



International policies and global trade of GMO/NGTs

By Nicolas Defarge and Gustavo R. Rodriguez

Within the framework of the Darwin Project, the National University of Rosario (Argentina) is happy to provide a summary of international approaches to NGT regulation.

We draw upon an update of regulation of NGTs worldwide based on a synthesis and analysis of the literature (see references), as well as elements provided by CONABIA and CTNBio, the regulatory bodies for biotechnology in Argentina and Brazil respectively. We also provide some figures regarding international trade of these organisms and products.

1. NGTs and the Cartagena Protocol

What are NGTs?

Over the past 20 years, new breeding methods have been developed for which the general term 'new breeding techniques' (NBT), also called 'new genomic techniques' (NGT) is being used. Those techniques are defined as "techniques that are capable of altering the genetic material of an organism and that have emerged or have been mainly developed since 2001" (Joint Research Centre). As mentioned in Whelan and Lema (2015), "'New Breeding Techniques' was not defined for scientific reasons but emerged as a way of referring to an array of technologies where their advocates hope they will not be considered transgenic or 'genetically modified' organisms (GMOs) in the usual regulatory sense -and therefore be exempted of the regulation for transgenic products-...".

The main international reference instrument for GMO regulation (LMO for Living Modified Organisms in the Convention terminology) is the Cartagena Protocol on Biosafety (CPB, Secretariat of the Convention on Biological Diversity, 2000). In accordance with the precautionary approach, contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of the Protocol *“is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of 'living modified organisms resulting from modern biotechnology' that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements”* (Article 1 of the Protocol, SCBD 2000).

The Protocol defines a 'living modified organism' as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology, and 'living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids. 'Modern biotechnology' is defined in the Protocol to mean the application of in vitro nucleic acid techniques, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and are not techniques used in traditional breeding and selection. 'Living modified organism (LMO) Products' are defined as processed material that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

Hence, most countries that have reduced regulation (including Argentina, Brazil, the USA and Canada) base classification on the absence of foreign DNA in the final product. NGT products or outcomes that meet prescribed criteria (e.g. “Absence of a new combination of genetic material” or “Absence of foreign DNA”) are exempt from GMO regulations. Countries such as Australia and Japan have introduced subcategories when sequence templates have been used in the genome editing process (Sprink and Wilhelm, 2024). This refers to the process of Site-Directed Nuclease (SDN), and 3 classes of directed mutations have been defined (SDN-1,2 and 3) leading to different regulatory outcomes (Sprink and Wilhelm, 2024).

Since current legislations or guidelines may distinguish between the genome editing techniques, SDN(-)1, SDN-2, SDN-3, and whether foreign DNA and/or sequence templates have been used during generation of the genome-edited organism, a basic knowledge of the

CRISPR-Cas9 technology (which is currently the most important tool for developing NGT plants) and its outcomes in necessary in order to understand the scientific bases of the regulation of NGTs in the world (see Box 1).

On the contrary, in the European Union, directive 2001/18/EC still applies to genome-edited organisms or products derived from them, following the Court of Justice of the European Union (CJEU) 's ruling of July 25, 2018 (Case C-528/16), which concluded that “only organisms obtained by means of mutagenesis techniques/methods which have traditionally been used for various applications and whose safety has long been proven are excluded from the scope of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms”. This directive includes, in particular, appropriate measures to implement the procedures established by the internationally agreed Cartagena Protocol (Secretariat of the Convention on Biological Diversity, 2000). As a result, in the EU, plants obtained by NTGs (mostly CRISPR-Cas nowadays) are subject to the current regulatory framework applying to classical genetically modified organisms (i.e. transgenic organisms meaning containing foreign DNA), particularly in terms of risk assessment. But this is debated and changes in the regulation of NGT are likely to occur.

The international legislative landscape is thus diverse and dynamic (Figure 2) and the heterogeneity of regulatory regimes poses a challenge for international trade (Sprink and Wilhelm, 2024).

Box 1. Description of the directed mutagenesis using the CRISPR-Cas system

The CRISPR-Cas system is a complex consisting of a DNA-cutting enzyme (endonuclease), Cas, and a strand of guide RNA with a sequence complementary to that of the DNA targeted for mutation. The CRISPR-Cas system is used to create a DNA double-strand break at a specific site, and consequently activate intracellular DNA repair mechanisms. As these mechanisms are more or less error-prone, genome modifications can then occur.

Following this DNA double-strand break (DSB), intracellular repair mechanisms are activated, and several pathways are possible (Figure 1).

- In the absence of a DNA sequence added to serve as a repair template, the repair pathway involved is known as non-homologous repair (NHEJ). The results obtained are point mutations or insertions/deletions of DNA fragments (SDN-1 mechanism); these mutations will, in general, lead to gene inactivation. The site of the mutation is predetermined, but the types of modification obtained are not.

- When a DNA sequence is added as a repair template, the repair pathway involved is said to be “homology-based” (HR). The results obtained are either a modification of the sequence of one or more genes (SDN-2 mechanism, the template is not integrated into the genome), or the integration of this sequence into the genome (SDN-3 mechanism). The site and nature of the mutation are predetermined.

The “repair” DNA template has identical ends at the two adjacent regions of the chosen cut site. Even in the presence of this template, the cut may, like any DNA double-strand cut, also be repaired by NHEJ and therefore not result in the desired modification.

The SDN-3 mechanism does not correspond to site-directed mutagenesis, but to transgenesis, cisgenesis or intragenesis.

It should be kept in mind that whatever the class of SDN, even SDN-1 techniques routinely create unintended transgenic intermediates and even transgenic final products and only verification can reduce the risk of releasing unintended SDN-1, 2, and 3 outcomes (Heinemann et al., 2025b; Chu and Agapito-Tenfen, 2022).

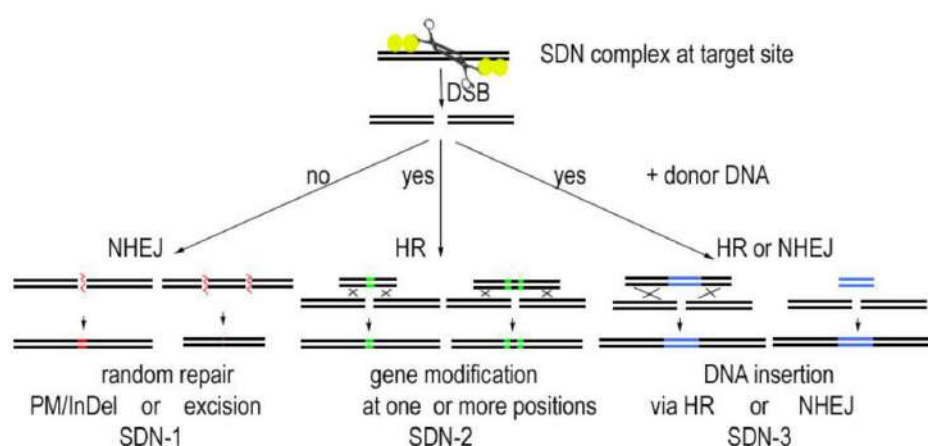


Figure 1: Intended repair outcomes of double-strand breaks (DSBs) induced by site-directed nuclease (SDN). An SDN complex is shown at the top in association with the target sequence. The repair can be achieved by non-homologous end-joining (NHEJ) or homologous recombination (HR) using the donor DNA. In the SDN-1 technique, double-strand DNA breaks result in site-specific random point mutations (PM) and short insertions/deletions (indel) or in excision. In the SDN-2 technique, homologous donor DNA is used to induce specific nucleotide sequence changes by HR. In the SDN-3 technique, DNA may be integrated in the plant genome using either NHEJ or HR. (Reproduced from EFSA GMO Panel, 2012)



Figure 2. Regulations on genome edited food around the world. The regulatory status of genome-edited (Ged) crops on a global schema. Reproduced from Sprink and Wilhelm (2024)

2. Worldwide regulation of NGTs

2.1. Worldwide panorama

According to the review by Hernández-Soto and Gatica-Arias (2024), “there are at least three different approaches to regulating genome-edited crops. The first establishes equivalency to conventional breeding products which excludes such from GMO regulations. The second concerns countries that seem to be evolving toward conventional equivalency by relaxing their laws; while the third group displays a conservative, restrictive approach.

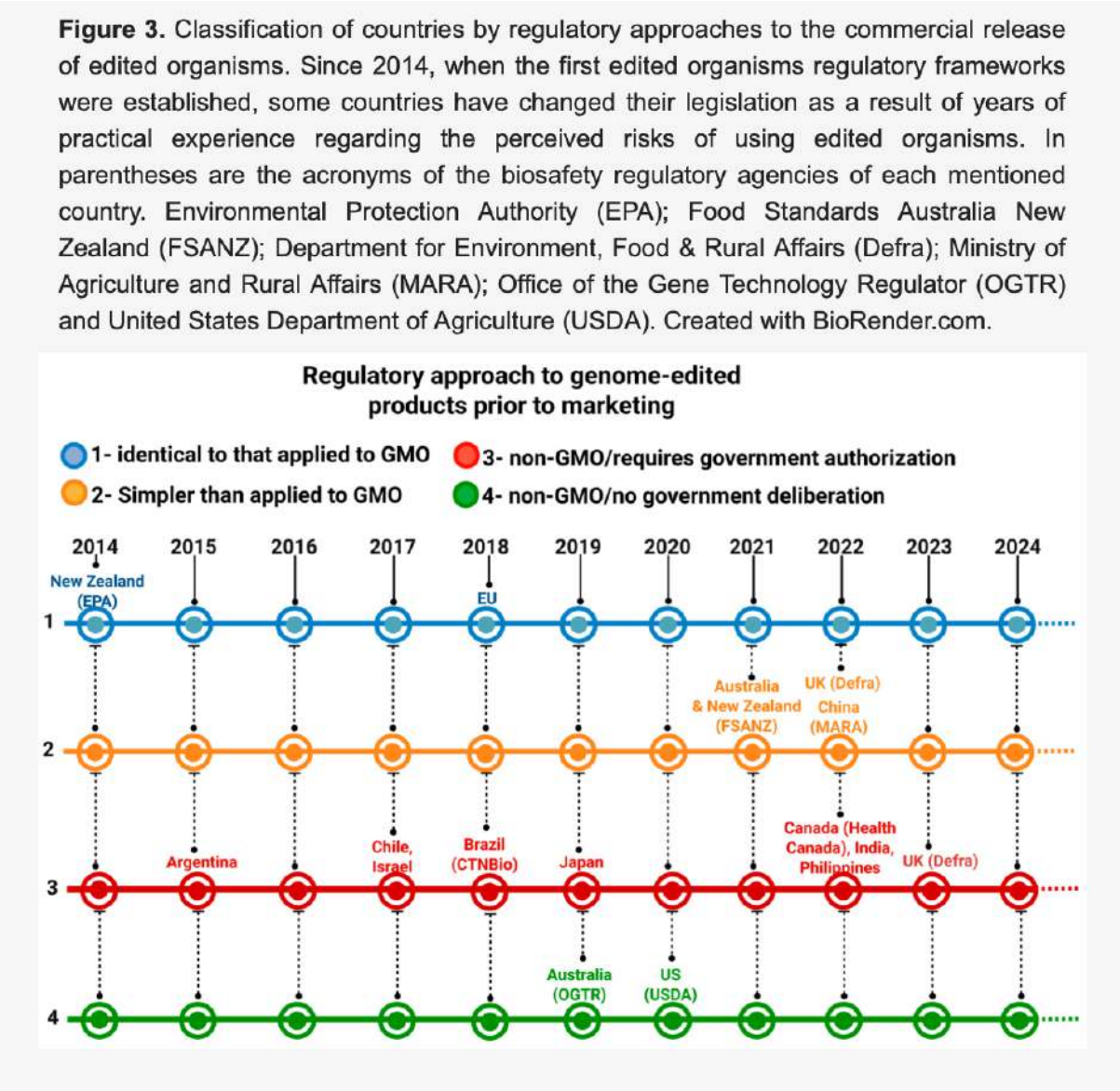
The first group includes Australia, several countries in Africa (Kenya, Nigeria, Ghana, Malawi), Asia (Japan, Philippines), and North America (USA, Canada), as well as the Latin American countries of Argentina, Chile, Brazil, Colombia, Paraguay, Guatemala, Honduras, Costa Rica, and Ecuador. On the other hand, the UK, Uruguay, and El Salvador are also moving towards a similar approach, while Singapore is approving new bills that follow the same rationale. In Latin America, countries have taken a common approach by considering the gene pool, natural variation, and conventional breeding methods used to regulate plant genome editing. As explained previously, “*foreign genetic material*,” also called “*new combination of genetic material*,” alternatively triggers GMO regulations.

The second group includes countries that relaxed their systems, such as India, Bangladesh, China, and Russia, and may be presumed to be more permissive.

Finally, in the third group, South Africa and Switzerland are probably the only countries that retain a conservative, restrictive approach. They currently regulate all products as GMOs. The EU and New Zealand have a restrictive approach similar to those of South Africa and Switzerland. Still, it differs because, in both cases, new regulatory proposals for more permissive systems are both under discussion and already implemented. “

But we find more accurate the classification in Da Cunha et al. (2025), the most recent update in worldwide regulation of NBT. In this article, after recalling that, in general, the regulatory frameworks for GMOs and edited organisms differ from country to country (Rios et al., 2021; Tachikawa and Matsuo, 2023; Turnbull et al., 2021), the authors consider four categories of countries based on the level of regulatory restrictions regarding the commercial release of edited organisms: (1) countries in which the regulatory framework is identical for edited organisms and GMOs (countries with more restrictive regulatory frameworks); (2) countries in which the regulatory framework for edited organisms is similar to that of GMOs but is occasionally simpler; (3) countries whose regulatory framework allows edited organisms obtained through specific approaches to be considered non-GMOs, whose regulatory framework is extremely simpler than that of GMOs, but whose commercial release depends on prior approval by a public institution/government agency; and (4) countries in which edited organisms are considered non-GMOs and do not depend on government approval for commercial release (Lane and Martin, 2015; Tripodi, 2023). With the publication of RN16 and

the possibility of obtaining mutant organisms edited by SDN-1 and SDN-2, Brazilian regulatory framework positioned the country in category 3 (Figure 3).



Among the articles reviewing and updating the worldwide regulations of NGTs, another recent one comes from the Food Standards Australia New Zealand (FSANZ, 2024) and especially to their Table 3 (Summary of international approaches to NBT regulation), reproduced below as Table 1. This was analyzed by Jack Heinemann from the University of Canterbury in New Zealand, Heinemann et al, 2025a). It should be noted that The FSANZ report was written before the United States reversed its changes and reinstated its previous regulations (Heinemann, pers.com.).

According to Pr. Heinemann’s analysis, posted on the Open-ended Online Forum on Risk Assessment and Risk Management (2025-2026, Convention on Biological Diversity), a relatively small minority of countries have acted to reduce their regulations on products of

modern biotechnology (<20), and these include non-Parties to the Protocol (see Box 2 and Figure 4). A larger number are discussing doing so (~30) but combined still represent a minority of countries. Of the ~19 countries that have reduced regulation (and most discussing their regulations), almost all exempt from GMO regulations those products made using described techniques (e.g. SDN-1, such as Australia) or outcomes that meet prescribed criteria (e.g. “Absence of a new combination of genetic material” or “Absence of foreign DNA”). Only 2 countries, both non-parties to the Protocol, have no confirmation requirement to establish that the products meet the exemption criteria prior to release. These are Canada, but limited to only plants, and Australia, but limited to intended outcomes of SDN-1 techniques.

Table 1: Summary of international approaches to NGT regulation

Highlighted in light green – New approaches since the release of the 1st CFS in 2021;

Grey italics – Proposed approaches, not yet in force.

	Some NBTs excluded from GMO regulation/pre-market assessment?	Criteria for exclusion	Notification/ Confirmation Required?	Year approach adopted/updated	Applies to
North America					
US	Yes	Specific criteria (refer to Table 2)	In some cases	Revised Biotechnology Regulations finalised 2020; updates ongoing	Plants and Animals
Canada	Yes ⁴¹	Absence of foreign DNA in final plant product; no new or increase in toxins, allergens, and antinutrients; no compositional changes; no new food use	Voluntary	Updated guidance published July 2022	Plants
Europe and Middle East					
<i>European Union (proposed)</i>	Yes	<i>Specified maximum number of genetic modifications compared to parent plant (still under consideration)</i>	<i>Yes - proposed database</i>	<i>European Commission proposal adopted 2024, negotiations with European Council ongoing</i>	<i>Plants</i>
European Union (current)	No	N/A	GMO assessment framework applies	2018 decision of the Court of Justice of the European Union (CJEU)	Plants
UK (England only)	Yes	Could have been produced by traditional breeding	Yes	Genetic Technology (Precision Breeding) Act passed in 2023	Plants and vertebrate animals
Israel	Yes	Absence of foreign DNA	Yes *	2017	Plants
South and Central America					

⁴¹ Exclusion from regulation as “novel foods”, not GMOs

Some NBTs excluded from GMO regulation/pre-market assessment?		Criteria for exclusion	Notification/ Confirmation Required?	Year approach adopted/updated	Applies to
Argentina	Yes	Absence of new combination of genetic material in NBT organism/final product free of transgenes	Yes *	2015	Plants, Animals, Microorganisms
Brazil	Yes	Absence of recombinant DNA/RNA in final organism	Yes *	2018	Plants, Animals, Microorganisms
Paraguay	Yes	Absence of new combination of genetic material in NBT organism/final product free of transgenes; prior approval in other countries with established regulatory processes	Yes *	2019	Plants, Animals, Microorganisms
Columbia	Yes	Absence of foreign DNA sequences in final organism	Yes *	2018	Plants, Animals, Microorganisms
Chile	Yes	Absence of new combination of genetic material in NBT organism	Yes *	2017	Plants, Animals, Microorganisms
Ecuador	Yes	Absence of recombinant/foreign DNA in final organism	Yes *	2019	Plants, Animals, Microorganisms
Guatemala	Yes	Absence of new combination of genetic material in NBT organism	Yes *	2019	Plants, Animals, Microorganisms
Honduras	Yes	Absence of new combination of genetic material in NBT organism	Yes *	2019	Plants, Animals, Microorganisms
Costa Rica	Yes	Absence of new combination of genetic material in NBT organism	Yes	2023	Plants, Animals, Microorganisms
Asia-Pacific					
Japan	Yes	Absence of foreign DNA	Yes *	Approach adopted in 2019, updated 2020	Plants, Animals, Microorganisms
China	Unclear how rules will apply	NBTs classified into risk categories	Yes *	Rules issued in 2023	Plants
Republic of Korea	Proposed exemption from risk assessment	Absence of foreign DNA	Yes *	Draft revision to regulations under consideration	Plants
India	Yes	Absence of foreign DNA	Yes *	2022	Plants
Philippines	Yes	Absence of a new combination of genetic material	Yes *	2022	Plants
Singapore	Proposed exemption from pre-market assessment	Absence of foreign DNA	Yes *	Consultation on proposed framework completed in 2024	Plants
Africa					
Nigeria	Yes	Absence of a new combination of genetic material in final product	Yes *	2021	Plants, Animals, Microorganisms
Kenya	Yes	Absence of foreign DNA	Yes *	2022	Plants, Animals, Microorganisms
Malawi	Yes	Absence of novel combination of DNA	Yes *	2022	Plants, Animals, Microorganisms
Ghana	Yes	Absence of foreign genes in final product	Yes *	2023	Plants, Animals, Microorganisms
South Africa	No	N/A	GMO assessment framework applies	2021	Plants, Animals, Microorganisms

* Exclusion is on a case-by-case basis

Box 2. What is the difference between signing and ratifying the Protocol?

At the closing date for signature i.e. 4 June 2001, the Protocol had 103 signatures. By signing the Protocol, States indicate general support for its objective and provisions, as well as their intention to become parties to the Protocol in the future and be legally bound by it. However, the Protocol does not become legally binding until a State joins the Protocol by depositing an instrument of ratification, accession, acceptance, or approval with the Depository – the Secretary-General of the United Nations, signed by the Head of State or Government or the Minister for Foreign Affairs. Once a State deposits such an instrument, the Protocol enters into force for that State ninety days later provided the Protocol itself has already entered into force at that time; at this point the State is bound by the provisions of the Protocol and must comply with the obligations therein.

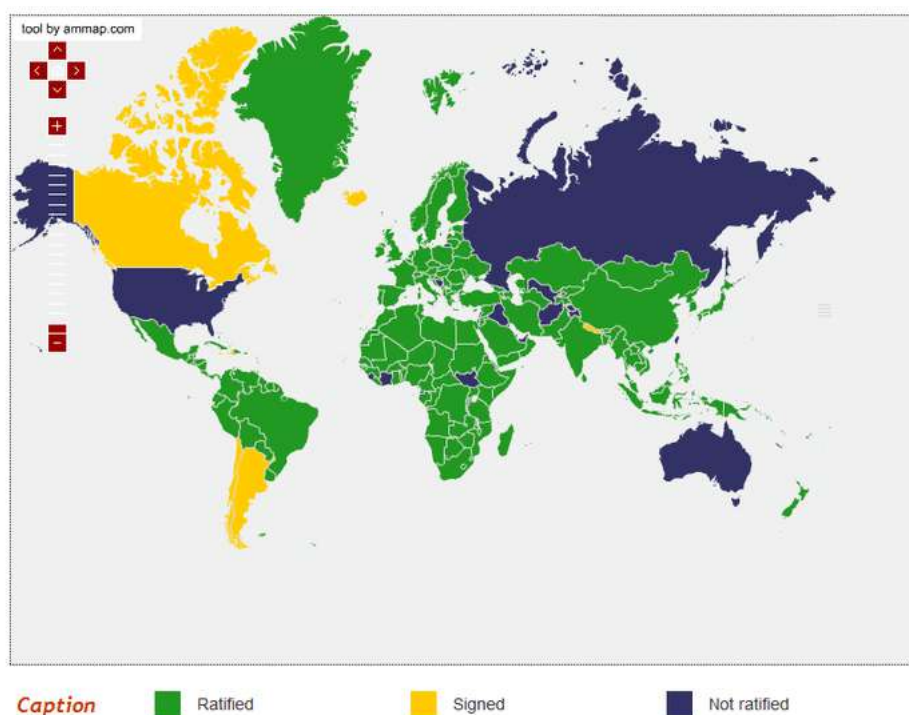


Figure 4. Map of the ratification of the Cartagena Protocol on Biosafety

This map shows the countries which have ratified, signed and not ratified the Cartagena Protocol on Biosafety. Indeed “signed” should read “signed but not ratified” (see Box.2). Reproduced from Pazzi et al. (2014).

2.2. Example of “liberal” regulation: regulation of NGTs in Argentina

We choose to present regulation landscape in Argentina since Argentina was the first country to clarify the regulation in 2015, using the Cartagena Protocol on Biosafety as a legal starting point to define LMOs versus conventional genotypes, in resolution 173/2015 (www.argentina.gob.ar/normativa/nacional/resolución-173-2015-246978/texto). Then over the next four years Chile (2017), Brazil (2018), Colombia (2018), Paraguay (2019), Honduras (2019), and Guatemala (2019) followed the Argentine model (Entine et al. 2021). Argentina is a signatory to the Cartagena Protocol on Biosafety (CPB), and although it has not ratified it.

This regulation is a product-based approach, meaning that the analysis focuses on the product rather than the technology used to obtain it. The latest version, explicitly separating the regulatory framework of NBTs from the rest of the GMO regulations (Goberna et al., 2022), was published in 2021 and has three specific annexes for each organism (animals, plants, or microorganisms). These annexes are forms called Prior Consultation Instances (PCI) that the developing entity must complete beginning the consultation process.

As reported by the authors: “The updated regulation more precisely defines that “novel combination of genetic material” refers to “any change produced in the genome of the organism by the incorporation, stably and cohesively, of one or more genes or nucleic acid sequences that are part of a defined genetic construct” (Goberna et al., 2022).

Regarding scientific information, a taxonomic description of the organism and the name assigned to the genotype should be included. In addition, a detailed description of the technique used, molecular description of the target nucleotide sequences of the organism in its pretechnique and posttechnique states and the function of the target sequences in its pretechnique and posttechnique states should be provided. A map of any genetic construct or nucleic acid fragment used in the breeding process must be provided, detailing the genetic elements and analysis of possibly affected sequences outside the target sequences.

To submit, an applicant must be officially registered in the National Registry of Operators with GM Plant Organisms through the National Seeds Institute (INASE) which is the official entity that authorizes seed commercialization (obtained either by conventional or by modern biotechnology breeding) in Argentina. Following these NBTs regulation guidelines, applicants

must describe in detail the intended modifications and the way they plan to obtain them in a PCI (see Fig. 5).

This procedure implies that CRISPR-edited (or other NBT-edited) intermediate are still subject to regulation until it is determined that it does not contain any stable DNA insertions in their genomic constitution. Before that determination, all associated material must be handled in contained and confined conditions, according to GMO regulations. Therefore this NBT ad hoc regulation did not change the preexisting GMO regulations (Gatica-Arias, 2020). This was only established to determine whether a gene-edited crop should be subjected to preexisting GMO regulations or not. If the final gene-edited product is considered as “non-GMO,” these crops are derived to the conventional breeding registration system for final commercialization, like the already mentioned National Seeds Institute that deals with intellectual property issues (like following the International Union for the Protection of New Varieties of Plants-UPOV—intellectual property agreements) and controls the registration and commercialization of varieties. Alternatively, if the final gene-edited product is considered a “GMO,” it must follow the GMO Argentine regulation system for commercialization (Whelan and Lema, 2015, Goberna et al., 2022)”.

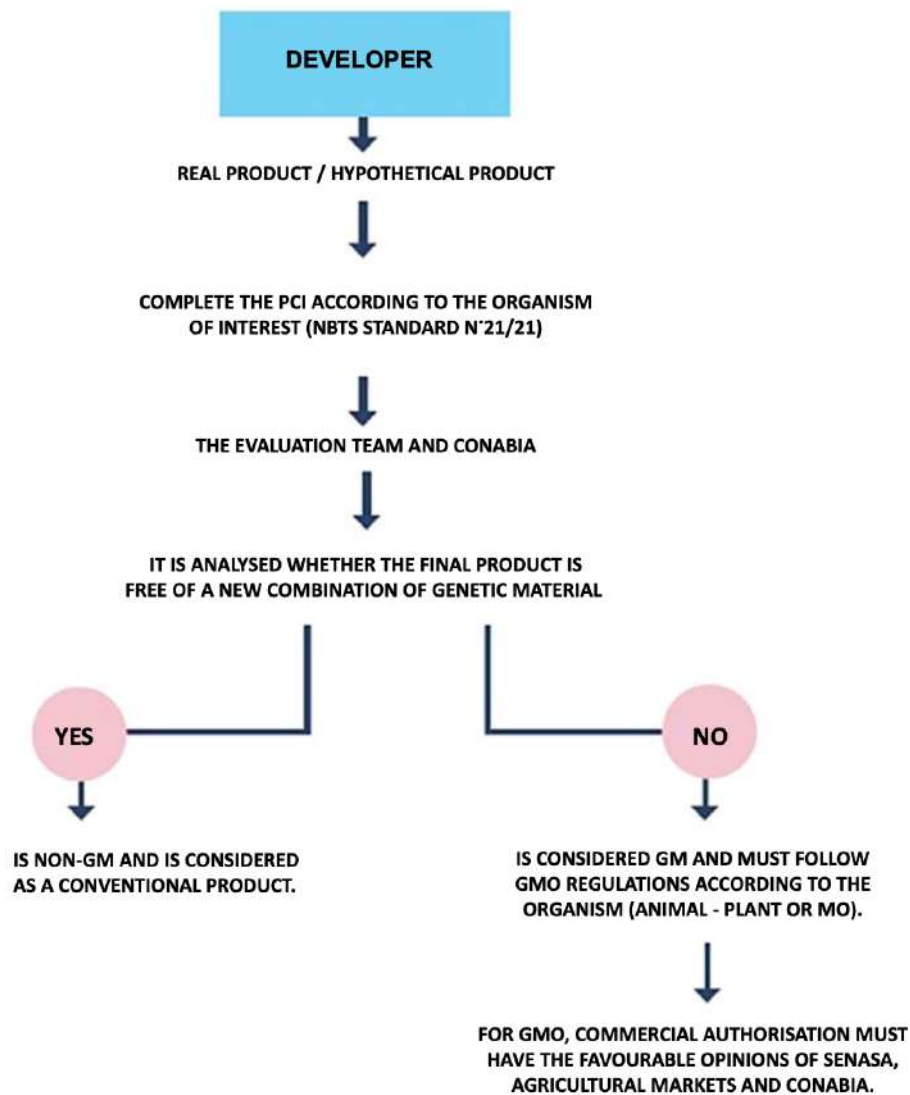


Figure 5. Regulatory framework for CRISPR- edited crops in Argentina: Route of analysis of a NGT-derived product. Reproduced from Goberna et al., 2024.

3. International trade of NGTs organisms and products

We found little figures on trade trends on NGTs, especially regarding to those placed on the market, in the scientific litterature. Sprink and Wilhem (2024) draw a Table listing , but until May 2023, reproduced below (Table 2).

Table 2. Genome-edited products/organisms released to national markets

Product	Target gene(s)	Method	Phenotype	Market release	Company
Soybean [2, 3]	FAD2-1A, FAD2-1B	TALEN	High oleic acid	2019 ^a	Calyxt (USA)
Tomato [4]	GAD3	CRISPR-Cas9	High GABA	2021	Sanatech Seeds (Japan)
Red sea bream [5]	Myostatin	CRISPR-Cas9	More muscle mass	2021	Regional Fish Institute (Japan)
Tiger puffer fish [5]	Leptin receptor	CRISPR-Cas9	Increased appetite	2021	Regional Fish Institute (Japan)
Mustard greens [6]	Myrosinase	CRISPR-Cas9	Reduced pungency	2023	Pairwise (USA)

^aThe product pipeline and business model of Calyxt has changed. The product was marketed by Calyxt until 2021

In countries like Brazil and Chile (Sanchez, 2024), information on edited organisms is accessible, at least to specialists in the field and those familiar with regulatory systems. In contrast, Argentina do not disclose this information publicly. Below we provide figures regarding Brazil regarding plants only (Table 3, reproduced from Hernández-Soto and Gatica-Arias, 2024) as well as a more updated one, but that extends to microorganisms and animals (Figure 6, reproduced from Da Cunha et al., 2025).

Table 3. Comprehensive overview of biotechnology applications in Brazil for plant organisms. Reproduced from Hernández-Soto and Gatica-Arias (2024)

Applicant	Organism classification	CTNBio review number	Details of the organism under revision	Reference
Du Pont do Brasil	Waxy Corn	6208/2018	Waxy corn for agricultural purposes	01250.033737/2018–67
Embrapa Agroenergia	Sugarcane	7836/2021	Sugarcane produced by CRISPR/Cas9 with increased digestibility and sugar accumulation	01245.019608/2021–31
GDM Genética do Brasil S. A	Soybean	7913/2022	Low raffinose soybeans edited by CRISPR/Cas for enhanced nutritional properties	01245.002127/2022–77
GDM Genética do Brasil S. A	Soybean	8013/2022	Soybeans edited by CRISPR/Cas for drought tolerance	01245.003707/2022–81
Embrapa Soja—Centro Nacional de Pesquisa de Soja	Soybean	8151/2022	Soybeans are genetically edited by CRISPR/Cas technology to silence the lectin gene (LE1)	01245.009925/2022–20
Embrapa Agroenergia	Sugarcane	8107/2022	Sugarcane edited using RNP methodology (DNA-Free System)	01245.005737/2022–22
Corteva Agriscience do Brasil Ltda	Corn	8595/2023	Corn NLB18-R genetically edited by CRISPR/Cas9 for pathogen and pest resistance	01245.004586/2023–76
Bioheuris	Rice	8586/2023	Genetically edited rice with base substitutions in the acetolactate synthase (ALS) gene	01245.005960/2023–51
Bioheuris	Cotton	8587/2023	Cotton genetically edited with a base substitution in the protoporphyrinogen oxidase gene	01245.005966/2023–28

Source: CTNBio-Brazil, <http://ctnbio.mctic.gov.br/>

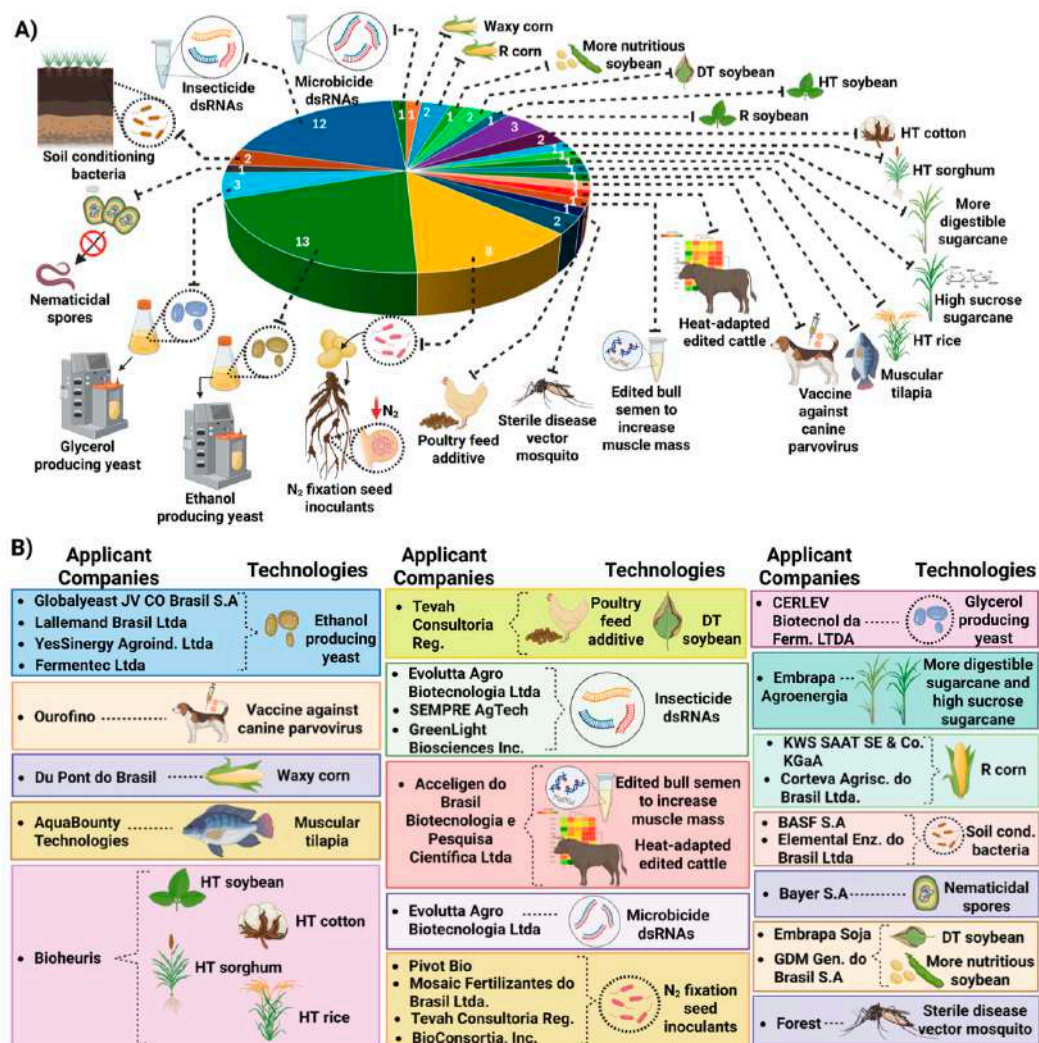


Figure 6. (A) Technologies obtained with NGTs whose commercial release requests were submitted to CTNBio between 2018 and 2024. (B) Technologies developed by NBTs listed by their respective developer companies (Heather and Chain, 2016). R insect resistant; HT herbicide tolerant; DT drought tolerant; dsRNA double-stranded RNA. Created with BioRender.com. Reproduced from Da Cunha et al. (2025).

References

- Chu, P. and Agapito-Tenfen, S.Z. (2022) Unintended Genomic Outcomes in Current and Next Generation Gm Techniques: A Systematic Review. *Plants* 11 (21), 2997.
- Da Cunha, N.B.; Silva Junior, J.J.d.; Araújo, A.M.M.; de Souza, L.R.; Leite, M.L.; Medina, G.d.S.; Rodriguez, G.R.; dos Anjos, R.M.; Rodrigues, J.C.M.; Costa, F.F.; et al. (2025) Updates on the Regulatory Framework of Edited Organisms in Brazil: A Molecular Revolution in Brazilian Agribusiness. *Genes*, 16, 553. <https://doi.org/10.3390/genes16050553>
- EFSA GMO Panel (2012). « Scientific Opinion Addressing the Safety Assessment of Plants Developed Using Zinc Finger Nuclease 3 and Other Site-Directed Nucleases with Similar Function ». *EFSA Journal* 10 (10): 2943. <https://doi.org/10.2903/j.efsa.2012.2943>.
- FSANZ, Updated Compilation of Regulatory Approaches and Definitions, P1055 – Definitions for gene technology and new breeding techniques, 2024. FSANZ, 2024, https://consultations.foodstandards.gov.au/fsanz/p1055/user_uploads/p1055-supporting-document-1-updated-Compilation-of-regulatory-approaches.pdf
- Gatica-Arias, A. (2020) The regulatory current status of plant breeding technologies in some Latin American and the Caribbean countries. *Plant Cell Tissue Organ. Cult.* 141, 229242.
- Goberna, M.F., Whelan, A.I., Godoy, P., Lewi, D.M. (2022) Genomic editing: the evolution in regulatory management accompanying scientific progress. *Front. Bioeng. Biotechnol.* 10, 835378. Available from: <https://doi.org/10.3389/fbioe.2022.835378>.
- Goberna, M.F, Lewi, D.M., Godoy, P., Simeone, F., Hopp, E.H. (2024). Chapter 10 - Regulatory framework for CRISPR-edited crops in Argentina, In *Genome Modified Plants and Microbes in Food and Agriculture, Global Regulatory Outlook for CRISPRized Plants*, Academic Press, 2024, <https://doi.org/10.1016/B978-0-443-18444-4.00009-0>
- Heather, J.M.; Chain, B. (2016) The Sequence of Sequencers: The History of Sequencing DNA. *Genomics*, 107, 1–8.
- Heinemann, J.A. et al (2025a) <https://ir.canterbury.ac.nz/server/api/core/bitstreams/0e1aa118-5e68-4b43-b395-2a4487d90aa4/content>
- Heinemann, J.A.(2025b) <https://ir.canterbury.ac.nz/server/api/core/bitstreams/05dd6485-82e0-4f54-844b-8860e8548b68/content>
- Hernández-Soto, A., Gatica-Arias, A. (2024) Genome editing in Latin America: research achievements and regulatory evolution. *Plant Cell Tiss Organ Cult* **159**, 55 <https://doi.org/10.1007/s11240-024-02904-4>
- Lane, N.; Martin, W.F. (2015) Eukaryotes Really Are Special, and Mitochondria Are Why. *Proc. Natl. Acad. Sci. USA*, 112, E4823.

Pazzi, Francesco & Lauria, Pino & Libera, Dario & Cillis, Nicoletta. (2014). Biosafety Scanner Software for the management and control of GMOs - USER'S GUIDE. 10.13140/RG.2.2.17881.95845.

Rios, L.V.; Natália, V.; Freitas, C.; Justen, F.; Fuganti-Pagliarini, R.; Soares, M.S.; Hugo, F.; Correa, B.A.; Domingues, M.E.; Romano, V.E.; et al. (2021) Regulatory Framework of Genome Editing in Brazil and Worldwide. In *CRISPR Technology in Plant Genome Editing: Biotechnology Applied to Agriculture*; Embrapa: Brasilia, Brazil.

Sánchez, M. A. (2024). The Global Advance of Genome-Edited Plants to the Market: The Key Role of Chile in Its Development. *Plants*, 13(24), 3597. <https://doi.org/10.3390/plants13243597>

Secretariat of the Convention on Biological Diversity (2000) *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes*. Montreal, Quebec, Canada. [ISBN 92-807-1924-6](https://doi.org/10.1017/9781009051224)

Sprink, T., Wilhelm, R. (2024). Genome Editing in Biotech Regulations Worldwide. In: Ricoch, A., Eriksson, D., Miladinović, D., Sweet, J., Van Laere, K., Woźniak-Gientka, E. (eds) *A Roadmap for Plant Genome Editing*. Springer, Cham. https://doi.org/10.1007/978-3-031-46150-7_25

Tachikawa, M.; Matsuo, M. (2023) Divergence and Convergence in International Regulatory Policies Regarding Genome-Edited Food: How to Find a Middle Ground. *Front. Plant Sci.*, 14, 1105426

Tripodi, P. (2023) The Evolution of Molecular Genotyping in Plant Breeding. *Agronomy*, 13, 2569.

Turnbull, C.; Lillemo, M.; Hvoslef-Eide, T.A.K. (2021) Global Regulation of Genetically Modified Crops Amid the Gene Edited Crop Boom—A Review. *Front. Plant Sci.*, 12, 630396.

Whelan, A.I., Lema, M.A. (2015) Regulatory framework for gene editing and other new breeding techniques (NBTs) in Argentina. *GM Crops Food* 6, 253265. Available from: <https://doi.org/10.1080/21645698.2015.1114698>.