P. ISSN: 0971-8184 II E. ISSN: 0976-1926
DOI: 10.61949/0976-1926.2024.v00i00.00

Indian Journal of Plant Genetic Resources

REVIEW ARTICLE

Navigating the Regulatory Landscape: Biosafety and Environmental Assessment of GMOs in Colombia

Adriana Castaño Hernández

Abstract

Colombia regulates all activities related to the use of genetically modified organisms (GMOs): laboratory research, confined activities, commercial planting, the importation of GMOs, human and animal consumption, and their use as raw materials for food processing. Regulations for developments with recombinant DNA technology have been in place since 1993, several years before the Cartagena Protocol was negotiated and adopted, of which the country was one of the leaders in formulation and negotiation. By 2023, 154,689 ha of GM crops of cotton, corn, soybeans, and flowers were planted in Colombia. Biological risks are defined by the possible negative effects on human or animal consumption and the environment in which they are released. As a megadiverse country, it has taken the challenge of developing technical and institutional capacities to ensure that applications of biotechnological developments do not pose risks to human and animal health or the environment.

Key Words: Biosafety, Cartagena Protocol, Colombia, GMOs Regulation, GM crops

Agrobiotechnology and GMO Regulatory Affairs Advisor and Consultant, Bogota, Colombia, South America.

***Author for correspondence:**

acastanoh@gmail.com

Received: 18/10/2024 **Revised:** 28/11/2024

Accepted: 02/12/2024

How to cite this article: Castaño Hernández A. (2025). Navigating the Regulatory Landscape: Biosafety and Environmental Assessment of GMOs in Colombia. Indian J. Plant Genetic Resources. 1-9. **DOI:** 10.61949/0976-1926.2024.v00i00.00

Introduction

The Republic of Colombia is located in the Northwestern corner of South America; its territorial extension corresponds to 1,141,748 km^2, while the maritime extension represents 928,660 km^2. Colombia is at the territorial level the twenty-sixth largest country in the world and the fourth in South America, after Brazil, Argentina and Peru. With coasts on the Pacific and Atlantic oceans, the country has a privileged geographical location that is evident in its biodiversity and great climatic variety. It is one of the few megadiverse countries in the world; it is estimated that between 200,000 and 900,000 species could exist in the country (Arbeláez-Cortes, 2013).

It can be said that, approximately, for every 10 species that exist on the planet, one lives in the country. According to the Biodiversity Information System (SIB in Spanish), the existence of 79,828 species is reported in the national territory; of which 75,723 live in the interior of the continent and 7,633 in the sea (SIB, 2024a). Colombia occupies the fourth place among the countries with the greatest biodiversity on the planet, after Brazil, Indonesia and China. It is the country with the greatest diversity of birds, orchids and butterflies, it is the second country with the greatest diversity of amphibians, freshwater fish, reptiles, palms and plants in general and the sixth country with the greatest diversity of mammals (SIB, 2024b).

Such biodiversity is a source of numerous ecosystem services and human livelihood and well-being, including provisioning services such as food, wood and non-wood forest products (skins, meat and ornamental fauna), genetic resources, natural ingredients, medicinal plants, pharmaceutical and cosmetic products, and water, among others.

Due to its position and physiography, Colombia has a great diversity of climatic zones and abundant agricultural resources. Agriculture is characterized by technified monocultures by region (*e.g.,* sugar cane, coffee, flowers, cotton, plantain, banana, sorghum, corn, rice, African palm, potato and cassava, among others) (Hodson *et al*., 2017). To a large extent, food and nutritional security depends on the production of cereals in small plots that allow them to supply themselves and trade in local markets. The most important cereals are rice and corn. Perennial crops for domestic consumption and export generate 41% of agro-industrial employment (Ramírez-Villegas *et al*., 2012). There are crops for domestic consumption and high-value crops such as coffee, bananas, sugar cane and African palm are exported.

Food and Agriculture Organization of the United Nations (FAO) recognizes that the relationship between sustainable agriculture and biodiversity is complex in terms of the management of biological resources and that agriculture can have a significant potential impact on biological diversity, including the impact related to the use and distribution of commercial genetically modified organisms (GMOs). Also promotes a strategic and integrated approach that includes policies and regulatory frameworks that analyze and manage risks in the sectors of food safety, animal and plant life and health, including associated environmental risks (FAO, 2010). This is how, during the years of strengthening and structuring the national biosafety system in Colombia, FAO, the Global Environmental Facility (GEF) together with the World Bank and United Nations Environment Program (UNEP), would play a decisive role in providing resources and developing capacities (training of human resources, creation of a GMO detection laboratory, regulatory and normative development, capacities to carry out risk assessments, information systems, among others), where these principles of biodiversity protection and the development of sustainable agriculture were considered as fundamental elements in the process of adopting GMOs for different uses in the country.

Also, recognizing that biosafety is a multisectoral responsibility, the Ministers of the Environment, Agriculture, Health, and International Trade, agreed to a task force made up of representatives of these four Ministries, the Institute for Colombian Agriculture (ICA for its name in Spanish) and the Alexander von Humboldt Institute (IAvH) in June 2001. This group has been developing a Plan of Action to promote a coordinated approach to GMO biosafety in Colombia. Central to the Plan of Action would be the development of a mechanism to facilitate an intersectoral approach to biosafety and to policy formulation and decision-making at the national level (Silva, 2001).

Colombian GMO Biosafety System

In the country, all activities related to the use of GMOs are regulated: laboratory research, confined activities, commercial planting, GMO imports, human and animal consumption, and their use as raw materials for food processing.

The regulatory framework for biosafety in Colombia in relation to GM crops has two components. The first is composed of constitutional mandates and different legislative acts related to the environment, biodiversity, genetic resources and agricultural issues that constitute the legal framework for agricultural crops in Colombia. The second component refers to specific legislation on biosafety developed, for the most part, in compliance with the Cartagena Protocol and the International Agreements to which Colombia is a Party (Hodson *et al*., 2012).

Colombia was one of the leading countries in the formulation and negotiation of the Cartagena Protocol on Biosafety, as well as the Nagoya-Kuala Lumpur Protocol on Liability and Redress Supplementary to the Cartagena Protocol. Cartagena is the name of a Colombian city where the Protocol was expected to be adopted by the countries in February 1999. However, due to certain issues that could not be concluded, it was finalized and adopted a year later, on January 29, 2000, in Montreal, Canada.

Through Law 165 of 1994, the country ratified the Convention on Biological Diversity, and in 2002 ratified the Cartagena Protocol through Law 740 of 2002. In addition to being part of the Convention on Biological Diversity (CBD) and the Cartagena Protocol, the general regulatory framework for biotechnology and biosafety in Colombia includes adherence to several international and regional conventions and agreements on intellectual property rights and other aspects related to trade, access to genetic resources and biodiversity such as the World Trade Organization (WTO); the Paris Agreement (industrial property); the General Agreement on Tariffs and Trade (GATT); the International Convention for the Protection of New Varieties of Plants (UPOV); the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS); the Agreement on Technical Barriers to Trade (TOT); the International Plant Protection Convention; the FAO-WHO *Codex Alimentarius*; the Aarhus Convention, among others. As a member of the Andean Community of Nations (CAN), it is governed in regulatory aspects related to biotechnology and related areas by the following agreements: Andean Decision 345 (Breeders of Plant Varieties), Andean Decision 391 (Access to genetic resources), Andean Decision 486 (Industrial property).

The country has a consolidated National Biosafety System for GMOs, with specific regulations for GMO biosafety since 1993 (research with recombinant nucleic acids) and since 1996 for products derived for food production purposes through regulations issued by the Ministry of Health. Likewise, for the agricultural and livestock sectors since 1998, when the first Technical Committee on biosafety was established.

Following the ratification of the Cartagena Protocol by the country in 2002, it was considered necessary to redefine the structure of the National Biosafety System through Decree 4525 of 2005, which applies to transboundary movements, transit, handling and use of Genetically Modified Organisms (GMOs) that may have adverse effects on the environment and biological diversity, taking into account the risks to human health, productivity and agricultural production. This decree established the framework regulations for GMOs in relation to (i) the competent authorities, (ii). the authorization to develop activities with GMOs (understood as the Advance Informed Agreement Procedure-AIA- for the first transboundary movement of GMOs), (iii) risk assessment and risk management, (iv) the creation of National Technical Committees on Biosafety (sectoral), and (v) monitoring and surveillance, information, education and research.

The three designated National Competent Authorities (NCAs) and their respective National Biosafety Technical Committees (NTCs or CTN in Spanish) are discussed hereunder and shown in Figure 1:

1. The Ministry of Agriculture and Rural Development (MADR), through the Colombian Agricultural Institute ICA (by its name in Spanish), is responsible for evaluating and authorizing GMOs exclusively for agricultural, livestock, fishing, commercial forest plantations and agro-industrial use, with its National Technical Committee on Biosafety of GMOs for agricultural, livestock, fishing, commercial forest plantations and agro-industrial use: CTNBio.
2. The Ministry of Health and Social Protection (MSPS), through the National Institute for the Surveillance of Medicines and Food (INVIMA) (by its name in Spanish), is responsible for evaluating and authorizing GMOs whose destination is for use in human food or health; with its National Technical Committee on Biosafety of GMOs for use in health and human food: CTNSalud.
3. Ministry of Environment and Sustainable Development MADS is responsible for evaluating and authorizing GMOs for exclusively environmental use – with its National Technical Committee on Biosafety of GMOs for Environmental Use: CTNAmbiente.

For planting, food and feed in the country, the interested party must request authorization from the relevant competent authority for one or all of the uses of GMOs. This authorization must be obtained before the first international transboundary movement of a GMO intended for deliberate introduction into the environment or intended for direct use as human food animal feed or for processing.

Risk assessment is carried out following international criteria and methodologies established by, among others, the Codex Alimentarius for Foods Obtained by Biotechnology (Documents: CAC/GL 44-2003, CAC/GL 45-2003 and CAC/GL 46-2003), Law 740 (Cartagena Protocol: Annex I, II and III), the FAO risk assessment guidelines, and international regulations on the matter. Research with GMOs in a confined environment requires prior authorization based on the information provided by the requesting Research Unit in relation to the infrastructure and equipment available, waste management, description of the research group, parental and recipient organisms to be used, type of research to be conducted, and containment and isolation measures to be used.

Also, there are specific regulations for the labeling of foods derived from or containing GMOs (Resolution 4254 of 2011) and a Low-Level Presence (LLP) threshold for seeds and grains for animal consumption, the LLP threshold for grains for human consumption is under discussion for its establishment.

In relation to new breeding techniques as gene editing, the Colombian Agricultural Institute (ICA), the designed competent authority for agriculture, forestry, and fisheries, issued Resolution 29299 (ICA, 2018), which establishes a procedure for the evaluation of an improved cultivar obtained by innovative biotechnological techniques, and verify that the final product does not contain foreign genetic material, in order to determine if the given cultivar corresponds to a living modified organism (LMO) or not, and, consequently, determine whether the regulation of LMOs should apply.

In Colombia, the term GMO is understood as any living organism that possesses a new combination of genetic material, that has been obtained by the application of recombinant DNA technology, its developments or advances, as well as its parts, derivatives, or products containing them, capable of reproducing or transmitting genetic information (Decreto 4525, 2005). This concept includes the term LMO as referred to in the Cartagena Protocol. In such a way in Colombia, the legal term used is GMO, however, since the term LMO is included, it can be found in some regulations without distinction.

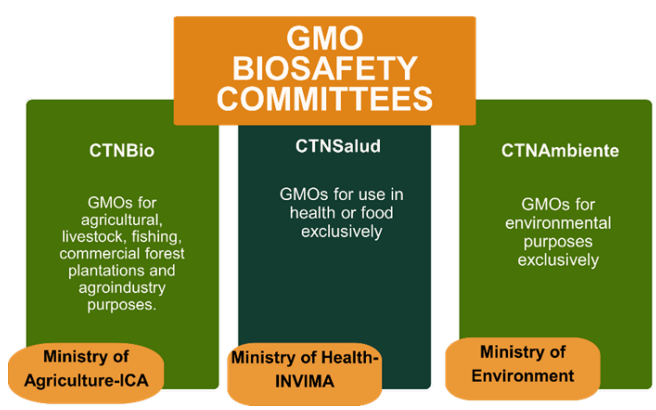

Figure 1: Competent National Authorities and National Technical Committees on Biosafety for GMOs in Colombia

The structure that the country, currently, has not only to comply with the Cartagena Protocol, but also to respond to the international agreements it has signed, is solid and consistent with advances in technology, is taken as a point of reference by countries in the region, follows the international guidelines that have been generated in the matter, and is under permanent review and updating so that the competent authorities can respond to society (Mora *et al*., 2018).

Genetically Modified Crops in Colombia

In Colombia, different transgenic technologies have been commercially released in corn and cotton crops: resistance to lepidopteran insects resulting from the expression of *cry* genes derived from *Bacillus thuringiensis* Bt, tolerance to the herbicide glyphosate resulting from the expression of the *cp4epsps* gene derived from *A. tumefaciens*, and double gene cultivars containing both technologies in different versions. In the case of corn, the technology for tolerance to the herbicide glufosinate ammonium resulting from the expression of the bar gene derived from *Streptomyces hygroscopicus* has also been released. Transgenic carnations and roses with blue flower phenotypes have also been commercially released, as well as chrysanthemums with the same phenotype for experimental planting.

The first approval for the commercial cultivation of a GM plant in Colombia was granted in 2000 for blue carnations which were first planted, in confined greenhouses, in 2002. Environmental release of a GM crop was first approved for Bollgard™ cotton in 2003 (Mora *et al*., 2018). GM maize was first grown commercially in 2006, initially on a restricted basis and post 2007, on an unrestricted basis. The first available traits conveyed resistance to common maize pests like Corn borer (*Diatraea*) and corn earworm (*Helicoverpa*) (Brookes, 2020).

By 2023, the planting of GM crops reached 154,689 ha, 23,640 ha more than in 2022 (Figure 2). The distribution of GM crops in 2023 in the country shows that the number of hectares cultivated with GM corn was 142,711, of GM cotton 7,409, of flowers 12 and of GM soybeans 4,557 (ICA, 2024. personal communication), being the first time that transgenic soybeans have been commercially planted in the country, despite having been approved for release into the environment since 2010.

Regarding authorizations for human consumption, the first approval was given in 2003 for the event MON-00531-6 Cotton with insect resistance was approved for the production of oils for human consumption. As of August 2024, as direct food or raw material for food processing, 252 genetic transformation events have been approved in Colombia (Figure 3), 45 of which are cotton, 146 of corn, 46 of soybeans, 2 of rice, 2 of wheat, 1 of sugar beet, and 10 of canola (Invima, 2024).

GM cotton was introduced in Colombia in the 2003/04 planting season, since then, the generation of economic benefits from this technology reached US $134.1 million. Of this total, 63.2% (US $84.7 million) was achieved by Colombian cotton producers, in the form of a reduction in production costs (US $12.4 million) and an increase in productivity (US $72.3 million). The remainder was accumulated by the technological breeders, 37.1% or US $49.4 million (Céleres, 2015).

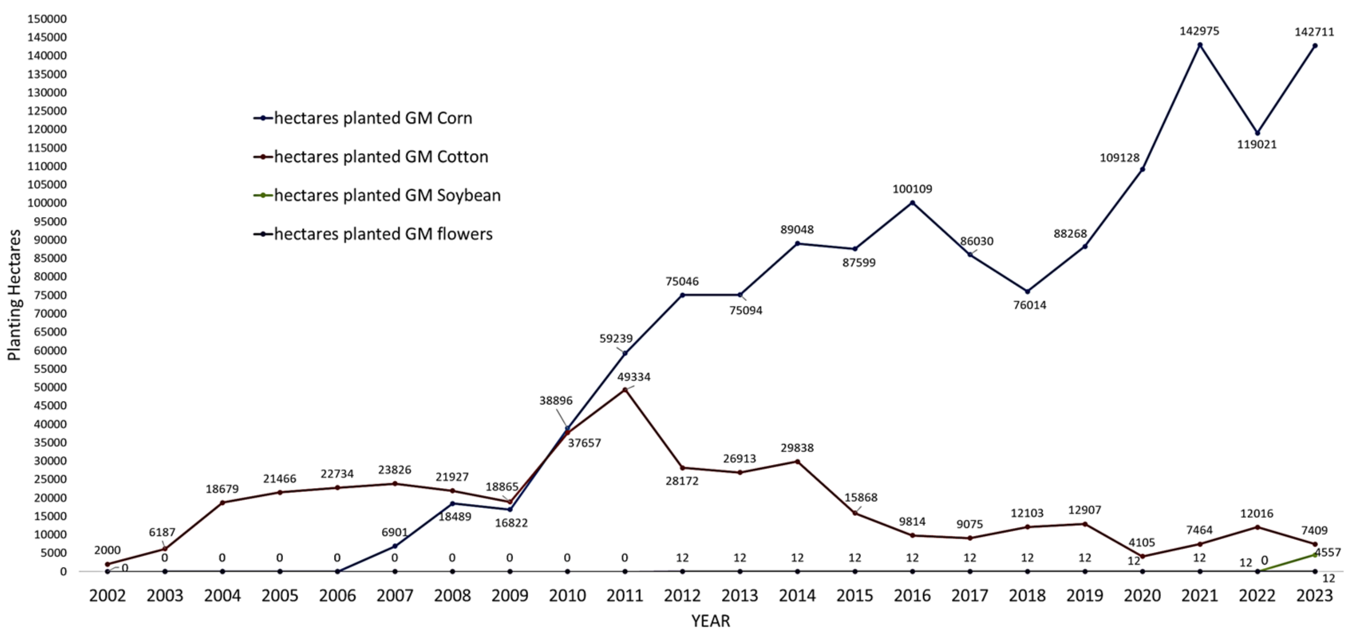

Figure 2: Evolution of adoption for planting GM Corn, Cotton, Soybeans and Flowers in Colombia 2002-2023 (Official data from the Colombian Agriculture Institute ICA Colombia)

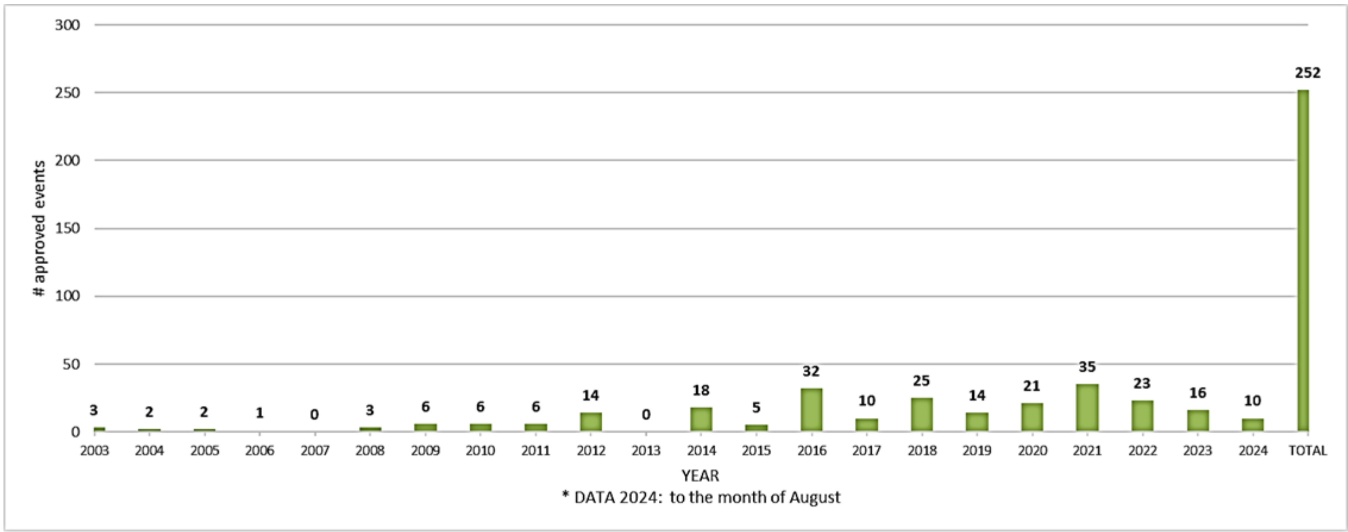

Figure 3: Number of genetic transformation events approved as food or raw material for the production of food for human consumption 2003-2024 (Official data from INVIMA Colombia)

The same study shows that, in the case of maize, the Colombian farmer who adopts transgenic technology earns US $28 per ha using these technologies (considering events with stacked genes). In addition to the profit derived from a reduction in the cost of production, the Colombian rural producer derives economic benefits from increased productivity, which will result in higher sales, through the prices paid per ton of maize. In the case of the breeder of transgenic technology (industry), the economic gain is calculated by the price difference between GM and conventional seed, which results in the achievement of economic benefits, which were stipulated, on average, in US $71.0 per ha. Since the adoption of biotechnology in maize in Colombia in 2007/08, to the 2014/15 sowing season, rural producers have accumulated direct and indirect economic benefits. In the case of rural producers, the direct economic benefits accrued came to US $77.9 million, including cost reduction and the surplus of production generated with the technology.

In 2018, a study carried out to measure the economic and environmental contributions to farmers from the use of GM crops showed that the seed technology has helped farmers grow more food and feed (567,000 tons of additional maize 2007–2018 and 68,000 tons of cotton lint 2003–2018). The extra production and reduced cost of pest and weed control have provided maize farmers with higher incomes equal to an average of US $294/ha and an average return on investment equal to +US $5.25 for each extra US $1 spent on GM maize seed relative to conventional seed. For cotton farmers, the average increase in income has been + US $358/ha, with an average return on investment equal to +US$3.09 for each extra US $1 spent on GM seed relative to conventional seed (Brookes, 2020).

Research on Genetically Modified Crops in Colombia

The first reports of work carried out in plant genetic engineering in Colombia were presented at the IV National Congress of the Colombian Society of Plant Breeding and Crop Production in 1995. A work by the Biotechnology Institute of the National University of Colombia (UNC), works by the International Center for Tropical Agriculture (CIAT) and the Colombian Corporation for Agricultural Research (CORPOICA now AgroSavia) (Chaparro, 2015).

In Colombia, the main research organizations working on GM crops are the International Center for Tropical Agriculture (CIAT), Biological Research Corporation (CIB), Sugarcane Research Center of Colombia (CENICAÑA), National Center for Coffee Research (CENICAFE), Javeriana University in Bogotá, National University of Colombia, and EAFIT University in Medellín. Rice, cassava, cotton, potato, sugarcane, coffee, corn, soybeans, stevia and flowers are some of the crops in which these types of initiatives have been developed, supported by the main associations of the productive sector. Some examples of local developments are presented in Table 1.

Regarding genome editing, in Colombia, there are developments that already have commercial approval. These have focused on the improvement of rice, beans, cassava and cocoa, under the leadership of CIAT. Research on rice aims to create resistance to the white leaf virus, a very common disease in Latin America that kills the leaves of the plant and negatively affects yield. In the case of cocoa, they are focusing on the genes responsible for the absorption of heavy metals in an attempt to reduce the amounts of toxic metals in harvested cocoa seeds (Chavarriaga, 2020).

The Colombian Agricultural Institute (ICA) and the United States Department of Agriculture (USDA) approved

Table 1: Current research for the development of GM crops in Colombia

Crop	*Trait*	*Research Institution*
Potato	Resistance to the Guatemalan moth	Corporation for Biological Research (CIB) (Villanueva, 2014)
Sugarcane	Resistance to yellow leaf virus Insect Resistance Higher Sucrose content	Sugarcane Research Center of Colombia (Cenicaña) (Ángel-Salazar, 2023; Trujillo *et al*., 2024)
Soybeans and Corn (local varieties)	Agro-biogenerics[1] with herbicide tolerance	National University of Colombia, Bogotá Campus, Plant Genetic Engineering Group ((Barreto *et al*., 2024, Mora *et al*., 2024).
Sacha inchi and castor oil plant (Higuerilla in Spanish)	High oleic acid content	EAFIT University (Villanueva, 2021)
Rice, cassava (manioc) and forage grasses	Resistant to diseases	International Center for Tropical Agriculture (CIAT)

[1]An entirely new event can be produced by genetically transforming a variety with expression cassettes, genes, or regulatory sequences that have been previously used but are now in the public domain, thus producing an agbiogeneric that does not necessarily have the exact same inserted sequence as prior events and may have a different insertion site in the genome (Barreto *et al*., 2024, Mora *et al*., 2024).

the use of genome-edited rice to be resistant to bacterial blight. These regulatory authorities took into account the breeding method used for their evaluation, concluding that it is not transgenic and that it can be regulated under the regulations of a crop obtained by conventional techniques. This edited rice was developed and evaluated in Colombia, with the participation of a scientific team from five countries led and with the participation of CIAT.

More than 30 years later, the appropriation of genetic engineering to solve problems in national agriculture is still not part of the strategies for strengthening and growing agriculture and is even the subject of political initiatives seeking its prohibition, despite the country's extensive experience in GMO biosafety, as well as progress in local developments in varieties of agricultural interest.

Genetic engineering has to take into account issues related to intellectual property rights and biosafety regulation of GMOs, as well as the will to build an ecosystem of biotechnological innovation, which helps in the appropriation of biodiversity, as a real exercise of national sovereignty in the field of genetic resources (Chaparro, 2015).

Environmental Assessment of GM crops in Colombia

The risk assessment strategy seeks to implement appropriate methodologies and approaches to compare the GM crop with its non-GM counterparts. This comparison is the starting point of the evaluation that focuses on intentional or unintentional differences. To this end, the concept of familiarity of the OECD (1993a, 1993b) WHO/FAO (2000) has been developed for the environmental safety assessment of GMOs.

Environmental risk assessment for the release of GM crops is carried out following the principle of "case by case" and "step by step", based on the analysis of information and studies prepared by the developers of the technologies, and the data generated from field biosafety trials conduct under the supervision of the competent authority (ICA), in a representative region of the crop in the country. In addition, the requirements of Annexes I and III of the Cartagena Protocol, which is complied with in the country (Congress of the Republic, 2002), must be taken into account. The main support is the constantly updated scientific knowledge, as well as the familiarity with the organism or crop under evaluation, considering the proposed application or use and the potential receiving environment.

Biosafety studies carried out include:

- Agronomic behavior of the modified variety in different sowing regions in the country.
- Evaluation of weed control and crop damage (if applicable).
- Costs for management and crop yields.
- Evaluation of wild species in the GM planting areas.
- Determination of the effects of the new proteins expressed on nontarget pests (if applicable).
- Establishment of planting distances between GM crops and conventional crops, by determining the transport of pollen from the GM material to be planted.

In addition, a detailed molecular review of the transformation event is performed, based on information from the donor organism, the transformation vector, the receiving organism and the description of the GMO.

When a risk is identified, a management plan is designed which must be followed throughout the time that the GMO is being planted. The management plan aims to: (i) control the use and commercialization of GM seeds, (ii) avoid the generation of resistance by the target pests through refuge strategies and monitoring of the baseline susceptibility to proteins that confer resistance to insect attack, (iii) ensure the effective use and management of herbicides in GM crops with herbicide tolerance to avoid the emergence of resistant weed species and (iv) prevent gene flow from GM crops to wild varieties by using forms of isolation.

The monitoring actions are carried out during all the stages of the crop from the pre-sowing season, during the cultivation and at the end and closing of the harvest. During this time there is a verification of: (i) training, (ii) establishment of refuge schemes, (iii) monitoring the development of possible resistance by target pest species, (iv) weed management and (v) isolation.

The development of GM crops seeks to obtain higher yields, improve resistance to pests, increase tolerance to herbicides and reduce production costs. Despite their potential benefits, these crops can cause direct or indirect environmental effects on wild species (Tovar *et al*., 2015). Wild species are essential for the improvement of cultivated species and, therefore, for the sustainability of agriculture. However, GM crops present in Colombian territory increase the risk of transgene transfer to wild relatives, just as the eventual adoption of more crops of this type opens the possibility of overlapping with wild populations. However, gene flow is not the main concern: the biggest problem lies in the nature of the transgenes disseminated and the effects they produce on the recipient species, such as the loss of genetic diversity.

A study, carried out by the Ministry of the Environment with the support of the Alexander von Humboldt Institute, on the genetic characterization of wild relatives in rice, reveals the existence of a high diversity in all species and suggests a predominant genetic exchange between close individuals of the same population. Therefore, there is the possibility of genetic flow between GM rice and its wild relatives and, although it would be limited by the existence of genetic barriers, it is a risk that cannot be ruled out (Thomas *et al*., 2017). To understand and mitigate the ecological impact of transgene flow, strategies must be developed that allow (Tovar *et al*., 2015):

1. Establish actual and potential distribution zones of species at risk, with a view to identifying possible areas of overlap with GM crops at present and in the future.
2. Develop genetic diversity studies prior to the introduction of GM crops, in order to determine the composition and genetic variability of the species.
3. Develop a gene and seed bank to maintain and promote natural genetic variability, as well as guarantee its future availability.
4. Develop methodologies, with their respective monitoring programs, to detect transgenes in recipient species.

In the face of the environmental impact of the use of transgenic corn and cotton events with insect resistance (IR) and herbicide tolerance (HT), Brookes (2020) found that genetically modified traits have contributed to reducing the environmental impact associated with the use of insecticides in a significant proportion of the areas dedicated to these crops.

Since 2003, insecticide use on IR cotton acreage has been reduced by 176,500 kg of active ingredient, and the environmental impact associated with insecticide use on these crops, as measured by the EIQ (Environmental Impact Quotient) indicator, has decreased by 27%. Since 2007, herbicide use on HT cotton has decreased by approximately 45,000 kg, and the associated environmental impact has also decreased by 5% (Brookes, 2020).

In the case of GM corn, since 2007 the use of insecticides has decreased by 279,400 kg of active ingredient, and the environmental impact associated with the use of insecticides on these crops has decreased by 65% (EIQ indicator). And the use of herbicides on corn (available since 2009) has decreased by 278,000 kg, and the associated environmental impact has also decreased by 22% (Brookes, 2020).

Previously, Mendez *et al*., (2011) in a study carried out to analyze the environmental impact of transgenic and conventional corn crops in the municipality of Valle de San Juan, in the Tolima region (Colombia), found in the evaluated area, GM corn produced 0.97 tons/ha more than conventional technology. A reduction in environmental impact was also found in the application of transgenic technology in that particular area of the country since there was no application of insecticides. The calculated EIQ shows a difference of 191.88 points in favor of transgenic technology, which represents a reduction of more than 100% of the numerical value of the quotient for the joint evaluation (insecticides and herbicides). A 100% reduction in insecticide applications was achieved, which brings environmental and economic benefits to farmers who adopted this technology in the study area.

The scope for impacts on greenhouse gas emissions associated with GM crops in Colombia has come from one main source; fuel savings associated with less frequent insecticide and herbicide applications. The use of GM IR cotton and maize has resulted in total savings equal to 8,761 million kg of carbon dioxide not released into the atmosphere, arising from less fuel use of 3.28 million liters (Brookes, 2020).

Finally, and as one of the actions to protect conservation areas and wild species, in the case of GM corn planting, these cannot be done in areas recognized as indigenous reservations and must always be planted leaving at least 300 meters away from native variety corn crops and in the case of cotton up to 500 meters. Also, for insect-resistant varieties, a refuge scheme should always be sown with a conventional cultivar or with a GM cultivar with tolerance to the application of herbicides.

Conclusion

Colombia has developed a comprehensive biosafety regulatory framework focused on environmental protection and safety for human and animal consumption, with technical and scientific foundations and in accordance with international regulations on the subject. The strict risk assessment protocols governing the release of GMOs into the environment seek to ensure that their introduction into agroecosystems is safe, in addition to biosafety and monitoring plans for commercial planting of GM crops with insect resistance and/or tolerance to the application of herbicides. However, to further promote the cultivation of transgenic crops in Colombia, it is crucial to continue addressing public perception and the regulatory challenges that arise with the evolution of technology. The economic advantages of growing transgenic crops in Colombia highlight the potential of the technology to boost agricultural productivity, access to smallholder farmers in the country and contribute to food security. To fully take advantage of these benefits, it is essential to adopt a regulatory approach based on scientific evidence and foster education and public awareness regarding GM technology. Other developing countries, can learn from Colombia's more than 25 years of experience, implementing not only effective biosafety regulations but also the necessary support structure such as GMO detection laboratories, risk management plans, ongoing training of the competent authorities, and leveraging transgenic technology and new plant breeding developments to address their unique agricultural challenges, ultimately contributing to food and nutrition security and improving the livelihoods of their farmers.

References

Ángel-Salazar JS, C Echeverri-Rubiano, J Rodríguez-Chalarca, J López-Gerena, RF Dos Santos, JL Jurat-Fuentes, AM Revynthi and G Vargas (2023) Development of a bioassay method to test activity of cry insecticidal proteins against *Diatraea* spp. (Lepidoptera: Crambidae) sugarcane stem borers. *PLoS ONE* 18(10): e0292992.

Arbeláez-Cortés E (2013) Knowledge of Colombian biodiversity: published and indexed. *Biodivers. Conserv.* 22(12), 2875–2906. https://doi.org/10.1007/s10531-013-0560-y

Barreto-Jiménez JP, JE Vargas-Sanchez, J Mora-Oberlaender and A Chaparro-Giraldo (2024) First Latin American off-patent corn event - Fenaltec 22. *Crop Breed. Appl. Biotechnol.* 24(2): e46582428:1-6.

Brookes G (2020) Genetically modified (GM) crop use in Colombia: farm level economic and environmental contributions, *GM Crops Food* 11:3: 140-153. DOI:10.1080/21645698.2020.1715156

Céleres (2015) Los beneficios agronómicos, económicos y socio ambientales de la biotecnología agrícola en Colombia: El caso del algodón, del maíz y de la soya genéticamente modificados. Uberlandia:Celeres®; Agro-Bio. Bogotá. 121 p.

Chaparro Giraldo A (2015) La Ingeniería Genética de Plantas en Colombia: Un Camino en Construcción. *Acta Biol. Colomb.* 20(2): 13-22. https://doi.org/10.15446/abc.v20n2.43412

Chavarriaga P (2020) Introducción a las Técnicas de la Edición Génica y su Aplicación. Plataforma de Mejoramiento Avanzado Alianza de Bioversity Internacional y CIAT. Available from: <https://acosemillas.org/wp-content/uploads/2020/11/02.-Paul-chavarriaga-CIAT-Edicion-de-Genes.pdf> [accessed October 17 2024]

Congress of the Republic (2002) Law 740 by means of which the "Cartagena Protocol on Biosafety of the Convention on Biological Diversity" is approved, done in Montreal, on the twenty-ninth (29) of January of two thousand (2000). Official Journal N° 44.816 – May29, 2002

Decreto 4525 de 2005 [Ministerio de Agricultura y Desarrollo Rural, Ministerio de la Protección Social, Ministerio de Ambiente y Desarrollo Sotenible]. Por el cual se reglamente la Ley 740 de 2002. 6 de diciembre de 2005.

Hodson de Jaramillo E, A Castaño and MA Uscátegui (2012) Biotecnología Agrícola Moderna, Organismos Genéticamente Modificados y Bioseguridad. Consejo Superior de la Judicatura, Sala Administrativa. Escuela Judicial "Rodrigo Lara Bonilla." Módulo de Aprendizaje Autodirigido - Plan de formación de la Rama Judicial. 220 p. ISBN: 978-958-99102-2-1

Hodson de Jaramillo E, J Castaño, G Poveda, G Roldán and P Chavarriaga (2017). Seguridad alimentaria y nutricional en Colombia, In: IANAS, Retos y oportunidades de la seguridad alimentaria y nutricional en las Américas: El punto de vista de las Academias de Ciencias. La Red Interamericana de Academias de Ciencias (IANAS), Ciudad de México. MX, pp 220-221.

ICA-Instituto Colombiano Agropecuario (2018) Resolución 0029299 Procedimiento para el trámite ante el ICA de solicitudes de un cultivar mejorado con técnicas de innovación en fitomejoramiento a través de Biotecnología moderna. Bogotá, Colombia.

INVIMA-National Institute for the Surveillance of Medicine and Food (2024) CTNSalud Database - Applications to the National Technical Committee on Biosafety of GMOs for Use in Health and Human Food Exclusively. INVIMA, Bogotá.

Méndez KA, A Chaparro Giraldo, GR Moreno and CS Castro (2011) Production cost analysis and use of pesticides in the transgenic and conventional corn crop [*Zea mays* (L.)] in the valley of San Juan, Tolima. GM Crops. 2011 Jun-Dec;2(3): 163-8. doi: 10.4161/gmcr.2.3.17591. Epub 2011 Jun 1. PMID: 22008311.

Mora-Oberlaender J, Y Rodriguez-Abril, M Estrada-Arteaga, L Galindo-Sotomonte, JD Romero-Betancourt, JP Jiménez-Barreto, C López-Carrascal and A Chaparro-Giraldo (2024) Agbiogeneric soybean with glyphosate tolerance: Genetic transformation of new Colombian varieties. *Crop Breed. Appl. Biotechnol.* 24(1): e474324113.

Mora-Oberlaender J, A Castaño-Hernández, SA López-Pazos and A Chaparro-Giraldo (2018) Genetic engineering of crop plants: Colombia as a case study. In: Kuntz M (ed) Transgenic plants and beyond. Advances in Botanical Research, vol 86. Academic Press, London, pp 169-206.

Jiménez-Barreto JP, JEV Sanchez, J Mora-Oberlaender and A Chaparro-Giraldo (2024) First Latin American off-patent corn event-Fenaltec 22. *Crop Breed. Appl. Biotechnol.* 24(2): e46582428.

FAO (2010) Organización de las Naciones Unidas para la Agricultura y la Alimentación – Desarrollo Bioseguridad de Capacidades en Bioseguridad experiencias y perspectivas de la FAO. FAO, Roma. 66 p.

Ramírez-Villegas J, M Salazar, A Jarvis and CE Navarro-Racines (2012) A way forward on adaptation to climate change in Colombian agriculture: perspectives towards 2050. *Climatic Change* 115: 611. doi:10.1007/s10584-012-0500-y.

SIB Sistema de Información de Bioseguridad en Colombia (2024a) Biodiversidad en Cifras. <https://cifras.biodiversidad.co/colombia> [Accessed October 08, 2024].

SIB Sistema de Información de Bioseguridad en Colombia (2024b) Biodiversidad de Colombia en el mundo. <https://cifras.biodiversidad.co/> [Accessed October 08, 2024].

Silva C (2001) Experiencia colombiana en la aplicación de la reglamentación sobre bioseguridad agrícola. *Rev. Colomb. Biotecnol*. 3(2): 17–22.

Thomas E, E Tovar, C Villafañe, J Bocanegra and R Moreno (2017) Distribution, genetic diversity, and potential spatiotemporal scale of alien gene flow in crop wild relatives of rice (*Oryza* spp.) in Colombia. *Rice* 10: 13 (2017). https://doi.org/10.1186/s12284-017-0150-9.

Tovar E, E Thomas, J Bocanegra and R Moreno (2015) Parientes silvestres, transgénicos y la conservación de los recursos genéticos, Biodiversidad. Instituto Alexander von Humboldt. <http://reporte.humboldt.org.co/biodiversidad/2015/cap4/411/#seccion1> [Accessed October 09, 2024].

Trujillo Montenegro JH, MC Martínez Villa and JJ Riascos Arcos (2024) Biotecnología para el mejoramiento de la caña de azúcar. In: Centro de Investigación de la Caña de Azúcar de Colombia (ed) Agroindustria de la caña de azúcar en Colombia. Cenicaña. Cali, Colombia.

Villanueva D, J Torres, H Rivera, V Nuñez, R Arango and F Angel (2014) Colombian genetically modified potato lines resistant to *Tecia solanivora* (Lepidoptera: Gelechiidae) under a confined field. *Rev. Colomb. Entomol.* 40(2):148-157. ISSN 0120-0488.

Villanueva Mejía DF (2021) Estudio de Sacha Inchi (*Plukenetia volubilis*) en 5 municipios del departamento de Antioquia. v1.1. Universidad EAFIT. Dataset/Occurrence. https://doi.org/10.15472/zy45rd.