New GMOs

in Cultivation
in Development
withdrawn from the Market

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Table of Contents

Editorial		3	
Executive Summary		4	
Graphic 1: New GMOs in Development		6	
Graphic 2: New GMOs in Development: Where the Developers are based		7	
Current GMO Regulation in the US		8	
Legislative Update EU		10	
Regulatory Hotspots around the Globe		12	
Detection Methods: Project Report DETECTIVE		14	
Table 1: New GMOs in Cultivation		16	
Table 2: New GMOs in Development		17	
Table 3: New GMOs withdrawn from the Market		24	
Imprint		25	
Editors		26	



Editorial

Dear Readers,

elcome to the first edition of the New GMOs Market Report, the first publication tailored to food business operators who want a concise overview of which New GMOs they may need to deal with today and in the near future. The editors of this report bring together their international expertise to offer the food industry a vital synopsis of New GMOs. ENGA is representing the Non-GMO food and feed industry in Europe, the Non-GMO Project is the main certifier of Non-GMO food in North America, and Eva Gelinsky is a researcher based in Switzerland.

We have decided to use the term New GMO for an international audience instead of the term 'New Genomic Techniques' used by EU institutions or 'gene editing', which is commonly used in North America to describe GMOs into which no 'foreign' DNA has been incorporated. New GMOs are not allowed in Non-GMO commodity chains. In other words, products that carry a Non-GMO label must exclude New GMOs. We also use the term 'old genetic engineering' or old GMOs for transgenic GMOs.

The main criteria for including a plant in our report are cultivation and "cleared for market access"; cultivation is a prerequisite for appearing in commercial food streams, "cleared for market access" means "cleared for cultivation" or clearance is to be expected. The latter crops are listed in our table "New GMOs in development". Our chapter "Regulatory Hotspots around the Globe" describes what clearance means in selected countries.

In addition, our readers should be aware that it is often an open question whether plants "in development" will reach the market, become a success or simply disappear again. In other words, if the companies that develop New GMOs are not obliged to disclose cultivation data, we are confronted with uncertainties.

Our recommendation to the food and feed sector: As a minimum requirement, you should explicitly exclude New GMO products in your supplier requirements. If possible, use goods from certification systems that also exclude New GMOs. Further chapters of our report include New GMOs that have been withdrawn from the market, regulatory developments in the EU and the USA and the status of research into detection methods.

With our report we would like to provide clarification: New GMOs are often a promise, but not a market reality. Up to now, not a single plant contributes to sustainability. At the moment, the food sector is by no means faced with a flood of New GMOs, but only with individual plants.

We thank Dennis Eriksson (Associate Professor Genetics and Plant Breeding, Swedish University of Agricultural Sciences), Pat Thomas (Beyond GM, UK), Claire Robinson (GMWatch, UK), and Lucy Sharratt (Canadian Biotechnology Action Network, CBAN) for their valuable contributions.

We hope you find our research helpful, and we look forward to your feedback and input.

THE EDITORS

Hans Eisenbeis, The Non-GMO Project (USA) Eva Gelinsky, Researcher (CH) Heike Moldenhauer, ENGA (BE)



Executive Summary

Our report shows the huge discrepancy between the hype surrounding New GMOs and the worldwide market reality.

Currently only three New GMOs are being cultivated, while the first two plants that were ever cultivated have disappeared from the market (*see table 3*). 49 crops are in development, often cleared for market access but not cultivated (*see table 2*).

Until now, despite sweeping claims, not a single New GMO contributes or has contributed to sustainability.

New GMOs in cultivation (Table 1)

Currently three New GMOs are being cultivated in two countries. In the USA, two herbicide- and insectresistant maize varieties developed with CRISPR are being cultivated. Both varieties are also transgenic. Insect and herbicide resistance as dominant characteristics of "old" (transgenic) genetic engineering have been produced with a new technique, CRISPR. In Japan, a tomato with increased GABA content is on the market, intended to lower blood pressure, also developed with CRISPR.

New GMOs in development (Table 2)

In development there are 49 New GM crops which belong to 20 species (*see graphic 1*). While the application of old genetic engineering largely focussed on four plants - soy, maize, rapeseed and cotton - used as animal feed, processed food ingredients, fuel or clothing, the spectrum of application of the New GMOs is far broader.

With new genetic engineering, companies are working on a variety of plants that are intended for direct human consumption. The developers of New GMOs have also become more diverse: Whereas old GMOs were mainly produced and marketed by the 'four gene giants' Corteva, Bayer, BASF and Syngenta, many companies are involved in the development of New GMOs, as are state institutes. According to our table "New GMOs in development" their developers are based in nine countries. The USA is far and away in the lead, followed by China (*see graphic 2*).

In our research we identified 30 New GMOs in the USA that are "cleared for market access" but

are not being cultivated. Many may never reach the market.

CRISPR is by far the most used technique, only three out of 49 crops were developed with another genome editing technique. In view of the broad sustainability claims made for New GMOs, often tactically used in the EU legislative debate to justify far-reaching deregulation, a look at the traits is sobering: only two of the crops "in development" could contribute to countering the climate crisis or the loss of biodiversity, a drought tolerant and a salt tolerant crop. Quite apart from the question of whether the plants will make the leap from "New GMO in development" to "New GMO in cultivation" ...

New GMOs withdrawn from the market (Table 3)

The media constantly reports on New GMOs that are supposedly soon to come onto the market. On the other hand, failures and plants that have disappeared from the market are barely worth a marginal note. This was the case with the first two New GMOs ever



introduced to the market, which were economic flops: They did not bring the companies any boon: one -Cibus - took over the other - Calyxt, and Cibus is under investigation by a series of US law firms for deceiving investors by 'over-hyping' its technology.

Regulatory Landscape

Our articles on legislation in the USA and the EU and on "Regulatory Hotspots around the Globe" show that the deregulation of New GMOs is very often triggered by the assumption that "no foreign DNA" has been incorporated into a plant and/or that the genetic change could have occurred through conventional breeding. If this is the case, safety assessments and traceability and labelling requirements will be abolished. Of the countries we have looked at, only Mexico and South Korea regulate "old" the same way as New GMOs and only South Korea has tightened its GMO legislation. However, there seems to be some movement in the US, for decades the pioneer of constant deregulation. At the end of 2024, a federal court overturned certain parts of the 2020 SECURE rule, which exempted many gene-edited plants from US Department of Agriculture regulation. Consequently, the USDA has been ordered to change the way it regulates some geneedited crops. This decision reinstates the pre-2020 regulatory framework, requiring the USDA's Animal and Plant Health Inspection Service to conduct caseby-case assessments of genetically engineered crops. More recently, discussions have started to revise the Generally Recognized As Safe (GRAS) pathway that allows biotech companies to self-determine safety without Food and Drug Administration review. Proposed reforms would require more rigorous and transparent scientific documentation and potentially a mandatory FDA assessment.



GRAPHIC 1 New GMOs in Development





GRAPHIC 2 New GMOs in Development: Where the Developers are based





n the US, the regulatory system for GMOs is shared between the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA). The FDA regulates human and animal foods, including GM foods. The EPA regulates pesticides, including so-called "plant-incorporated protectants" (PIPs) that are in some GM plants to kill insects, such as Bt toxins. The USDA regulates all plants, including GM plants, based on whether they could act as plant pests or noxious weeds. (References: <u>1</u>, <u>2</u>, <u>3</u>, <u>4</u>)

The US regulatory landscape for GMOs continues to operate with a persistent trend toward deregulation for the past 20 years. This trend has broadly influenced the regulatory environment in many other countries (see article <u>"Regulatory Hotspots around the Globe"</u>).

However, in late 2024, a US federal court struck down the "SECURE Rule," a key 2020 regulation made by the US Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), which has oversight on plant health, invasiveness and agricultural risk issues. The SECURE rule dramatically reduced APHIS oversight of genetically engineered crops, including those developed using gene editing techniques like CRISPR. This authority is limited to evaluating whether a GMO poses risks as a plant pest or a noxious weed, rather than conducting broader environmental or health risk assessments.

(<u>Reference</u>)

Introduced under the first Trump administration, the SECURE rule exempted many genetically engineered crops from environmental and safety reviews, particularly when the applicant argued that their genetic changes could have occurred naturally or through conventional breeding. It allowed developers to selfdetermine that their products were exempt from regulation without independent government review. As a result, exempt gene-edited crops were not subject to federal traceability, mandatory labelling, or pre-market oversight.

A coalition of 29 farming, environmental, and public interest groups – including the National Family Farm Coalition and the Center for Food Safety – filed a lawsuit in 2021, arguing that the rule violated federal laws including the Plant Protection Act, Endangered Species Act and National Environmental Policy Act. (*Reference*)

The lawsuit claimed the USDA failed to adequately assess environmental risks, ignored its own scientific experts' concerns and improperly delegated regulatory authority to private entities. The court ruled that the SECURE rule was "arbitrary and capricious" and violated the Plant Protection Act by not exercising its authority to regulate potential plant pests as well as noxious weeds – plants that threaten agriculture, biodiversity, or the environment. The court vacated the rule, though plants previously approved under SECURE remain unaffected. (*Reference*)

This decision reinstates the pre-2020 regulatory framework, requiring the USDA's Animal and Plant Health Inspection Service to conduct case-by-case assessments of genetically engineered crops. The USDA could still appeal this decision – though as of May 2025 there is no indication of this happening.

In March 2025 Health and Human Services Secretary Robert F. Kennedy Jr. led discussions to revise the Generally Recognized As Safe (GRAS) pathway, potentially affecting GM foods (*reference*). Under current practice, the US FDA holds that most GM foods can be marketed without prior safety testing or government oversight because they are GRAS, in that "the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food." Substances resulting from GM that do not fit this definition, in that they are different



from substances commonly found in food, must be authorised by the FDA as food additives. (*Reference*)

Currently biotech companies can self-affirm GRAS status for GMO-derived food ingredients and additives (but not crops or whole foods) without Food and Drug Administration (FDA) review. FDA has oversight on food safety, nutrition and labelling issues in the US.

Under US Federal law, for a food that has not been in common use before 1958 (which applies to all GM foods), GRAS status is "based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food". In addition, the food must be shown to be safe through "scientific procedures" and is "based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published." Based on these criteria, any review of the GRAS pathway for GM foods would require more rigorous and transparent scientific documentation and potentially a mandatory FDA assessment. (References: <u>1</u>, <u>2</u>)



inal negotiations between the EU institutions on New GMO started in May. The EU trilogue negotiations between the Parliament, Council, and Commission on New Genomic Techniques (or "New GMOs") will determine the final shape of the new legislation.

"Plants obtained by certain new genomic techniques and their food and feed", the deregulation proposal for New GMOs (or NGTs), was submitted by the EU Commission the 5th of July 2023 (*reference*). According to the proposal, NGT plants should have their own regulation and be divided into two categories: those considered equivalent to conventional plants (category 1 NGT plants) and which, therefore, will be exempted from the EU's GMO legislation, i.e. they are no longer subject to any risk assessment and labelling and traceability requirements; and those which will continue to have to comply with the stricter rules the EU's GMO legislation (category 2 NGT plants), including a risk assessment 'light'.

Labelling and traceability

One of the biggest sticking points in the trilogue is the labelling and traceability of NGT1 plants and products, essential for all food producers and retailers who want to continue to have no GMOs (old and new ones) in their supply chains or just want to keep their entrepreneurial freedom of choice. And it is just as important for consumers, who want to decide for themselves whether they want to buy and eat New GMOs.

While the Commission and Council propose only seed-level labelling, Parliament wants full supply chain labelling, all the way to the supermarket shelf. The proposed label: "New Genomic Techniques." This matters because 94% of the NGTs currently in the pipeline fall under category 1, according to Germany's Federal Agency for Nature Conservation (*reference*). For category 2 NGTs GMO labelling is mandatory according to all three institutions.

In addition, Parliament voted for the traceability of all NGTs, taking a different stance from the Council and Commission. According to the Parliament, at each stage of their marketing, information must be transmitted and retained for any products that contain or consist of NGT plants and products. Each NGT must also have a unique code.

Why labelling throughout the whole chain is essential for food companies

A legal opinion by the Berlin law firm GGSC (*reference*) emphasises the importance of labelling throughout the whole value chain for food companies. According to recital 22 of the NGT legislative proposal food, companies must check whether an NGT1 plant requires authorisation under the Novel Food Regulation. If it does, food companies are responsible for safety tests. However, food companies cannot know that they are placing food on the market that contains category 1 plants and that they could have to fulfil the Novel Food Regulation requirements. That is because the Commission's proposal only provides for a labelling obligation for seeds and plant propagating material, but not for food and feed.

Transparency rules would only apply to seed companies, but not to all other economic operators. Furthermore, according to the Commission's proposal, NGT1 seeds could be allowed to be placed on the market even if the foodstuffs produced from them were not authorised under the Novel Food Regulation and therefore are not allowed to be sold. This means that food companies along the entire food chain, from farmers to retailers, could unknowingly violate the





Novel Food Regulation. To avoid the entire EU food sector running the risk of violating the obligations which the Commission's legislative proposal assigns to them, the labelling obligation for category 1 NGTs must be extended to the whole food chain. For seeds that are used for food production, it must be clarified before they are placed on the market whether the food is subject to the Novel Food Regulation. If this is the case, the corresponding safety assessment must be completed, and the food must be included in the Union list of authorised Novel Foods. Regarding the EU food sector an extended labelling would be desirable: Is an NGT of category 1 a Novel Food and does it have a Novel Food authorisation?

As far as liability risks for the food sector are concerned, the legal opinion explains: In the event of damage, claims would primarily be made against food manufacturers and retailers. They are liable for defective food and the resulting damage. Even if they can take recourse against the developers of the NGT1 products, such claims will often not be enforceable, particularly in the case of biotechnology companies abroad or companies with limited assets. Food companies are usually insured against liability risks, such as damage to health. However, there is no insurance that covers GMO/NGT risks. Due to these liability risks alone, the food sector should know - through labelling across the supply chain - whether it has NGT1 products in its supply chains.

Detection methods

Of all three institutions, the Council is the only one that is in favour of detection methods for NGT1 plants. Even if "the introduced modifications of the genetic material are not specific to the NGT plant in question", and "they do not allow the differentiation of the NGT plant from conventional plants" (...) "an analytical method should still be provided by the notifier or applicant." This should apply with the following restriction: "if duly justified, the modalities to comply with analytical method performance requirements should be adapted."

Mandatory detection methods for NGT1 plants would be a major relief for the European food sector. They would have analytical methods at their disposal that would allow them to know whether NGT 1 plants are present in their supply chains. Conventional and organic Non-GMO producers in particular would have another option in addition to traceability, to guarantee that their products are Non-GMO (*reference*).

How will the trilogue proceed?

Predicting an outcome at this stage is pure guesswork. The Parliament, the Council and the Commission can agree on a joint law quickly, or they could negotiate for a long time. There is no time limit.

The new law will be passed when the Council reaches a qualified majority (this is a majority of countries, or 55%, comprising at least 15 of them, that represent 65% of the EU population) and the Parliament reaches a simple majority. The law must be applied two years after it comes into force.

As always with trilogues: Nothing is agreed until everything is agreed.



Canada has removed most regulatory mechanisms for New GMOs. In May 2023, Health Canada issued new guidance (*reference*) clarifying that foods from gene-edited plants (those that do not contain foreign DNA and/or meet certain other criteria) are not automatically considered "novel foods" and will therefore not require government safety assessments or disclosure and traceability measures. In September 2024, Bayer stated an intention to market gene-edited mustard greens in Canada (see table 2).(*Reference*)

China is progressing toward widespread commercialization of GM crops, as well as refining a regulatory framework for gene-edited crops. In 2022, China's Ministry of Agriculture and Rural Affairs issued its first guidelines that generally align with efforts in many other countries to streamline approval of these New GMOs. Some observers note that detection methods and food safety assessments are not yet adequately developed in China's approval framework. (*Reference*)

New Zealand has long been considered a Non-GMO haven, due to the island's 30-year restrictions against genetic modification outside of laboratories. The government aims to pass legislation by the end of 2025 to permit gene editing techniques without stringent regulation. However, concerns have been raised about potential economic impacts on the country's NonGMO export market, valued at NZ\$20 billion annually. (*Reference*)

Japan has adopted a permissive stance on geneedited foods, allowing products like GABA-enriched tomatoes and gene-edited fish to be sold without safety evaluations, provided no foreign genes are introduced.

The Philippines and Singapore are taking similar positions. This approach has faced criticism from consumer groups advocating for mandatory safety assessments, traceability measures and labelling. (*Reference*)

By contrast, **South Korea** is tightening its GMO regulations, which apply to all GMOs regardless of whether they are gene-edited. Proposed amendments to the Food Sanitation Act would require labelling of all genetically modified foods, regardless of whether modified DNA or proteins are present, and it would lower the threshold for unintended GMO presence from 3% to 0.9%. Additionally, a bill has been introduced to implement a comprehensive GMO labelling system (*Reference*)

Mexico has taken steps to constitutionally protect Non-GMO white corn, a staple in traditional cuisine and a cultural icon. On March 18, 2025, the Mexican Congress approved a constitutional reform that prohibits the planting of GM corn nationwide. [*Reference*] The reform aims to safeguard native corn varieties, emphasizing the importance of biodiversity and cultural heritage. This move follows previous efforts to limit imports of genetically modified (GM) corn, which the US and Canada successfully fought through a tri-national trade agreement (US-Mexico-Canada Agreement, USMCA). Under Mexico's longstanding Biosafety Law, gene-edited crops are regulated the same as transgenic or "old" GMOs, and all require labelling and traceability.

In 2022, India's Department of Biotechnology issued final guidelines [*reference*] for the assessment of New GMOs that exempts any plants with no exogenous DNA from biosafety assessment. There are no mandated traceability or labelling requirements. (*Reference*)

Argentina has, since 2015, been a leader in creating pathways for the exemption of gene-edited crops from existing GMO regulation regimes. These exemptions, intended for crops claimed not to contain foreign DNA, are typically granted on a case-by-case basis and require developers to register plants with Argentina's National Advisory Commission on Agricul-



tural Biotechnology (CONABIA) for evaluation. Brazil follows a similar approach through its National Technical Biosafety Commission (CTNBio). (*Reference*)

As of 13 May 2025, the UK government has implemented new regulations under the Genetic Technology (Precision Breeding) Act 2023, allowing the environmental release and sale of genome-edited "precision-bred organisms" (PBOs) in England. Through the UK Internal Market Act, these rules are expected to affect the broader UK market for sales. While PBOs are classified as GMOs, they are exempt from many regulations if they do not contain foreign DNA, though no tests are required to confirm this. The new framework, effective 14 November 2025 after a six-month WTO notice period, enables applications for PBO status to be submitted to the Department for Environment, Food and Rural Affairs (DEFRA) and for marketing authorization to the Food Standards Agency (FSA). A <u>two-tiered risk system</u> governs food and feed: Tier 1 PBOs mimic natural changes and face minimal review, while Tier 2 PBOs require a limited safety assessment. Approved PBOs, regardless of tier, will not require mandatory labelling or traceability. The rules currently apply only to plants. However, draft regulations for genome-edited animals are underway and may be introduced by 2027. (Reference <u>1</u> and <u>2</u>)



By Dennis Eriksson, Associate Professor Genetics and Plant Breeding, Swedish University of Agricultural Sciences, Project Coordinator of the Horizon Europe Project DETECTIVE "Detection of NGT products to promote innovation in Europe".

P lant breeding continues to explore and incorporate novel scientific breakthroughs and innovations into the toolbox, and it is certain that new challenges for legal enforcement of product detection and monitoring requirements will arise in the future. It is reasonable to expect that we will need a combination of creative technical and non-technical approaches together with proportionate and workable legal frameworks to maintain appropriate control of both regulated and unregulated food and feed products on the market. The EU-funded project DE-TECTIVE works closely with stakeholders to address these challenges and to develop adequate solutions.

The current EU legislation requires that a detection, identification, and quantification (DIQ) method that is able to unambiguously identify the specific modified variety is presented and validated before a regulated GMO can be authorised for placing on the market for food or feed use, to enable market control for correct labelling of authorised products. As of today, real-time PCR is the preferred method for ordinary transgenic GMOs since it can be made event-specific by targeting the junction between the transgene and the host genome. PCR-based methods are also used for import control to screen for the possible presence of unauthorised GMOs, assuming that one of the common regulatory elements has been used in the transformation process.

So far, so good. What happens though if there is no obvious or clearly defined DNA sequence to target with the PCR? Take gene editing through targeted mutagenesis for instance – the latest tool in the breeder's toolbox. This method introduces specific edits, such as base substitutions, insertions or deletions, at predetermined sites in the genome. These introduced sequence variants are often not large or specific enough to enable identification, since the very same variation could also be a result of naturally occurring mutations. As a consequence, detection and identification of these products is challenging and generates not only technical but also legal problems for the required authenticity. Any conclusion on the eventspecificity of a method may not be court-proof.

It is likely that a combination of approaches will be needed for market control and legal enforcement if gene-edited products continue to be regulated as GMOs in the EU. Moreover, even if certain gene-edited products would be exempted from the GMO regulations, following a European Commission proposal for new regulation on plants obtained by certain new genomic techniques (European Commission, 2023/0226), it will still likely be necessary to maintain an organic production value chain that is free from these products. There have already been a number of attempts at developing DQ (detection, quantification) methods for specific gene-edited products, such as a real-time PCR method targeting a herbicide-tolerant canola from the US-based company Cibus. However, such methods hitherto suffer from the double drawback that they require prior knowledge of the event and that they do not allow unambiguous identification. Enter sequencing technology, which has developed rapidly in the past decade and now presents promising alternatives for both known and unknown targets.

In the Horizon Europe Project DETECTIVE (2024-2027), we are developing a portfolio of DIQ methods targeting specific gene editing-generated mutations in a number of important crops on the European market. We are also investigating the power of sequencing technology, coupled with machine learning-based algorithms to assess whether or not it is possible to determine the likelihood for different types of mutations without prior knowledge of the edited locus. It



remains to be seen if these technical approaches will meet the minimum performance requirements for validation and be suitable for routine implementation and legal enforcement. Furthermore, it is crucial to tackle the challenge of securing adequate funding and skilled staff. Advanced techniques like whole genome sequencing could detect edits, but currently they are expensive, time-consuming and not all reference laboratories have the necessary instruments or training. As a complement to analytical detection, DETECTIVE goes a step further by exploring knowledge-based discovery as a screening tool for unknown targets. Information available from various sources in the agri-food domain, such as the common catalogue of registered plant varieties, other plant variety registers, results of enforcement actions, available information from seed companies, and scientific literature, will be queried to identify points of interest for further enforcement actions.

Responsible Research and Innovation (RRI) is central in DETECTIVE and a structured RRI Roadmap©[™] guides our stakeholder engagement activities. This allows a proactive response to opportunities and challenges while building public and stakeholder trust. Through a series of RRI workshops, we are aligning technical and regulatory requirements, incorporating stakeholder priorities into project outputs and developing a tailored training programme on our developed analytical and non-analytical approaches together with their respective standard operating procedures and validation criteria. A key outcome in this process is the establishment of the DETEC-TIVE Community of Practice (CoP). The CoP is proposed as a science-based network for knowledge-sharing and mutual learning that creates a unique platform to foster collaboration among researchers, regulatory authorities, laboratories, policymakers, and other agri-food and feed value chain operators across Europe. It is our goal that the CoP becomes long-lasting after the project ends.

Project website: detective-ngt.eu



TABLE 1 New GMOs in Cultivation

Crop	Trait	Technique	Developer	Country (of Developer)	Cleared for market access*	Remarks	References	Further remarks
Maize	Tolerance to glufos- inate herbicide and resistance to corn rootworm pests (DP915635)	Transgenic, CRISPR	Corteva	USA	USA, Canada (2022), EU Food and Feed (2024)	Must be labelled as GMO in the EU according to current EU ge- netic engineering legislation. Import approval (food and feed) in the EU (see reference).	https://efsa.eu- ropa.eu	
Maize	Tolerance to glufos- inate herbicide and resistance to lepi- dopteran insect pests (DP910521)	Transgenic, CRISPR	Corteva	USA	USA, Canada (2022), Food and Feed (EU)	Must be labelled as GMO in the EU according to current EU ge- netic engineering legislation. Application for import authoriza- tion (food and feed) in EU. August 2024: Positive scientific opinion (EFSA) published (see reference).	https://www.ef- sa.europa.eu	
Tomato	Increased GABA- content	CRISPR	Sanatech Seed	Japan	Japan	As the US magazine Wired re- ports, Sanatech president Shim- pei Takeshita said at 28 May 2024 event in the Netherlands, the company has expanded distribu- tion in Japan and has completed all the regulatory paperwork to introduce its tomato in the Philip- pines. It's also looking to bring its edited tomato to the US (see ref- erence).	https://www. wired.com	Genome-edited GABA tomatoes have been reported as mini-tomatoes and medium-sized tomatoes (both claimed to be "high GABA"), but only mini-tomatoes (Sicilian Rouge High Gaba) are on the market. Sicilian Rouge High GABA is marketed as fruit/vegetables and as pro- cessed products in the form of puree and dried tomatoes. Their dried High GABA tomatoes have been on the market since April 2025. All of these products have been submitted as "food with functional claims" due to their high concentration of GABA, and are being marketed as health food products. However, food with functional claims is just a notification system and is accepted as long as all the documents are in order. There is no independent verification by a government body or anyone else. Genome-edited tomatoes are sold through the online store of the sales company and over-the-counter in some supermarkets in the Kanto/Tokyo region. The tomatoes were also sold in supermarkets in the Kyushu re- gion, but sales have been discontinued due to opposition from civil soci- ety and other factors. The product has been confirmed to be approved in the Philippines, but sales there or in the US or any other countries have not been confirmed (Martin J. Frid, Consumers Union of Japan, by mail, 2 May 2025).

* For more information see chapter "GMO Regulatory Hotspots around the Globe". As of 3 June 2025





Crop	Trait	Technique	Developer	Country (of Developer)	Cleared for mar- ket access*	Remarks	References
Maize	High Yield	CRISPR	Origin Agritech Ltd.	CHN	China	The commercialization of Origin's gene-editing corn is expected to begin in 1-2 years. Statement from 2024.	https://originagritech.com
Maize	Resistance against Maize Lethal Necrosis Disease	CRISPR	Corteva, CIM- MYT	USA, MEX	Different African countries (see ref- erence. No more information avail- able)	By 2025, subject to compliance with regulatory procedures, commercial seeds of the gene-edited MLN-resistant elite maize hybrids will be available to up to 20,000 smallholder farmers for approximately 40,000 hectares of planting.	https://www.cimmyt.org
Maize	Waxy Corn	CRISPR	Corteva	USA	USA, Brazil, Ar- gentina, Chile, Japan	The Canadian Biotechnology Action Network concluded (2021) that this prod- uct is not in commercial production and not designed for immediate release (see reference). This conclusion is confirmed by research from the Consumers Union of Japan (CUJ) (2025). According to the notification to the Consumer Affairs Agency of Japan, the product has not yet been placed on the market. Corteva stated, that the waxy corn has been grown in the US for reserach and pre-commercial tri- als, but was not distributed or marketed (2023). (Martin J. Frid, Consumers Union of Japan, by mail, 2 May 2025).	https://cban.ca
Maize	Fungal resistance	CRISPR	Corteva	USA, BRA	Brazil		https://one.oecd.org
Maize	High Yield	CRISPR	Weimi Biotech- nology (Hainan) Co., Ltd., Huazhong Agricultural University	CHN	China	Mutated ZmNL4 gene to improve corn yield traits (KN-NL4-2).	https://apps.fas.usda.gov
Maize	Insect resistance	CRISPR	KWS Saat AG	DE, BRA	Brazil		https://one.oecd.org
Maize	Dwarf maize	CRISPR	Inari	USA	USA	Field trials in Belgium (2023).	https://www.health.belgium.be
Maize	Dwarf maize	CRISPR	Corteva	USA	No information	According to the company: To be expected in 2027.	https://investors.corteva.com
Maize	Production of anthocyanin in response to pathogen infection	CRISPR	INSIGNIUM AGTech, Beck's	USA	USA	Field trials in the US (at least for two years).	https://www.seedquest.com
Maize	Multiple disease resistance	CRISPR	Corteva	USA	No information	According to the company: To be expected in 2028.	https://investors.corteva.com



Crop	Trait	Technique	Developer	Country (of Developer)	Cleared for market access*	Remarks	References
Soybean	Improved digestibility	CRISPR	Agricultural Research Corporation (EMBRAPA)	BRA	Brazil		https://www.embrapa.br
Soybean	Reduced lecithin	CRISPR	Agricultural Research Corporation (EMBRAPA)	BRA	Brazil		http://ctnbio.mctic.gov.br
Soybean	Reduced raffinose and stachyose sugar	CRISPR	GDM	ARG	Brazil	Greater nutritional value because it has fewer raffinose and stachyose sugars, indigestible by monogastric animals, such as por try, pigs, and humans.	https://www.reuters.com
Soybean	High-oleic	CRISPR	Shandong BellaGen Biotechnology Co.	CHN	China		http://shandong.chinadaily.com.cn
Soybean	High Yield	CRISPR	Suzhou Qihe Biotechnology Co., Ltd. (Qi Biodesign)	CHN	China	Mutated GmLn gene to improve soybean yield traits (QH64112).	https://apps.fas.usda.gov
Soybean	Improved physiological traits	CRISPR	China Seed Group Co., Ltd	СНИ	China	Mutated GmE1 and GmE1Lb genes to improve soybeans physiolog cal traits (E001SYFT).	i- <u>https://apps.fas.usda.gov</u>
Soybean	Improved protein con- tent	CRISPR	Amfora	USA	No information	According to the company: Commercialization expected in a few years.	https://leaps.bayer.com
Soybean	Different traits	CRISPR	Inari	USA	No information	According to the company: Commercialization expected in a few years.	https://agfundernews.com
Soybean	Drought tolerance	CRISPR	GDM	ARG	No information	According to the company: To be expected in 2026/2027.	https://www.reuters.com



Crop	Trait	Technique	Developer	Country (of Developer)	Cleared for market access*	Remarks	References
Wheat	Powdery mildew resistance	CRISPR	Suzhou Qihe Biotechnology Co., Ltd. (Qi Biodesign), Chinese Academy of Sciences	CHN	China		https://www.reuters.com
Wheat	Herbicide tolerance	CRISPR	Suzhou Qihe Biotechnology Co., Ltd. (Qi Biodesign), Institute of Genetics and Developmental Biology, Chinese Academy of Sci- ences	CHN	China	Mutated TaALS gene herbicide-tolerant wheat TaALS-4.	https://apps.fas.usda.gov
Wheat	High Yield	CRISPR	Inari, InterGrain	USA, AUS	No information	Australian seed breeder InterGrain early 2024 imported several thousand wheat seeds created by U.S. agritech company Inari, including hundreds of new genetic variations. These seeds are now growing in a testing green- house in southeast Queensland. Seeds from those plants will be used to grow more plants, producing enough seeds to plant at more than 45 trial sites across the country in the 2025 growing season.	https://www.reuters.com
Rice	Improved rice quality traits	CRISPR	Biotechnology Company Limited, Jiangsu Academy of Agricultural Sciences, Beijing Qi-Biodesign Suzhou Qi-Biode- sign Biotechnology Company Limited	CHN	China		https://apps.fas.usda.gov
Rice	Herbicide tolerance	Rapid Trait Development System [™] or RTDS® that integrates crop specific cell biology platforms with a series of gene editing technologies	Cibus Inc., Loveland Products	USA	No information	Cibus was expected to have field scale demonstrations of the HT rice traits in the US Mid-South in 2024 and expand to other geographies in 2025.	https://investor.cibus.com
Rice	Herbicide tolerance	Rapid Trait Development System [™] or RTDS® that integrates crop specific cell biology platforms with a se- ries of gene editing technologies	Cibus Inc., Albaugh LLC, RTDC Corporation Limited, Loveland Products	USA	No information	Cibus announced an agreement affirming its collaboration with RTDC Corporation Limited and Albaugh LLC to provide Clethodim as part of Cibus' weed management solution for U.S. rice farmers using Cibus' HT-3 trait.	https://www.seedquest.com



Crop	Trait	Technique	Developer	Country (of Developer)	Cleared for market access*	Remarks	References
Rice	Herbicide tolerance	CRISPR	Bioheuris	ARG, USA	No approval yet	The executive revealed that the technology is already being tested in rice and sorghum fields in Brazil and the United States. While not yet in the commercial phase, they have passed technical and regulatory challenges. "We ob- tained approval from CONABIA (National Advisory Com- mission for Agricultural Biotechnology) in Argentina and similar approvals in countries like the United States, Brazil, Chile, and Colombia," Pérez said. BioHeuris projects these rice and sorghum varieties will be available in the market by 2026 or 2027 (see reference).	https://news.agropages.com
Rice	High-yielding (Kamala, DRR Dhan 100)	CRISPR	Indian Institute of Rice Research (ICAR-IIRR), Hyderabad	IND	No information	The variety named as DRR Dhan 100 Kamala, was developed from a popular high yielding green rice Samba Mahsuri. According to the developer the new variety can be harvested 15-20 days ahead of its original. The yield is almost 25% more, which is about eight tonnes more per hectare. The new variety delivers significantly higher yields than the original variety. The variety was formally an- nounced in New Delhi on Sunday (May 4, 2025) by Union Agriculture Minister Shivraj Singh Chouhan.	https://www.thehindu.com
Rice	Salt-tolerant (Pusa DST Rice 1)	CRISPR	Indian Agricultural Research Institute (IARI), Delhi	IND	No information	The variety Pusa DST Rice 1 is from Maruteru 1010 (MTU1010), which is widely used by farmers across the country. According to the developer, the variety named as Pusa DST Rice 1 is a 'salinity tension tolerant' crop. When cultivated under areas that have national average of salinity, the new variety produced 9.66% additional yield than MTU1010. Similarly, in alkaline conditions, the new variety gave 14.66% more yield than its original and under 'salinity tension' conditions, the yield of the new variety was 30.36%. The variety was formally announced in New Delhi on Sunday (May 4, 2025) by Union Agriculture Minister Shivraj Singh Chouhan.	https://www.thehindu.com
Sugar cane	Improved digestibility (Canaflex I)	CRISPR	Agricultural Research Corporation (EMBRAPA)	BRA	Brazil		futurefarming.com
Sugar cane	Increased sucrose content (Canaflex II)	CRISPR	Agricultural Research Corporation (EMBRAPA)	BRA	Brazil		futurefarming.com



Сгор	Trait	Technique	Developer	Country (of Developer)	Cleared for market access*	Remarks	References
Sorghum	Herbicide tolerance	CRISPR	Bioheuris	ARG, USA	No information	The executive revealed that the technology is already being tested in rice and sorghum fields in Brazil and the United States. While not yet in the commercial phase, Bioheuris has passed technical and regulatory challenges. "We obtained approval from CONABIA (National Advisory Commission for Agricultural Biotechnology) in Argentina and similar approvals in countries like the United States, Brazil, Chile, and Colombia," Pérez said. BioHeuris projects these rice and sorghum varieties will be available in the market by 2026 or 2027 (see reference).	https://news.agropages.com
Lettuce	Extended shelf-life, non- browning	CRISPR	Green Venus	USA	USA, Canada	Seeds are sold in small packets for home gardeners in the US.	https://greenvenusproduce.com
Salad Greens	Reduced bitter compounds	CRISPR	Pairwise, Bayer Crop Science	USA	USA, Canada	Bayer has acquired a license to commercialize Pairwise's genome edited mustard greens (Brassica juncea) and these could be culitvated and sold in the US and Canada as early as 2025, but their status is not confirmed.	https://cban.ca
Potato	Higher tuber set	CRISPR	Simplot Plant Sciences	USA	No information	Simplot had stated (2022) that it could enter the Canadian market in fresh and processed food as early as 2024 but it is not confirmed to be in commercial production or on the market.	There is no indication that it is on the market nor commercially grown in Canada. (Lucy Sharratt, Canadian Biotechnology Action Network, by mail, 2 May 2025).
Potato	Reduced content of glycoalkaloids (including sola- nine) and resis- tance to black spotting ("non- browning")	CRISPR	Simplot Plant Sciences	USA	Canada	Simplot stated (2024) that it could enter the Canadian mar- ket in fresh and processed food as early as 2025 but has not confirmed release.	There is no indication that it is on the market nor commercially grown in Canada. (Lucy Sharratt, Canadian Biotechnology Action Network, by mail, 2 May 2025).
Potato	Non-browning	CRISPR	Instituto Nacional de Tecnología Agropecuaria (INTA)	ARG	Argentina	Field trials (at least for two years).	https://www.potatobusiness.com



Crop	Trait	Technique	Developer	Country (of Developer)	Cleared for market access*	Remarks	References
Camelina	Increased oil content	CRISPR	Yield10 Bioscience Inc.	USA	USA, Argentina, Chile, Canada	Yield10 Bioscience, Inc., along with its two affiliates, filed a voluntary petition for reorganization under Chapter 11 in the US Bankruptcy Court for the District of Delaware on December 6, 2024.	https://www.seedquest.com
Camelina	Increased Omega- 3	CRISPR	Yield10 Bioscience Inc.	USA	USA, Chile	Yield10 Bioscience, Inc., along with its two affiliates, filed a voluntary petition for reorganization under Chapter 11 in the US Bankruptcy Court for the District of Delaware on December 6, 2024.	https://www.yield10bio.com
Camelina	Increased Omega- 3	CRISPR	Yield10 Bioscience Inc., Rotham- sted Research, Nufarm US Inc., BioMar Group	USA	USA	Over the next year, Yield10 expects to scale-up planted acres of Camelina to supply BioMar with oil for formulation and testing while also working towards securing regulatory approval for commercial production of Omega- 3 Camelina oil and meal (fish feed) in the targeted produc- tion geographies. (Statement from 2024)	https://www.biomar.com
Horsetail	Increased oil content	CRISPR	CoverCress Inc., Bayer Crop Sci- ence, Bunge, Chevron	USA	USA	Since 2024: Farm Adoption Program allows producers to test CoverCress in their operations with no economic risk. Cover Cress provides the seed free of charge, which can then be treated as a typical cover crop for a few years until a decision is made to move forward with it as a cash crop.	https://www.farmprogress.com
Horsetail	Reduced levels of erucic acid, fiber and glucosino- lates in its seeds, improved resis- tance to seed shatter	CRISPR	CoverCress Inc., Bayer Crop Sci- ence, Bunge, Chevron	USA	USA		https://www.biofuelsdigest.com
Alfalfa	Improved nutrient composition, bet- ter digestibility, high yields	TALEN	Calyxt, S&W Seeds, Alfalfa Part- ners	USA	USA	According to the company: To be expected soon.	https://alfalfapartners.com/iqa/
Avocado	Non-browning	CRISPR	Green Venus	USA	No information		https://cdn.shopify.com



Crop	Trait	Technique	Developer	Country (of Developer)	Cleared for market access*	Remarks	References
Almond	Improved agronomic property	CRISPR	Ohalo Genetics Inc.	USA	USA	"After four years of dedicated research and development, Ohalo is proud to announce completion of its USDA Regulatory Status Review process for FruitionOne with availability for early orders in late 2026 and first commercial deliveries beginning in 2027. The first FruitionOne trial orchard plantings are underway in California." (See reference).	https://www.prnewswire.com
Banana	Non-browning	CRISPR	TROPIC Bioscience	UK	Philippines	June 2024: The banana varieties with improved reduced- browning characteristics (new trait) have been determined as non-genetically modified organisms (GMOs) in the Philippines.	https://www.isaaa.org
Wine grapes	Wine grape cultivars that possess natural preservation properties	CRISPR	Green Venus	USA	USA	Wine grape cultivars that possess natural preservation properties, diminishing or negating the need for sulfites as preservatives during winemaking. GreenVenus' new Colombard and Malbec grape varieties are currently available for planting to growers and winemakers through licensing agreements. In addition, the company will complete gene editing on Chardonnay, Sauvignon Blanc, Grenache and Gruner Veltliner later this year and Cabernet Sauvignon, Cabernet Franc, Pinot Noir and Zinfandel by this time next year. (Statement from 2024)	https://www.wineindustrynetwork. <u>com</u>
Strawberry	Remontant strawberry	CRISPR	Simplot Plant Sciences	USA	Canada	Simplot stated (2024) that it could enter the Canadian mar- ket in fresh and processed food as early as 2025 but has not confirmed release (May 2025).	There is no indication that it is on the market nor commercially grown in Canada. (Lucy Sharratt, Canadian Biotechnology Action Network, by mail, 2 May 2025).
Blackberry	Seedless Blackberry	CRISPR	Pairwise	USA	No information	Further traits in progress: thornlessness, compact growth. Pairwise announced 2024 to advance these berries into the next phase of product development, including outdoor field trials, as we work toward scaling up and making them available to the public in a few years.	https://www.pairwise.com
Water- melon	Natural sweetener	CRISPR	Elo Life Sciences	USA	No information	According to the company: To be expected in 2026.	https://techcrunch.com

* For more information see chapter "GMO Regulatory Hotspots around the Globe".

 Table 2: Remarks are sometimes company statements. "Cleared for market access" does not automatically mean cultivation. Company announcements about future cultivation do not mean that these plants will be cultivated/reach the market. This could be information spread to acquire money from investors. Despite intensive research and thorough examination of accessible data, the table makes no claim to completeness.

 As of 3 June 2025



TABLE 3 New GMOs withdrawn from the Market

Crop	Trait	Technique	Developer	Country (of Developer)	Cleared for market access*	Remarks	References
Canola	Herbicide toler- ance	Rapid Trait Development System [™] or RTDS® that in- tegrates crop specific cell biology platforms with a se- ries of gene editing tech- nologies	Cibus Inc.	USA	USA, Canada in 2014	Cibus stated in 2020, that the SU canola varieties on the market in North America are "not gene-edited". They disap- peared from the market in 2022.	https://www.greenpeace.org
Soybean	High-oleic	TALEN	Calyxt	USA	USA	The oil extracted from the soybeans was sold in the USA under the brand name "Calyno" from 2019 to 2021.	https://non-gmoreport.com

* For more information see chapter "GMO Regulatory Hotspots around the Globe". As of 3 June 2025

Poor Performance: First two New GMOs on the Market withdrawn

The first two New GMOs on the market, introduced as a scientific breakthrough, have since been withdrawn by their developers. The reason: Both, the herbicide tolerant SU canola by the US firm Cibus and the high oleic acid "Calyno" soybean by the US company Calyxt, didn't convince farmers who complained about poor harvests.

Since 2024, Cibus has been under investigation by a whole series of US law firms for deceiving investors. This follows a research report for investors that argued they had been duped by company claims for its "over-hyped" gene-editing technology. Calyxt, economically weakened, was taken over by Cibus in 2023.

www.gmwatch.org/en/106-news/latest-news/20434

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Editors





The **European Non-GMO Industry Association** (**ENGA**) is the voice of the Non-GMO food and feed sector at the EU level. ENGA, founded in 2020, secures and supports the expansion of Non-GMO production and advocates for the strict regulation of old and New GMOs in order to keep untested and unlabelled GMOs from entering the EU food and feed chains. **The Non-GMO Project**, a US non-profit organization, was founded in 2007, with the aim to build and preserve the Non-GMO food supply for consumers. It offers certification for GMO avoidance. In the United States, the Non-GMO Project has verified more than 66,000 products representing more than \$45 billion in annual sales, making it the fastestgrowing label in the U.S. natural products industry and the most trusted Non-GMO label among consumers. The Non-GMO Project is operating in a market, where New GMOs already are in use. It excludes New GMOs in its verified products and does regular horizon scanning on which New GMOs are already on the market.

semnar

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