

Regulating biotechnology: Legal oversight as a tool for preventing genetic environmental damage

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Abstract---The rapid advancement of biotechnology and genetic engineering has created significant opportunities for scientific and economic development, while simultaneously introducing complex environmental and public health risks. This study examines the regulatory frameworks designed to prevent genetic environmental damage, highlighting the critical interplay between international agreements and national administrative oversight. International instruments, such as the Cartagena Protocol on Biosafety and the Convention on Biological Diversity, establish fundamental principles including the precautionary approach, transparency, prior informed consent, and cross-border cooperation, which aim to mitigate potential adverse impacts of genetically modified organisms (GMOs) on biodiversity and ecosystems. At the domestic level, administrative measures—licensing regimes, activity prohibitions, mandatory compliance obligations, and prior notifications—translate these international principles into enforceable safeguards. Using Algeria as a case study, this research analyzes the effectiveness of these mechanisms and identifies regulatory gaps, particularly regarding emerging biotechnologies outside traditional agricultural contexts. The study concludes that a comprehensive, multi-level regulatory strategy is essential to balance scientific innovation with environmental protection. Key recommendations include modernizing national legislation in line with scientific and technological advances, integrating the precautionary principle more explicitly, strengthening inter-agency coordination, and promoting public awareness and participation. This integrated framework not only enhances biosafety and environmental sustainability but also ensures alignment with international obligations while supporting responsible biotechnological development.

Keywords---Biotechnology regulation, GMOs, Environmental law, Biosafety, Precautionary principle, Biodiversity, National oversight, International agreements.

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Introduction

The rapid advancements in biotechnology and genetic modification techniques have given rise to complex legal and regulatory challenges that directly affect the protection of the environment, human health, and biodiversity. These challenges are particularly acute due to the inherent uncertainty surrounding the potential risks of genetic interventions. In response, both the international community and national states have recognized the necessity of adopting precautionary legal approaches that combine pre-emptive and post-activity oversight to mitigate potential environmental harms. The precautionary principle has emerged as a cornerstone of contemporary environmental policy, guiding both preventive strategies and regulatory interventions.

In this context, international oversight provides a reference framework defining general principles and shared obligations for states through relevant conventions and protocols. Chief among these are the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety, which establish an international legal system designed to regulate the use of genetically modified organisms (GMOs), enhance international cooperation, facilitate information exchange, and ensure the safe and responsible transfer of biotechnology. However, the effectiveness of these mechanisms depends largely on their implementation at the national level.

Consequently, national administrative oversight complements international regulation by operationalizing these commitments through administrative control mechanisms, including licensing, prohibition, mandatory obligations, and prior notification procedures. These instruments enable states to intervene preventively and regulate activities that may pose genetic or environmental risks. This study analyzes the role of both international and administrative oversight in protecting the environment from genetic modification risks, highlighting their effectiveness in balancing scientific development with environmental protection, with reference to Algerian legislation and relevant international frameworks. The analysis is divided into two main sections: the first examines international oversight mechanisms for environmental protection, and the second addresses national administrative oversight procedures.

I. The Role of International Oversight in Environmental Protection

The Cartagena Protocol on Biosafety places significant emphasis on biosafety, aiming to protect human health and the environment from potential adverse effects of biotechnology products, particularly those involving genetic modification techniques. While acknowledging the scientific and developmental benefits of these technologies, the protocol establishes legal and regulatory mechanisms to minimize their potential risks to public health and biodiversity. It also emphasizes the sustainable transfer of biotechnology between states, ensuring the safety of genetically modified products and monitoring their potential impacts. International collaboration involves technologically advanced countries supporting others through knowledge transfer, capacity building, and training of specialized personnel to ensure responsible handling of GMOs.

Articles 8, 10, and 13 of the Cartagena Protocol on Biosafety (2000) specify the data and information required in the prior informed consent documentation for genetically modified products, while Article 11 addresses information concerning GMOs intended for food or feed. Algeria has demonstrated a strong commitment to scientific training in the life sciences, leveraging international grants and developing specialized expertise in biotechnology research. The agricultural sector has received particular attention through institutions such as the National Institute of Artificial Insemination and Genetic Improvement (KCNIAAG), the National Center for Plant Control and Seed Certification (CNCC), and the National Agricultural Research Institute, which prioritizes biotechnology applications in agriculture. Additionally, pharmaceutical and medical research increasingly focus on molecular biology and genetic engineering.

Algeria has also engaged with the Global Environment Facility (GEF) and the United Nations Environment Programme (UNEP) through the joint national project entitled *Development of National Biosafety Capacities*, and established a national coordination committee under the Ministry of Environment to guide the preparation of a national biosafety framework. Under the Convention on Biological Diversity, states are obligated to identify components of biodiversity of particular importance and monitor activities that may adversely affect biodiversity continuity (Convention on the Protection and Use of Transboundary Watercourses and International Lakes, 1992, Art. 7):

(a) *Identify components of biological diversity important for its conservation and sustainable use...*

(b) *Monitor, through sampling and other techniques...*

(c) *Identify processes and categories of activities which have or are likely to have significant adverse impacts...*

(d) *Maintain and organize data derived from identification and monitoring activities.*

These commitments require the establishment of effective domestic conservation mechanisms supported by robust internal oversight.

1. The Duties of Precaution and Prevention

Most international environmental agreements enshrine the precautionary principle (Stockholm Declaration on the Human Environment, 1972, Principle 21; Rio Declaration on Environment and Development, 1992, Principle 2; United Nations Framework Convention on Climate Change [UNFCCC], 1992, Art. 3(2); Convention on the Protection and Use of Transboundary Watercourses and International Lakes, 1992, Art. 2(5); Cartagena Protocol on Biosafety, 2000). However, applying this principle to genetic modification presents a fundamental challenge due to the absence of definitive scientific consensus regarding potential long-term harms.

The CBD and the Cartagena Protocol institutionalize the precautionary principle, enabling states to prohibit or restrict the entry of GMOs. The conventions also affirm state sovereignty over genetic resources within national borders, protecting developing countries from the exploitation of their genetic assets by technologically advanced nations. States are further required to establish comprehensive national biosafety legislation and adopt all necessary precautionary measures prior to engaging in GMO activities, reinforcing the integration of the precautionary principle into domestic law.

2. The Duties of Cooperation and Information

The Rio Declaration emphasizes international cooperation, urging states to work collectively to preserve the Earth's ecosystems. The CBD recognizes state sovereignty over genetic resources while asserting that biodiversity constitutes a shared human interest, necessitating equitable benefit-sharing.

However, intellectual property frameworks, including the General Agreement on Tariffs and Trade (GATT) and the World Trade Organization (WTO), have extended patent protections to genetic information and its applications, often imposing financial burdens on farmers required to pay royalties for patented genetically modified organisms. Landmark cases, such as the U.S. Supreme Court ruling in *Diamond v. Chakrabarty*, validated the patenting of genetically modified bacteria, illustrating the intersection of biotechnology, intellectual property, and environmental governance.

Transparency and public consultation are critical, particularly in developing countries, where public awareness mechanisms mitigate risks of regulatory evasion and misinformation. For instance, the case of genetically modified cotton trials in Burkina Faso highlighted deficiencies in prior notification and public consultation, which were only retroactively addressed through legislation enacted in 2006 to ensure human, animal, and environmental safety (Law No. 005-2006/AN, 2006, Art. 2), *The provisions of the present Law shall apply to the development, experimentation, production, dissemination, storage, destruction or disposal, and transboundary movement, including transit, of any genetically modified organism or derived product, with the exception of the transboundary movement of genetically modified organisms that are pharmaceutical products governed by other international agreements.*

Any action involving genetically modified organisms must be carried out in accordance with national priorities for sustainable development").

II. The Role of Administrative Oversight in Environmental Protection

Legislators have established a range of legal and regulatory mechanisms aimed at safeguarding the environment, primarily by extending public authority oversight over activities that could potentially harm various environmental elements. These mechanisms mainly include licensing systems, prohibitions, mandatory obligations, and prior notification or authorization procedures. The application of these regulatory measures is crucial for preventing environmental harm, particularly genetic damage, as they function as preventive legal tools that embody the precautionary principle and mitigate potential risks arising from biotechnology and genetic modification activities.

1. Licensing and Prohibition

1.1. Licensing

Administrative licensing refers to the prior authorization granted by competent administrative authorities, particularly regulatory agencies, under specific legal conditions. Its purpose is to regulate certain activities and ensure they do not compromise public order or legally protected interests, foremost among them environmental protection and public health.

A license is an individual administrative decision allowing a specific activity to be conducted once the legal requirements are met. Licensing may concern activities that are not inherently prohibited, in which case the administrative authority's role is limited to verifying compliance with legal conditions and determining the appropriate timing for granting the license. Conversely, if the activity is initially prohibited, the authority enjoys broad discretionary powers to grant or deny the license based on the potential risk to public order and the environment (Hassouna, 2013, p. 43).

In Algeria, the legislator has implemented licensing systems across various domains related to environmental protection, including urban planning, exploitation of natural resources, industrial operations, and research institutions. Particular attention has been given to regulating industrial activities, requiring licenses for the operation of classified facilities and the management of waste produced by these establishments. Classified facilities are defined as industrial or commercial enterprises that pose potential risks or nuisances to public order, public health, public hygiene, or the environment (Hassouna, 2013, p. 44).

While the law establishes a detailed list of licensed facilities, this approach has not fully accounted for emerging industrial activities, especially those linked to biotechnology and genetic modification, which are not explicitly included. To address emerging threats, the legislation provides for emergency measures: the governor may isolate operators, set deadlines for corrective actions, or suspend industrial activity if compliance is not achieved (Algerian Law No. 03-10, 2003, Art. 25). This reflects the administration's capacity for immediate preventive intervention to protect the environment.

Licensing also covers research institutions, authorizing them to import, possess, transfer, and use genetically modified plant materials for research and analysis under conditions set by the Ministry of Agriculture (Ministerial Decree of December 24, 2000, Art. 3). This exemplifies the adoption of a proactive regulatory approach to prevent environmental or public harm from genetically modified materials. However, the legislative framework governing genetic damage remains partial and limited, primarily focusing on the plant sector while neglecting other areas affected by genetic modification. Licensing is a central preventive administrative tool, designed to enforce prior oversight, eliminate legal obstacles that may disrupt public order, and achieve effective environmental and human protection.

1.2. Prohibition

Prohibition entails restricting individuals or entities from engaging in specific activities. Absolute prohibitions are generally considered unlawful due to their infringement on constitutional freedoms.

However, partial or temporary prohibitions, limited by time or location, are lawful when justified by the necessity to protect public order and the environment (Maifi, 2011, p. 69). Prohibition is exercised through administrative decisions leveraging public authority. Algerian legislation employs prohibitions for activities deemed particularly hazardous to the environment. Prohibitory measures are applied in several domains:

- **Agriculture:** A decree issued on 24 December 2000 banned the importation, production, distribution, marketing, and use of genetically modified (Art. 01), plant materials due to their potential risks to health and the environment. Environmental Law No. 03-10 maintains a cautious stance, reflecting a generally restrictive approach toward such products.
- **Biodiversity Protection:** Algerian Law No. 03-10 (Art. 40), defines biodiversity as the variability among living organisms, including diversity within and between species and ecosystems. The law prohibits actions that harm non-domesticated plant and animal species, such as destroying eggs or nests, mutilating animals, or destroying natural habitats.
- **Water and Aquatic Environments:** Legislation prohibits the discharge of wastewater or any hazardous material into water resources used for drinking or groundwater replenishment, aiming to preserve water quality and prevent pollution (Algerian Law No. 03-10, 2003, Arts. 51; Algerian Law No. 05-12, 2005, Art. 46).

2. Mandatory Obligations and Notification

2.1. Mandatory Obligations

Mandatory obligations require individuals or entities to undertake specific positive actions to protect public order or prevent environmental harm. Such obligations are preventive measures issued as binding administrative orders, compelling compliance to avoid direct risks to public welfare. For instance, Law No. 03-10 obliges industrial units to reduce or cease using substances that deplete the ozone layer. Key areas of application include:

- **Waste Management:** Producers or holders of waste must minimize waste generation, adopt clean technologies, and safely dispose of waste, including genetically modified products, whose legislative oversight remains limited.
- **Air and Water Protection:** Industrial facilities must limit emissions and ensure wastewater meets regulatory standards, with mandatory periodic testing at the operator's expense.
- **Consumer Health Protection:** Food safety and public hygiene laws require compliance throughout production, storage, and distribution, emphasizing the risks associated with genetically modified products.

2.2. Notification or Prior Information

Notification requires individuals to inform the administration of their intention to engage in a specific activity, without necessarily obtaining prior authorization (Maifi, 2011, p. 90). This mechanism enables authorities to take appropriate precautions to safeguard public order. Prior notification is less restrictive than licensing but ensures administrative oversight. Legal authorization for activities that affect constitutional freedoms must always be grounded in explicit legislation, safeguarding the principle of legality.

Conclusion

This study demonstrates that protecting the environment from the risks of genetic modification represents a complex legal challenge, necessitating a multi-level regulatory framework that integrates international oversight with national administrative mechanisms. International frameworks, including environmental conventions and protocols, establish general obligations for states to adopt preventive policies, promote cooperation, and ensure transparency and information exchange to mitigate transboundary environmental risks.

The effectiveness of these international rules depends on their translation into robust domestic legal and regulatory mechanisms, a function primarily fulfilled by administrative oversight. Analysis of Algerian legislation reveals a range of preventive administrative tools, notably licensing, prohibition, and mandatory obligations. Nonetheless, the legal regulation of genetic damage remains incomplete, with gaps in coverage and insufficient adaptation to the complex and latent nature of such harm.

Enhancing administrative oversight to protect the environment from genetic modification risks requires updating national legislation to align with scientific and technological advances, fully integrate the precautionary principle, strengthen coordination among regulatory bodies, and enhance public information and consultation. Furthermore, closer harmonization between national laws and international obligations is essential to ensure sustainable environmental protection and human health while supporting scientific and economic development.

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