Cabinet Resolution No. (84) of 2022

Concerning the Executive Regulation of Federal Law No. (9) of 2020 Concerning the Biosafety of Genetically Modified Organisms (GMOs) and the Products Thereof

The Cabinet,

- Upon reviewing the Constitution;
- Federal Law No. (1) of 1972 Concerning the Competences of Ministries and the Powers of Ministers, as amended;
- Federal Law No. (9) of 2020 on the Biosafety of Genetically Modified Organisms (GMOs) and the Products Thereof;
- Based on the proposal of the Minister of Climate Change and Environment and the approval of the Cabinet,

Has resolved:

Article (1)

Definitions

Definitions stipulated in the Federal Law No. (9) of 2020 on the Biosafety of Genetically Modified Organisms (GMOs) and the Products Thereof shall be applicable to this Resolution.

Article (2)

Importation, Transition and Circulation of GMOs or Products thereof

- 1. In order to import GMOs or Products thereof for the first time, the following conditions and requirements shall be fulfilled:
 - a. Requirements stipulated in the Annexes of this Resolution shall be fulfilled in accordance with the purpose of importation as follows:

- 1. Annex No. (1) in case GMOs or Products thereof are to be released in the environment.
- 2. Annex No. (2) in case GMOs or Products thereof are to be circulated.
- 3. Annex No. (3) in case GMOs or Products thereof are to be used as foods, feed or for manufacturing.
- 4. Annex No. (4) in case GMOs or Products thereof are to be under contained use.
- 5. In case there is more than one purpose for importation, all requirements in the Annexes shall be fulfilled according to the purpose stated.
- b. The following requirements and documents shall be submitted to the Ministry:
 - 1. A statement for risk assessment of GMOs or Products thereof on the human health and environment conducted by laboratories approved by the Ministry.
 - 2. A response plan for potential risks from GMOs or Products thereof.
 - 3. A plan for monitoring and observing GMOs or Products thereof.
 - 4. A plan to treat the impacts resulted from potential risks of GMOs or Products thereof and a plan to treat waste of GMOs or Products thereof.
 - 5. Prior permissions to export GMOs or Products thereof to other countries, if any.
- c. When the Ministry studies the request to approve importation, the following shall be considered:
 - 1. Registration of GMOs or Products thereof at the Ministry.
 - 2. The facility shall be registered at the Ministry as per the required activity.
 - 3. GMOs or Products thereof shall not have any adverse effects on the human health and environment according to risk assessment results.
- 2. Procedures of GMOs or Products thereof transit across border ports:
 - a. The transit shipment shall be licensed or approved by the competent authority in the country of destination.
 - b. Specialists may examine and inspect any shipment in case any transit, unloading or reshipment inside the State and validate the documents attached to the shipment.
- 3. Transit conditions of Genetically Modified Organisms (GMOs) and products thereof:

- a. GMOs or Products thereof shall be transferred in special containers that are in conformity with technical, environmental, health and safety specifications and requirements, and all shipment documents shall be attached.
- b. The transit shipment shall be in containers that are appropriately and technically sealed by customs departments. Adding other shipments to the transit shipment shall be prohibited.
- 4. Notification requirements on the transit of Genetically Modified Organisms (GMOs) and products thereof:

Customs departments shall track the path of the shipment until it exits the territory of the State, provided that the Ministry shall be promptly notified with the shipment exist.

- 5. In order to circulate GMOs or Products thereof inside the State, the facility shall obtain a permission from the competent authority and shall abide by the following requirements and controls:
 - a. In case of imported GMOs or Products thereof circulation, the requirements stipulated in Clause (1) of this Article shall be fulfilled.
 - b. In order to circulate GMOs or Products thereof that are manufactured, produced, developed and repacked in the State, a request to obtain a permission from the competent authority shall be submitted and attached with the following:
 - 1. Details stipulated in Annex No. (2) concerning circulation of GMOs or Products thereof attached to this Resolution.
 - 2. Details stipulated in Annexes (1), (3) or (4) or all the aforementioned annexes attached to this Resolution and according to the purpose of circulation.
 - 3. A list of GMOs or Products thereof that will be circulated.
 - 4. Risk assessment of GMOs or Products thereof.
 - 5. A plan for monitoring and observing GMOs or Products thereof.
 - 6. An approval and a permission to import the material that was used in manufacturing, in case the material was imported and used to manufacture GMOs or Products thereof and repacked in the State.

- c. The facility shall have a division or an independent place to store GMOs or Products thereof according to standards of global best practices.
- d. Keeping and storing GMOs or Products thereof in the original vacuum-sealed containers and these may not be opened, partitioned or repacked.
- e. Keeping a register to record the circulation movement for at least (10) ten years.
- f. Building capabilities of human cadres that deal with GMOs or Products thereof appropriately and keeping a register to prove such action.
- g. Any other requirements set by the competent authority, keeping in mind the human safety and health as well as the environment.

Article (3)

Conditions and controls for exportation or re-exportation of the GMOs or Products thereof

- 1. In order to export or re-export the GMOs or Products thereof, the following conditions and controls shall be fulfilled:
 - a. An application to obtain a Permit from the Competent Authority shall be submitted, attached with the following documents:
 - 1. Importation permit or permission from the country of destination.
 - 2. The customs declaration of the imported shipment.
 - 3. Importation permit or permission in case of re-exportation.
 - 4. A list of GMOs or Products thereof.
 - b. GMOs or Products thereof shall be registered at the Ministry.
 - c. The facility shall be registered at the Ministry as per the required activity.
 - d. Requirements of the country of destination shall be fulfilled.
 - e. A prior approval from the Ministry shall be obtained.
- 2. The period of the prior approval given by the Ministry for exportation or re-exportation shall be (6) six months as of the exportation date and shall be valid to be used for one time.

Article (4)

Contained Release and Use

- 1. Conditions and requirements of release:
 - a. An application to obtain a Permit from the Competent Authority shall be submitted, attaching the following requirements:
 - 1. Requirements stipulated in Annex No. (1) attached to this Resolution shall be fulfilled.
 - 2. Requirements stipulated in Annex No. (2) and Annex No. (3) attached to this Resolution shall be fulfilled according to the purpose of use.
 - 3. Risk assessment of GMOs or Products thereof.
 - 4. A summary for the results of contained use of GMOs or Products thereof arranged to be released.
 - 5. Potential risk management plan for release.
 - 6. Any other requirements set by the Competent Authority.
 - b. GMOs or Products thereof shall be registered at the Ministry.
 - c. The facility shall be registered at the Ministry as per the required activity.
 - d. Approval of the Ministry for the release of GMOs or Products thereof.
 - e. Compliance to approved health and safety specifications and standards upon initiating release.
 - f. Submitting periodic reports to the competent authority about the procedures taken and the results of releasing GMOs or Products thereof.
 - g. The release location shall be within the scope specified in the request to get the permission.
 - h. The release location shall be appropriate, and it is not possible that risks on human health and environment may arise.
 - i. GMOs or Products thereof shall not have harmful effects or are possible to bring harm to the human health or environment, and they shall not be invasive species where their spread causes environmental, social, economic or health damages.

- 2. Conditions and controls of contained use:
 - a. An application to obtain a Permit from the Competent Authority shall be submitted, attaching the following requirements:
 - 1. Requirements stipulated in Annex No. (4) attached to this Resolution shall be fulfilled.
 - 2. Risk assessment for GMOs or Products thereof.
 - 3. A plan of risk management for GMOs or Products thereof.
 - 4. A response plan for risks resulting from GMOs or Products thereof.
 - 5. A plan of risk treatment for GMOs or Products thereof.
 - 6. A waste treatment plan resulting from GMOs or Products thereof.
 - b. Prior approval of the Ministry concerning the contained use.
 - c. Submitting periodic reports to the competent authority about the procedures taken and the results of contained use for GMOs or Products thereof.
 - d. Reporting any changes that occur, a harm that may occur, or inconvenience of containment measures in use.
 - e. Compliance to use the laboratories and equipment that are consistent with the risk degree of GMOs or Products thereof according to the risk assessment document.
 - f. GMOs or Products thereof must be registered at the Ministry.
 - g. The facility must be registered at the Ministry as per the required activity.
 - h. Laboratories must be approved by and registered at the Ministry.
 - i. GMOs or Products thereof shall not be circulated unless a permission from the competent authority is obtained.
 - j. Taking all necessary measures to reduce unintended release of GMOs or Products thereof shall be adhered to.
 - k. Legislations, national policies, manuals and strategies that relate to biosecurity shall be enforced.
 - I. The following GMOs shall be exempted from the request of prior approval and permission of contained use:

- 1. GMOs or Products thereof that were previously approved by the Ministry and the competent authority upon importation for the first time.
- 2. GMOs or Products thereof listed in the GMOs list for the purposes of education, scientific research and development for which a resolution is issued by the Minister in accordance with the controls and conditions regulating thereto.

Article (5)

Register

- 1. A register shall be established at the Ministry for registering GMOs or Products thereof that are produced, manufactured, developed, circulated, exported, imported, transit or transferred. This register shall include the following details:
 - a. Enterprise data.
 - b. Data of GMOs or Products thereof.
 - c. Approvals, permissions, certificates and notifications.
 - d. Suppliers lists.
 - e. Risk assessment for GMOs or Products thereof.
 - f. A response plan for risks of GMOs or Products thereof.
 - g. A risk management plan for GMOs or Products thereof.
 - h. A treatment plan for risks resulting from GMOs or Products thereof.
 - i. Any additional data or information according to the discretion of the Ministry.
- 2. The competent authority shall provide the Ministry with all permissions issued for GMOs or Products thereof and all relevant documents.

Article (6)

Obligations of the Facility Officer

- 1. The Facility Officer shall comply with the following:
 - a. Registering the facility with the Ministry.

- b. Obtaining permission from the Competent Authority to develop, manufacture, produce, import, transit, re-export, export or transfer GMOs or Products thereof.
- c. Registering GMOs or Products thereof that are produced, manufactured, developed, circulated, exported, imported, transit or transported through submitting a request to the Ministry for registration.
- d. Informing the Ministry and the competent authority with any accident or leakage of GMOs or Products thereof from the facility into the environment.
- 2. The conditions and controls the facility officer shall comply with:
 - a. Putting the data card according to the conditions and controls determined by Article (7) of this Resolution.
 - b. No GMOs or Products thereof may be announced unless they are registered at the Ministry and have the required permissions according to provisions of this Resolution.
 - c. To abide by, upon announcement of GMOs or Products thereof, the information and data recorded in the register on the contents, percentages and uses of the products.
 - d. Periodic reports shall be submitted to the Ministry and the competent authority about monitoring and controlling GMOs or Products thereof.
 - e. Taking all necessary measures to reach the minimal occurrence of harm caused by GMOs or Products thereof.
 - f. Building capabilities of human cadres that deal with GMOs or Products thereof appropriately and keeping a register to prove such action.
- 3. The officer of the facility working in the field of education and scientific research shall register at the Ministry upon the regulatory requirements issued by the Minister in this regard.

Article (7)

Data Card

- 1. The importer, exporter, circulator, developer, manufacturer and producer of GMOs or Products thereof shall put a data card on each shipment and package, indicating that it contains GMOs or Products thereof, provided that the card shall contain the following data:
 - a. Product name and the country of origin.
 - b. Commercial name of the product and its trademark.
 - c. The product contains GMOs or Products thereof through stating the phrase "GMO or Product thereof that contains, consists of or produced from a GMO" in a clear readable font that is hard to be removed.
 - d. Scientific name of GMOs or Products thereof.
 - e. Country of origin of GMOs or Products thereof.
 - f. Percentage of the Genetically Modified Component in the product.
 - g. The GTIN number of the GMOs or Products thereof.
 - h. The required standard warning and guiding signs.
- 2. Data cards shall be always and clearly fixed in a manner that can not be removed, replaced or damaged.
- 3. Arabic and English languages shall be used in the data card on every shipment or package. Other languages may be added to the data card without prejudice to approved languages.
- 4. UAE technical regulation for data card of GMOs or Products thereof shall be adhered to.

Article (8)

Response Measures

1. 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 Ministry and the Competent Authority regarding the same according to the following conditions and controls:

- a. The Ministry and the competent authority shall be informed upon submitted the request for the approval of the Ministry and the permission of the competent authority concerning the potential risks on human health and environment.
- b. The Ministry and the competent authority shall promptly be reported in case new information appears about new risks that were not previously reported, and the following shall be submitted:
 - 1. An updated risk assessment of GMOs or Products thereof.
 - 2. A response and risk treatment plan updated according to the new information about the risks.
- 2. If the damage occurs, the following response measures shall be taken:
 - a. The facility shall report to the Ministry and the competent authority promptly about the following:
 - 1. The identity and quantity of the GMOs or Products thereof that caused the damage.
 - 2. An assessment of the damage extent on the human health and environment.
 - 3. Determining the response measures and procedures taken to contain damage.
 - 4. Carrying out the response plan and the risk treatment plan under the supervision of the competent authority.
 - 5. Activating the tracking and retrieving measures for GMOs or Products thereof that caused the damage.
 - 6. Providing any other information that may be required by the Ministry of the competent authority.
 - b. The competent authority must, in case any damage occurs, take the following procedure:
 - 1. Determine the one who is responsible for the damage.
 - 2. Assess the damage report received from the one that caused the damage.
 - 3. Assess the response measures the officer took to contain the damage.
 - 4. Notify the one that is liable for the damage with the decisions taken with respect to the response measures.

- 5. Execute response measures in case the one that is responsible for the damage is unable to perform the tasks assigned to him.
- 6. The competent authority may retrieve the costs and expenses of the damage assessment and may carry out any suitable response measures on the cost of the one that is responsible for the damage.
- 3. As for the potential damage, a risk management plan shall be performed in a manner that is consistent with the risk assessment and management document.

Article (9)

Monitoring, Control and Inspection

- 1. The Ministry and the Competent Authority shall monitor and control GMOs or Products thereof that are released and circulated in the State through the monitoring and control regulation attached to Annex No. (5) attached to this Resolution.
- 2. The Ministry and the Competent Authority shall periodically inspect the facility and vehicles designated for transferring GMOs or Products thereof to ensure that provisions of the Law, this Resolution and implementing resolutions thereof are applied through the inspection regulation attached to Annex No. (6) attached to this Resolution.

Article (10)

Controls and Procedures of Grievance

- 1. Resolutions issued pursuant to the provisions of Article (17) of this Law may be appealed, provided that the following are adhered to:
 - a. The grievance shall be submitted to the entity that issued the decision imposing the administrative penalty according to the designated procedures of such entity within a period that does not exceed (15) fifteen days.
 - b. The necessary documents demonstrating the grievance reason shall be attached.

2. The entity shall issue the decision according to its discretion with respect to the grievance within a period that does not exceed (30) thirty days, the decision issued for this respect shall be final.

Article (11)

Cancellation of the Prior Approval and Permission and Circulation Suspension

- 1. Approval issued by the Ministry and permission issued by the competent authority shall be cancelled in case there is a violation of provisions of the Law or any of the following cases:
 - a. A damage occurred, or there is a potential damage, to the environment or human resulting from GMOs or Products thereof.
 - b. There are studies or scientific knowledge from a reliable source notifying that a potential damage resulting from GMOs or Products thereof may occur.
- 2. The Ministry and the competent authority shall perform the following procedures in case the approval and the permission are cancelled:
 - a. Withdraw products from the markets and inform the facility to suspend production or manufacturing and track the GMOs or Products thereof.
 - b. Suspend circulation, importation, exportation and re-exportation of GMOs or Products thereof.

Article (12)

Executive Resolutions

The Minister shall issue necessary resolutions to enforce this Resolution. Temporarily regulatory procedures with respect to importation, exportation, re-exportation, transition, circulation, manufacturing, production, research, development and transfer of GMOs or Products thereof may be issued.

Article (13)

Repeals

Any provision that violates or contradicts the provisions of this Resolution shall be repealed.

Article (14)

Publication and Entry into Force of the Resolution

This Resolution shall be published in the Official Gazette and shall come into force (4) four months after the date of its publication.

Mohammed Bin Rashid Al Maktoum

Prime Minister

Issued by Us: Date: 18 Muharam 1444 AH Corresponding to: 16 August 2022 AD

The Annexes Attached to Cabinet Resolution No. (84) of 2022 Concerning the Executive Regulation of Federal Law No. (9) of 2020 Concerning the Biosafety of Genetically Modified Organisms (GMOs) and the Products Thereof

Annex No. (1)

Release of GMOs or Products Thereof

Data that must be available upon submitting the request:

- 1. Information about the applicant.
- 2. Features of the GMO or Products thereof.
- 3. Information that relates to the recipient, donor, ancestors and the transmitter from which GMOs are taken.
- 4. Information that relates to genetic modification of the organism.
- 5. Information that relates to release.
- 6. Information that relates to interaction of GMOs or Products thereof with the environment.
- 7. Information that relates to monitoring and observing GMOs or Products thereof.
- 8. Information that relates to waste treatment of GMOs or Products thereof.
- 9. Information that relates to risk response plans for GMOs or Products thereof.
- 10. A plan to track GMOs or Products thereof.

Annex No. (2)

Circulation of GMOs or Products Thereof

Data that must be available upon submitting the request:

- 1. Information about the applicant.
- 2. Features of the GMO in the product composition.
- 3. Description of the product.
- 4. Purpose of Use.
- 5. The method to find out GMOs or Products thereof and its quantities in the product.
- 6. A list of countries where the products were circulated.
- 7. Information that relates to storing, treatment and circulation.
- 8. Information that relates to packaging.
- 9. Information that relates to data card.
- 10. Information that relates to waste disposal measures.

Annex No. (3)

GMOs or Products Thereof for the Use as Foods, Feed, or for Manufacturing

Data that must be available upon submitting the request:

- 1. Information about the applicant.
- 2. Features of GMOs or Products thereof.
- 3. An official document proving that the GMO is registered and allowed in the country of origin and the country from which the GMO is intended to be imported.
- 4. A list of the countries where GMOs or Products thereof were used as foods, feed or for manufacturing.
- 5. Information that relates to usage.
- 6. Description of the product.
- 7. Information that relates to risk assessment and management.
- 8. Information that relates to genetic modification.
- 9. The method to find out GMOs or Products thereof and its quantities.
- 10. Information resulting from health tests according to the following:
 - a. Toxicology.
 - b. Sensitivity.
 - c. Nutrition value.

11. Information that relates to monitoring and observing GMOs or Products thereof.

Annex No. (4)

GMOs or Products Thereof Directed for Contained Use

Data that must be available upon submitting the request:

- 1. Information about the applicant.
- 2. Features of the GMO or Products thereof.
- 3. A list of countries or institutions where the contained use of the GMO is used (if any).
- 4. Information that relates to potential effects in case the GMO is released into the environment.
- 5. Information that relates to the recipient, donor, ancestors and the transmitter from which GMOs are taken.
- 6. Information that relates to genetic modification of the organism.
- 7. Information that relates to risk assessment and management.
- 8. The method to find out GMOs or Products thereof and its identity.
- 9. Information that relates to the contained use.
- 10. Information that relates to monitoring and observing GMOs or Products thereof.
- 11. Information that relates to waste treatment of GMOs or Products thereof.
- 12. Information that relates to risk response plans for GMOs or Products thereof.
- 13. Information about the treatment plan for risks resulting from GMOs or Products thereof.

Annex No. (5)

Monitoring and Control System

The importer, exporter, circulator, developer, manufacturer, the producer and facility officer shall develop a monitoring and control system for GMOs or Products thereof independently, taking the following into account:

- 1. Assessment of risks on the human health and environment:
 - a. Outcome of use of GMOs or Products thereof.
 - b. Outcome of other environmental factors that are not determined upon releasing GMOs or Products thereof.
- 2. Relevant features of the GMO or Products thereof.
- 3. The directed use and the receiving environment.
- 4. Circumstances, activities and environmental changes upon analysing data that is collected through monitoring and control.
- 5. The use of information and data obtained through monitoring or control of GMOs or Products thereof release in the environment in similar cases.
- 6. Features of GMO, features and volume of intended use as well as the environmental circumstances in which the GMOs or Products thereof were released.
- 7. This can be merged with the public monitoring. When necessary, a special case is monitored with a focus on determining the adverse effects specified in risk assessment.
- 8. A specific monitoring must be made for the case for a sufficient period of time in order to find out the direct effects, and when needed, the late and indirect effects that were specified according to risk assessment.
- 9. GMOs or Products thereof must be monitored and controlled in the ecosystem in an organized manner and reports must be submitted to the competent authority about the human and animal safety and health as well as the environment.
- 10. The person in charge of performing the tasks designated in the monitoring and control program must be determined.

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- 11. Monitoring and controlling GMOs or Products thereof upon releasing in the ecosystem and upon circulation.
- 12. Updating GMOs or Products thereof risk assessment and risk management according to the results of GMOs or Products thereof monitoring and control.

Annex No. (6)

Inspection System

- 1. The Ministry and the competent authority shall conduct periodic inspection to the facility and shall ensure its compliance to the following:
 - a. Health and Safety Procedures.
 - b. Obtaining necessary permissions and certificates and keeping registers and books that organize its activity.
 - c. Checking validity and conformity of samples to technical specifications registered for GMOs or Products thereof.
- 2. Inspectors may take samples from GMOs or Products thereof for the purpose of analysis and checking its validity and conformity with the approved technical specifications.
- 3. Inspectors at the approved entry ports must inspect the imported, exported and transit shipments according to the following:
 - a. Checking that the shipments fulfil all necessary documents.
 - b. Checking that shipments conform with the UAE approved standards.
 - c. Detaining the shipment in case there is a need to analyse additional samples from the shipment to check validity and conformity until the result is reached. In case detaining is not possible as there is no suitable place or for any other reason, temporary release for the shipment may be decided on the condition that there is an undertaking in writing from the importer not to dispose the shipment unless there is a permission in writing from the Ministry.
 - d. Release of matching shipments according to applicable legislations of the State.
 - e. Rejecting the entry of imported shipments due to violating provisions of the Law, this Resolution and resolutions issued for implementing thereof and notifying the importer to remedy the violation, if possible, or to re-export the shipment to the country of exportation on its cost within (30) thirty days as of the notice date.

f. Obligating the importer, exporter, circulator, developer, manufacturer, producer, and transporter of GMOs or Products thereof to send back the shipment to the country of origin or to destroy it in coordination with the relevant authorities at the cost of the importer, in case it is not possible to the importer to re-export the shipment within (30) thirty days.