Federal Law No. (9) of 2020 Regarding the Biosafety of Genetically Modified Organisms (GMOs) and Their Products

We, Khalifa bin Zayed Al Nahyan

President of the United Arab Emirates,

- Having reviewed the Constitution;
- Federal Law No. (1) of 1972 Regarding the Competencies of Ministries and Powers of the Ministers, as amended;
- Federal Law No. (5) of 1979 Regarding Agriculture Quarantine, as amended;
- Federal Law No. (6) of 1979 Regarding Veterinary Quarantine, as amended;
- Federal Law No. (5) of 1985 Regarding the Issuance of the Civil Transactions Law, as amended;
- Federal Law No. (3) of 1987 Promulgating the Penal Code, as amended;
- Federal Law No. (35) of 1992 Promulgating the Criminal Procedure Law, as amended;
- Federal Law No. (38) of 1992 Regarding the Establishment of Nurseries and the Regulation of the Production, Importation and Circulation of Seedlings;
- Federal Law No. (39) of 1992 Regarding the Production, Importation, and Circulation of Fertilizers and Agricultural Conditioners;
- Federal Law No. (41) of 1992 Regarding Agricultural Pesticides;
- Federal Law No. (42) of 1992 Regarding the Production, Importation and Circulation of Seeds and Tubers;
- Federal Law No. (23) of 1999 Regarding the Exploitation, Protection and Development of the Living Aquatic Resources in the United Arab Emirates, as amended;
- Federal Law No. (24) of 1999 Regarding the Protection and Development of the Environment, as amended;
- Federal Law No. (28) of 2001 Establishing the Emirates Authority for Standardization and Metrology as amended;
- Federal Law No. (11) of 2002 Regarding the Regulation and Control of the International
 Trade in Endangered Species of Wild Fauna and Flora;

- Federal Law No. (17) of 2002 Regarding the Regulation and Protection of Industrial Property for Parent and Industrial Designs, as amended;
- Federal Law No. (24) of 2006 Regarding the Consumer Protection, as amended;
- Federal Law No. (16) of 2007 Regarding Animal Welfare, as amended;
- Federal Law No. (5) of 2009 Regarding Organic Inputs and Products;
- Federal Law No. (17) of 2009 Regarding the Protection of New Plant Varieties;
- Federal Decree by Law No. (2) of 2011 Establishing the National Emergency, Crisis and Disasters Management Authority, as amended;
- Federal Law No. (9) of 2011 Regarding the Land Transport;
- Federal Law No. (9) of 2013 Regarding Plant Genetic Resources for Food and Agriculture;
- Federal Law No. (2) of 2015 Regarding Commercial Companies, as amended;
- Federal Law No. (8) of 2015 Regarding the Federal Customs Authority;
- Federal Law No. (10) of 2015 Regarding Food safety;
- Federal Law No. (14) of 2016 Regarding the Administrative Violations and Penalties in the Federal Government;
- Federal Law No. (19) of 2016 Regarding Combating Commercial Fraud;
- Federal Law No. (8) of 2019 Regarding Medical Products, the Profession of Pharmacy and Pharmaceutical Establishments;
- Federal Decree by Law No. (26) of 2019 Regarding Public Finance;
- Federal Decree No. (75) of 2014 Regarding the State's Accession to the Nagoya Kuala
 Lumpur Supplementary Protocol Regarding Liability and Redress to the Cartagena
 Protocol on Biosafety;
- Federal Decree No. (77) of 2014 Regarding the State's Accession to the Cartagena Protocol on Biosafety; and
- Upon the proposal of the Minister of Climate Change and Environment, the approval of the Cabinet and the Federal National Council and ratification of the Supreme Federal Council.

Hereby promulgate the following Law:

Article (1)

Definitions

For the purpose of applying the provisions of this Law, the following words and expressions shall have the meanings assigned to each of them unless the context otherwise requires:

- **State** : The United Arab Emirates.
- **Establishment** : The Emirates Drug Establishment.
- **Chairman** : The Chairman of the Establishment.
- **Competent** : The Local Concerned Authority in each Emirate of the State.
- Authority
- Biodiversity : The variability among living organisms of all sources, including terrestrial and marine ecosystems, aquatic organisms, and ecological complexes that are a part thereof, including diversity among species, and between species and ecosystems.
- **Genetic Resources** : Any material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value.
- Biosafety : Measures followed for ensuring the safe use of modern biotechnology applications for both humans and environment, with a view to mitigating or eliminating the potential risks arising therefrom.
- Living Organism : Any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses, viroids, animals, plants, and microorganisms.

Genetic : Modifying genetic material by using modern biotechnology.

Modification

Genetically: A living organism that possesses a novel combination of geneticModified Organismmaterial, differing from its original genetic composition, obtained(GMO)through the use of modern biotechnology.

GMO Products	: Products formulated from or containing GMO, derivatives or
	residues thereof, or other products that include or are composed of a
	percentage of Genetically Modified Component.
Genetically	: Any part containing the genetically modified code.
Modified	
Component	
Modern	: In vitro nucleic acid techniques, including recombinant
Biotechnology	deoxyribonucleic acid (DNA) and direct injection of nucleic acid into
	cells or organelles, or the fusion of cells beyond the taxonomic family,
	that overcome natural physiological reproductive or recombination
	barriers and that are not techniques used in traditional breeding and
	selection.
Contained Use	: The activity that takes place within a facility, and that involves GMOs
	subject to specific measures that effectively prevent their contact with
	the external environment and their impact on such environment.
	the external environment and their impact on such environment.
Release	the external environment and their impact on such environment.The introduction of GMOs or Products thereof into the environment.
Release Circulation	
	 The introduction of GMOs or Products thereof into the environment. Sale or offer for sale, storage or possession, whether permanently or temporarily.
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Circulation	 The introduction of GMOs or Products thereof into the environment. Sale or offer for sale, storage or possession, whether permanently or temporarily.
Circulation	 The introduction of GMOs or Products thereof into the environment. Sale or offer for sale, storage or possession, whether permanently or temporarily. The facility, installation or any other premises, whether fixed or
Circulation	 The introduction of GMOs or Products thereof into the environment. Sale or offer for sale, storage or possession, whether permanently or temporarily. The facility, installation or any other premises, whether fixed or mobile, permanent or temporary, authorized to manufacture,
Circulation Facility	 : The introduction of GMOs or Products thereof into the environment. : Sale or offer for sale, storage or possession, whether permanently or temporarily. : The facility, installation or any other premises, whether fixed or mobile, permanent or temporary, authorized to manufacture, produce, develop or circulate GMOs or Products thereof.
Circulation Facility	 : The introduction of GMOs or Products thereof into the environment. : Sale or offer for sale, storage or possession, whether permanently or temporarily. : The facility, installation or any other premises, whether fixed or mobile, permanent or temporary, authorized to manufacture, produce, develop or circulate GMOs or Products thereof. : Possibility of causing adverse effects as a result of exposure to the
Circulation Facility Risks	 The introduction of GMOs or Products thereof into the environment. Sale or offer for sale, storage or possession, whether permanently or temporarily. The facility, installation or any other premises, whether fixed or mobile, permanent or temporary, authorized to manufacture, produce, develop or circulate GMOs or Products thereof. Possibility of causing adverse effects as a result of exposure to the source of risk resulting from GMOs or Products thereof.
Circulation Facility Risks	 : The introduction of GMOs or Products thereof into the environment. : Sale or offer for sale, storage or possession, whether permanently or temporarily. : The facility, installation or any other premises, whether fixed or mobile, permanent or temporary, authorized to manufacture, produce, develop or circulate GMOs or Products thereof. : Possibility of causing adverse effects as a result of exposure to the source of risk resulting from GMOs or Products thereof. : The evaluation of the potential adverse effects of GMOs or Products

Article (2)

Objectives

This Law has the following objectives:

- 1. Preserving human health and safety from the risks of GMOs or Products thereof;
- Ensuring environmental protection with respect to the development, manufacture, production, transport, or circulation of GMOs or Products thereof resulting from modern biotechnology;
- 3. Preserving local genetic resources and biological diversity from the risks arising from the release or introduction of GMOs or Products thereof into the environment;
- 4. Ensuring control, reduction, elimination or treatment of damages that occur or are likely to be occurred by GMOs or Products thereof; and
- 5. Regulating scientific research activities on GMOs.

Article (3)

Scope of Application

- 1. The provisions of this Law shall apply to the importation, exportation, re-exportation, transit, circulation, development, manufacture and production of GMOs or Products thereof, in addition to other products that include or are composed of a percentage equal to or greater than 0.9% of Genetically Modified Component. The Cabinet may issue a Resolution to amend such percentage.
- 2. The following shall be excluded from the application of the provisions of this Law:
 - a. Products containing a Genetically Modified Component in a percentage of less than
 0.9%; and
 - b. GMOs or manufactured products thereof are pharmaceutical substances for humans and the genetic modification of humans and human cells.

Article (4)

Import, Transition and Circulation of GMOs or Products thereof

- GMOs or Products thereof may not be imported unless an authorization from the Competent Authority is obtained. In addition, in case the import is conducted for first time, the Establishment's approval shall be required, and the Executive Regulation thereof shall determine the controls and conditions for implementing such procedure.
- In all cases, the import of Genetically Modified Animals, products thereof or residues thereof, whose genetically modified component percentages as specified in Clause (1) of Article (3) thereof, shall be prohibited.
- 3. The Establishment shall be notified of any GMOs or Products thereof transiting through the State prior to such transit. The Executive Regulation thereof shall determine the conditions and procedures for transit and the notification requirements.
- 4. GMOs or Products thereof in the State shall not be circulated unless an authorization from the Competent Authority is obtained, in accordance with the conditions and controls determined by the Executive Regulation thereof.

Article (5)

Export and Re-export of the GMOs or Products thereof

In order to export or re-export the GMOs or Products thereof, a prior approval from the Establishment and an authorization from the Competent Authority shall be obtained, in accordance with the conditions and controls determined by the Executive Regulation of this Law.

Article (6)

Contained Use and Release

Upon release of GMOs or Products thereof, or contained use of the GMOs for research, development, education and production purposes, a prior approval from the Establishment and an authorization from the Competent Authority shall be obtained, in accordance with the conditions and controls determined by the Executive Regulation of this Law.

Article (7)

Register

A register shall be established with the Establishment to register the Facilities, GMOs and Products thereof that are produced, manufactured, developed, circulated, exported, imported, transited or transported, and the Executive Regulations of this Law shall determine the controls for implementing this Article.

Article (8)

Facility Manager's Obligations

The Facility Manager shall comply with the following:

- 1. Registering the Facility with the Establishment;
- 2. Obtaining an authorization from the Competent Authority to develop, manufacture, produce, import, transit, re-export, export or transfer GMOs or Products thereof; and
- 3. Registering Organisms that are produced, manufactured, developed, circulated, exported, imported, transited or transported.

The Executive Regulation of this Law shall determine the conditions and controls of this Article and any other obligations.

Article (9)

Risk Assessment

- Risk assessment shall be conducted on a scientific basis consisting of identifying and describing the risk source in addition to assessing the extent of exposure to the risk source and describing the risks.
- 2. The conditions and controls for analyzing, assessing and managing risks shall be determined by a decision of the Chairman.

Article (10)

Confidentiality of Information

The importer, exporter, circulator, developer, manufacturer and producer of GMOs and Products thereof, may request to treat any of the information, they provide to the Establishment as confidential, provided that such request is justified. If approved, then no person may use it or allow its use without the Applicant approval.

Article (11)

Labeling

The importer, exporter, circulator, developer, manufacturer and producer of GMOs or Products thereof shall affix a label to each shipment and package, indicating that it contains GMOs or Products thereof, and any other data determined by the Executive Regulation of this Law.

Article (12)

Response Measures

The importer, exporter, circulator, developer, manufacturer, producer, and transporter of GMOs or Products thereof, which may cause harm in case of release, shall notify the Establishment and the Competent Authority regarding the same. The Executive Regulation of this Law shall determine the conditions and controls of the notification and the response measures.

Article (13)

Disposing of GMOs

The importer, exporter, circulator, developer, manufacturer and the producer of GMOs or Products thereof shall dispose of, destroy or return to the country of origin, at their own expense, any GMOs or Products thereof that are in violation of the provisions of this Law and the Executive Regulation thereof, and under the supervision of the Competent Authority, in coordination with the Ministry.

Article (14)

Monitoring, Surveillance and Inspection

- 1. The Establishment and the Competent Authority shall monitor and control GMOs or Products thereof.
- 2. The Establishment and the Competent Authority shall inspect the Facility to assess its compliance with the provisions of this Law, its Executive Regulation and the resolutions in implementation thereof.
- 3. The Executive Regulations of this Law shall determine the controls for implementing this Article.

Article (15)

Prohibitions

All the following shall be prohibited:

- 1. Release of GMOs, without obtaining a prior approval from the Establishment and an authorization from the Competent Authority;
- 2. Contained use of GMOs, without obtaining a prior approval from the Establishment and an authorization from the Competent Authority;
- 3. Circulating, developing, manufacturing and producing GMOs or Products thereof, in violation to the provisions and Executive Regulations of this Law;
- 4. Transfer of GMOs or Products thereof, throughout the State, by any means without obtaining a prior approval from the Establishment and an authorization from the Competent Authority; and
- 5. Transfer of GMOs or Products thereof, with non-genetically modified living organisms or the Non-Genetically Modified Products, in in the same means of transport or container.

Article (16)

Civil Liability for Damages

The importer, exporter, circulator, developer, manufacturer, producer, and transporter of GMOs or Products thereof shall be liable for any damage caused by importing, exporting, re-exporting, transiting, circulating, developing, manufacturing or producing GMOs or Products thereof.

Article (17)

Administrative Penalties

Without prejudice to the penalties prescribed in this Law, the Establishment or the Competent Authority may apply the following administrative penalties against the violating Facility:

- 1. Warning.
- 2. Temporary closure for a period not exceeding three months.
- 3. Permanent closure.

The Executive Regulation of this Law shall determine the controls and procedures of grievance from administrative penalties.

Article (18)

Revocation of the Prior Approval, Authorization and Suspension of Circulation

The approval issued by the Establishment and the authorization issued by the Competent Authority in accordance with the provisions of this Law, shall be revoked, in the event of any violation of its provisions. The Executive Regulation thereof shall determine any other cases, conditions and controls of cancellation.

Article (19)

Penalties

Application of the Harsher Penalty

The application of the penalties stipulated therein shall not prejudice any harsher penalty stipulated by any other Law.

Article (20)

Whoever violates the provision of Clause (2) of Article (4) of this Law, shall be punished with imprisonment for not less than two years and with a fine of not less than AED Two Million (AED 2,000,000) and not exceeding than AED Four Million (AED 4,000,000), or with either of these two penalties.

Article (21)

Whoever imports, exports or re-exports GMOs or Products thereof, in violation of this Law provisions, shall be punished with imprisonment for not less than six months and with a fine of not less than AED Two Million (AED 2,000,000) and not exceeding than AED Three Million (AED 3,000,000), or with either of these two penalties.

Article (22)

Whoever commits one of the following violations, shall be punished with imprisonment for not less than six months and with a fine of not less than AED One Million (AED 1,000,000) and not exceeding AED Two Million (AED 2,000,000), or with either of these two penalties:

- 1. Releasing GMOs, without obtaining a prior approval from the Establishment and an authorization from the Competent Authority;
- 2. Conducting the contained use of GMOs, without obtaining a prior approval from the Establishment and an authorization from the Competent Authority; or
- 3. Circulating, developing, manufacturing or producing GMOs or Products thereof, in violation of the provisions of this Law and Executive Regulations thereof.

Article (23)

Whoever commits one of the following violations, shall be punished with imprisonment for not less than three months and with a fine of not less than AED Five Hundred Thousand (AED 500,000) and not exceeding than AED One Million (AED 1,000,000), or with either of these two penalties:

- 1. Transporting GMOs or Products thereof, throughout the State, by any means without obtaining a prior approval from the Establishment and an authorization from the Competent Authority; or
- 2. Transporting GMOs or Products thereof, with Non-GMOs or Non-Genetically Modified Products, in the same means of transport or container.

Article (24)

The penalties prescribed for the violations stipulated therein shall be doubled in cases of recidivism.

Article (25)

Judicial Enforcement

Any employee designated by a Resolution issued by the Minister of Justice, by agreement with the Chairman or the Head of the Competent Authority, shall have the capacity of a judicial enforcement officer in detecting the violations falling within their jurisdiction against the provisions of this Law and, its Executive Regulation f, and the Resolutions issued in implementation thereof.

Article (26)

Fees

The Cabinet shall issue a Resolution, in which it determines the prescribed fees, in accordance with the provisions of this Law.

Article (27)

Executive Regulation

The Cabinet shall issue the Executive Regulation thereof, upon the Chairman proposal, within twelve months from the date of its issuance.

Article (28)

Any provision which contradicts or conflicts with this Law provisions shall be repealed.

Article (29)

Law Publication and Entry into Force

This Law shall be published in the Official Gazette, and it shall enter into force from the day following the date of its publication.

Khalifa Bin Zayed Al Nahyan

President of the United Arab Emirates,

Issued by Us at the Presidential Palace in Abu Dhabi: Date: Shawaal 5, 1441 AH Corresponding to: May 28, 2020 AD