genetic engineering, and evaluate them in terms of potential harm to health and the environment. This must take into account direct and indirect effects, which may be immediate, delayed or cumulative.

In addition, specific risks arise from biologically active substances, such as GABA and vitamin D, and their effects and side effects on human health: alleged health-promoting effects ('health claims'), therefore, need to be examined in detail for effects and side effects.

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