A link to the announcement in English of the regulation can be found at the Emirati News Agency website here: <u>https://wam.ae/en/details/1395302864211</u>

The law in Arabic can be found here: https://www.moccae.gov.ae/assets/download/2de95d5b/c3c2994c.pdf.aspx?view=true

## **BEGIN UNNOFICIAL TRANSLATION**

# Federal Law no. (9) of 2020

## ON BIOSAFETY OF GENETICALLY MODIFIED ORGANISMS

We, Khalifa Bin Zayed Al Nahyan, President of the United Arab Emirates, After perusal of the Constitution,

- Federal Law no. (1) of 1972 on Competencies of Ministries and Powers of Ministers, and its amendments;
- Federal Law no. (5) of 1979 Concerning Agricultural Quarantine, and its amendments;
- Federal Law no. (6) of 1979 Concerning the Veterinary Quarantine, and its amendments;
- Federal Law no. (5) of 1985 promulgating the Civil Transactions Law and its amendments;
- Federal Law no. (3) of 1987 promulgating the Penal Code, and its amendments;
- Federal Law no. (35) of 1992 promulgating the Penal Procedure Law and its amendments;
- Federal Law no. (38) of 1992 Concerning the Establishment of Arboretums and the Regulation of the Production, Import and Circulation of Seedlings;
- Federal Law no. (39) of 1992 Concerning the Production, Import and Circulation of Fertilizers and Agricultural Additives;
- Federal Law no. (41) of 1992 on Agricultural Pesticides;
- Federal Law no. (42) of 1992 Concerning the Production, Import and Circulation of Seeds and Tubers;
- Federal Law no. (23) of 1999 on the Exploitation, Protection and Development of Living Aquatic Resources at the United Arab Emirates, and its amendments;

- Federal Law no. (24) of 1999 on the Protection and Development of the Environment, and its amendments;
- Federal Law no. (28) of 2001 on the Establishment of the Emirates Standardisation and Metrology Authority, and its amendments;
- Federal Law no. (11) of 2002 concerning Regulation and Controlling the International Trade in Endangered Species of Wild Fauna and Flora;
- Federal Law no. (17) of 2002: concerning Regulation and Protection of Industrial Property of Patents, Designs and Industrial Patterns, and its amendments;
- Federal Law no. (24) of 2006 on Consumer Protection, and its amendments;
- Federal Law no. (16) of 2007 concerning Animal Protection, and its amendments;
- Federal Law no. (5) of 2009 on Organic Inputs and Products;
- Federal Law no. (17) of 2009 on Protection of New Plant Varieties;
- Federal Decree-Law no. (2) of 2011 on the Establishment of the National Emergency Crisis and Disaster Management Authority, and its amendments;
- Federal Law no. (9) of 2011 on Land Transport;
- Federal Law no. (9) of 2013 on Plant Genetic Resources for Food and Agriculture;
- Federal Law no. (2) of 2015 on Commercial Companies and its amendments;
- Federal Law no. (8) of 2015 on the Federal Customs Authority;
- Federal Law no. (10) of 2015 on Food Safety;
- Federal Law no. (14) of 2016 on Violations and Administrative Sanctions in the Federal Government;
- Federal Law no. (19) of 2016 on Combating Commercial Fraud;
- Federal Law no. (8) of 2019 on the Medical Products, Profession of Pharmacy and Pharmaceutical Institutions;
- Federal Decree-Law no. (26) of 2019 on General Finance;
- Federal Decree no. (75) of 2014 on the State's accession to the Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety;
- Federal Decree no. (77) of 2014 on the State's accession to the Cartagena Protocol on Biosafety;
- And according to the suggestion of the Minister of Climate Change and Environment, the approval
  of the Cabinet and the Federal National Council and the ratification of the Federal Supreme Council,

## Issued the following Law:

#### Article 1 – Definitions

In the implementation of the provisions of this Law, the following words and expressions shall have the meanings stated beside them unless the context requires otherwise:

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State:	The United Arab Emirates.
Ministry:	Ministry of Climate Change and Environment.
Minister:	Minister of Climate Change and Environment.
Competent Authority:	Local authority concerned in every Emirate of the State.
<b>Biodiversity:</b>	Variability of living organisms derived from all sources, including terrestrial and marine ecosystems, aquatic organisms and ecological compounds considered a part of the same, including diversity within species and among species and ecosystems.
Genetic Resources:	Resources of plant or animal origin, micro-organisms or other origins containing functional genetic units of actual or potential value.
Biosafety:	Procedures followed to ensure the safe use of modern biotechnology applications on both humans and the environment, in order to reduce or eliminate the potential resulting risks.
Organism:	Biological organism able to transmit or multiply the genetic material, including sterile organisms, viruses, viroids, animals, plants and microorganisms.
Genetic Modification:	Modification of genetic material using Modern Biotechnology.
Genetically Modified Organism (GMO):	Organism having a new combination that is different of its original combination of genetic materials obtained through the use of Modern Biotechnology.
GMO Products:	Materials prepared from living Genetically Modified Organisms or containing living Genetically Modified Organisms or their derivatives, offal or other products containing or composed of a percentage of Genetically Modified Component.
Genetically Modified Component:	Any part containing genetically modified genetic code.
Modern Biotechnology:	Application of in-tube techniques for DNA and direct injection of DNA into cells or organelles, or integrating cells until they fall outside their taxonomic rank and overcome the natural physiological barriers of reproduction or recombination, and they are not considered techniques used in natural breeding and selection.

Contained Use:	Process taking place inside the Establishment, including Genetically Modified Organisms subject to specific measures that effectively prevent their contact with the external environment and prevent their impact on that environment.
Release:	Release of Genetically Modified Organisms or their products into the environment.
Trading:	Sale, offer for sale, storage or acquisition, whether permanently or temporarily.
Establishment:	Establishment, utilities or any other buildings, whether stationary or mobile, permanent or temporary, authorised to manufacture, produce, develop or trade in Genetically Modified Organisms or their products.
Risks:	Probability of adverse effects as a result of exposure to the source of risk resulting from Genetically Modified Organisms or their products.
Risk Assessment:	Assessment of potential harmful effects of Genetically Modified Organisms or their products on the conservation and sustainable use of Biodiversity and the health and safety of humans and the environment.
Response Measures:	Measures taken to prevent, minimise, contain or mitigate harm.

#### **Article 2 – Objectives**

This Law aims at:

- 1- Preserving human health and safety from the Risks of Genetically Modified Organisms or their products.
- 2- Ensuring the protection of the environment in the field of development, manufacture, production, transfer or Trading of Genetically Modified Organisms or their products resulting from Modern Biotechnology.
- 3- Preserving local Genetic Resources and Biodiversity from the Risks of Release or introduction of Genetically Modified Organisms or their products to the environment.
- 4- Ensuring control, reduction, elimination of remediation of damages that occur or are likely to occur due to the Genetically Modified Organisms or their products.
- 5- Organising scientific research activities for living Genetically Modified Organisms.

#### **Article 3 – Scope of Implementation**

- 1- The provisions of this Law shall apply to the import, export, re-export, transit, Trading, development, manufacture, production and transfer of Genetically Modified Organisms or their products and other products containing them or in which there is a rate of (0.9%) or more of the Genetically Modified Organism. The Cabinet may issue a decision to amend this rate.
- 2- The following shall be excluded from the application of the provisions hereof:
  - a. Products containing a Genetically Modified Component at a rate less than (0.9%).
  - b. Genetically Modified Organisms or their manufactured products considered pharmaceuticals for humans and Genetic Modification of humans and human cells.

#### Article 4 – Import, Transit and Trading of Genetically Modified Organisms or their Products

- 1- It shall be prohibited to import Genetically Modified Organisms or their products without obtaining a permit from the Competent Authority. If it is an import for the first time, the approval of the Ministry shall be obtained and the Implementing Regulation of this Law shall determine the conditions and rules of implementation of the same.
- In all cases, it shall be prohibited to import genetically modified animals or their products or offal where the percentage of the Genetically Modified Component is according to Clause (1) of Article (3) hereof.
- 3- The Ministry shall be notified of any Genetically Modified Organisms or their products that transit the State before their transit. The Implementing Regulation of this Law shall determine the rules and procedures of transit as well as the notification requirements.
- 4- It shall be prohibited to trade Genetically Modified Organisms or their products at the State without the permit of the Competent Authority, according to the conditions and rules set by the Implementing Regulation of this Law.

#### Article 5 – Export and Re-export of Genetically Modified Organisms or their Products

For the export or re-export of Genetically Modified Organisms or their products, the prior approval of the Ministry and the permit of the Competent Authority shall be obtained, according to the conditions and rules set by the Implementing Regulation of this Law.

#### Article 6 – Release and Contained Use

Upon Release of Genetically Modified Organisms or their Contained Use for the purposes of research, development, education and production, the prior approval of the Ministry and the permit of the Competent Authority shall be obtained, according to the conditions and rules set by the Implementing Regulation of this Law.

#### Article 7 – Register

A register shall be created at the Ministry to record the Establishments and the Genetically Modified Organisms and their products that were produced, manufactured, developed, traded, exported, imported, transited or transferred, and the Implementing Regulation of this Law shall determine the rules of implementation of this Article.

#### Article 8 – Obligations of the Person in Charge of the Establishment

The person in charge of the Establishment shall:

- 1- Register the Establishment at the Ministry.
- 2- Obtain a permit from the Competent Authority for the development, manufacturing, production, import, transit, re-export, export or transfer of Genetically Modified Organisms or their products.
- 3- Register the Organisms that are produced, manufactured, developed, traded, exported, imported, transited or transferred.

The Implementing Regulation of this Law shall determine the rules and conditions of implementation of this Article and any other obligations.

#### Article 9 - Risks Assessment

- 1- Risks shall be assessed based on scientific grounds, consisting of identifying and describing the source of risk in addition to the assessment of the exposure to the source of risk and description of risk.
- 2- A decision shall be issued by the Minister to determine the rules and conditions of analysis, assessment and management of Risks.

#### Article 10 – Confidentiality of Information

The importer, exporter, trader, developer, manufacturer and producer of Genetically Modified Organisms or their products may request that any information provided to the Ministry are treated as confidential, provided that such request is justified. In case of approval, no person shall use or request to use the same without the approval of the applicant thereon.

#### **Article 11 – Information Label**

The importer, exporter, trader, developer, manufacturer and producer of Genetically Modified Organisms or their products shall place information label on each shipment and package indicating that they contain Genetically Modified Organisms or their products, and any other data determined by the Implementing Regulation of this Law.

#### **Article 12 – Response Measures**

The importer, exporter, trader, developer, manufacturer, producer and carrier of Genetically Modified Organisms or their products, which are likely to cause harm in case of their Release, shall notify the Ministry and the Competent Authority of the same. The Implementing Regulation of this Law shall determine the conditions and rules of notification and Response Measures.

#### Article 13 – Disposal of Genetically Modified Organisms

The importer, exporter, trader, developer, manufacturer and producer of Genetically Modified Organisms or their products shall dispose of the Genetically Modified Organisms or their products that violate the provisions of this Law and its Implementing Regulation, or shall destroy them and return them to their country of origin, at their own expense under the supervision of the Competent Authority and in coordination with the Ministry.

#### Article 14 – Monitoring, Control and Inspection

1- The Ministry and the Competent Authority shall monitor and control Genetically Modified Organisms or their products.

- 2- The Ministry and the Competent Authority shall inspect the Establishment to assess its compliance with the provisions of this Law, its Implementing Regulation and decisions implementing the same.
- 3- The Implementing Regulation of this Law shall determine the rules of implementation of this Article.

## **Article 15 – Prohibitions**

The following shall be prohibited:

- 1- Release of Genetically Modified Organisms without obtaining the prior approval of the Ministry and the permit of the Competent Authority.
- 2- Contained Use of Genetically Modified Organisms without obtaining the prior approval of the Ministry and the permit of the Competent Authority.
- 3- Trading, development, manufacturing and production of Genetically Modified Organisms or their products, in violation to the provisions of this Law and its Implementing Regulation.
- 4- Transfer of Genetically Modified Organisms or their products through the State by any means of transport without obtaining the prior approval of the Ministry and the permit of the Competent Authority.
- 5- Transfer of Genetically Modified Organisms or their products with non-Genetically Modified Organisms or non-genetically modified products in one means of transport or container.

#### Article 16 – Civil Liability for Damage

The importer, exporter, trader, developer, manufacturer, producer and carrier of Genetically Modified Organisms or their products shall be liable for any damage resulting from the import, export, re-export, transit, Trading, development, manufacture or production of Genetically Modified Organisms or their products.

## Article 17 – Administrative Sanctions

Without prejudice to the penalties prescribed under this Law, the Ministry or the Competent Authority may impose the following administrative sanctions on the violating Establishments:

- 1- Warning.
- 2- Temporary closure for a period not exceeding (3) three months.
- 3- Final closure.

The Implementing Regulation of this Law shall determine the rules and procedures of grievance against administrative sanctions.

## Article 18 - Cancellation of Prior Approval and Permit and Suspension of Trading

The approval issued by the Ministry and the permit issued by the Competent Authority shall be cancelled according to the provisions of this Law in case of violation of any of its provisions. The Implementing Regulation of this Law shall determine any other cases of cancellation and the conditions and rules thereof.

#### Article 19 – Penalties

#### **Imposition of the Most Severe Penalty**

The imposition of the penalties set forth in this Law shall not prejudice any other more severe penalty stipulated in any other Law.

#### Article 20

Whoever violates the provisions of Clause (2) of Article (4) hereof shall be punished by imprisonment for a period not less than two years and a fine not less than (2,000,000) two million Dirhams and not exceeding (4,000,000) four million Dirhams, or by either of these penalties.

## Article 21

Whoever imports, exports or re-exports genetically modified organisms or their products in violation to the provisions of this Law, shall be punished by imprisonment for a period not less than six months and a fine not less than (2,000,000) two million Dirhams and not exceeding (3,000,000) three million Dirhams, or by either of these penalties.

## Article 22

Imprisonment for a period not less than six months and a fine not less than (1,000,000) one million Dirhams and not exceeding (2,000,000) two million Dirhams, or by either of the penalties, shall be imposed as punishment on whoever:

- 1- Releases Genetically Modified Organisms without obtaining the prior approval of the Ministry and the permit of the Competent Authority.
- 2- Carries out Contained Use of Genetically Modified Organisms without obtaining the prior approval of the Ministry and the permit of the Competent Authority.
- 3- Trades, develops, manufactures or produces Genetically Modified Organisms or their products, in violation to the provisions of this Law and its Implementing Regulation.

#### Article 23

Imprisonment for a period not less than three months and a fine not less than (500,000) five hundred thousand Dirhams and not exceeding (1,000,000) one million Dirhams, or by either penalties, shall be imposed as punishment on whoever:

- 1- Transfers Genetically Modified Organisms or their products through the State by any means of transport without obtaining the prior approval of the Ministry and the permit of the Competent Authority.
- 2- Transfers Genetically Modified Organisms or their products with non-Genetically Modified Organisms or non-genetically modified products in one means of transport or container.

## Article 24

The penalties prescribed for the crimes set forth in this Law shall be doubled in case of recidivism.

#### Article 25 – Judicial Officers

The employees specified by a decision from the Minister of Justice, under agreement with the Minister or head of the Competent Authority, shall have the capacity of judicial officers within their scope of competence, as per proving the violations to the provisions of this Law, its Implementing Regulation and the decisions issued in implementation thereof.

#### Article 26 – Fees

The Cabinet shall issue a decision to determine the fees prescribed as per the provisions hereof.

## Article 27 – Implementing Regulation

The Cabinet shall, upon the Minister's suggestion, issue the Implementing Regulation of this Law within twelve months from the date of issuance of this Law.

#### Article 28 – Abrogation

Any provision violating or contradicting the provisions of this Law shall be abrogated.

## Article 29 - Publication and Entry into Effect of the Law

This Law shall be published in the Official Gazette and shall enter into effect on the day following the date of publication thereof.

## Khalifa bin Zayed Al Nahyan

## **President of the United Arab Emirates**

Issued by us at the Presidential Palace in Abu Dhabi on 28 May 2020

Corresponding to: 5 Shawwal 1441 H

## END UNNOFICIAL TRANSLATION