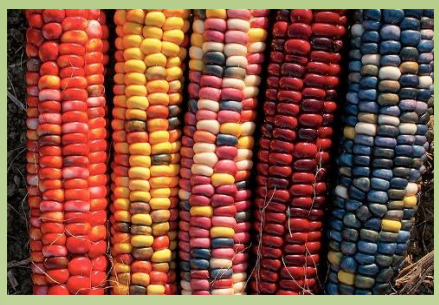
State of Palestine

Environment Quality Authority

NATIONAL BIOSAFETY FRAMEWORK FOR PALESTINE



2021

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Acknowledgment

EQA Team work: Dr. Issa Musa, D.G of Environmental Resources

Eng. Mohammad Mahassneh, Director of Biodiversity &

Protected Areas Dept, and CBD NFP

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Main Contributors

This project has been started on November 2020 to develop a National Biosafety Framework for Palestine and has been completed on September 2021.

Implementing agency: Palestinian Environment Quality Authority represented by Dr. Issa Adwan and Mr. Mohamad Mahasneh.

Funding agency: Swedish International Development Agency (Sida).

Project National consultant: Dr. Omar Darissa, Associate Professor. Head of the UNESCO Biotechnology Educational and Research Center at Bethlehem University. Tel: +972-2-265404. Email: odarissa@bethlehem.edu.

Project international technical expert: Dr. Ahmad Kamal El Attar, Head of Egyptian plant quarantine authority, the National Plant Protection Organization (NPPO) of Egypt, and the IPPC contact point of Egypt. He is also the Chief of Molecular Biology and Biotechnology unit at Virology Department, Plant Pathology Research Institute, Agricultural Research Center, Egypt.

Foreword

The accelerated development of modern biotechnologies and integration to the international market economy emphasizes different types of urgent and significant issues, such as protecting the environment from newly emerged and unknown living organisms and ensuring the safety of their use. The biosafety issues are highlighted in the Cartagena Protocol of the Convention on the Biological Diversity (CBD) and are based on the concept of necessity of protecting the environment, biodiversity and human health from the possible adverse effects caused by living modified organisms (GMO's/LMOs) obtained through the application of modern biotechnologies.

Without complete investigation of the behavior and features of GM)'s/LMOs in various environments, the unpredictable threats to the biodiversity and human health will continue exist. This mainly relates not only to living modified organisms, but also to food, foodstuff and drugs obtained from LMOs processing and development. Another issue of concern is the gradual transformation of the modern biotechnologies to the high industrial branch of economy. The products of this sphere comprise a significant part of the worldwide trade and the market is hardly manageable concerning biological safety, due to poor regulatory framework and improper mechanisms for control. The Cartagena Protocol on Biosafety internationally regulates the obtaining, use and transfer of LMOs (or their constitute components) resulted from the application of modern biotechnologies. Such regulatory procedures for the trans-boundary movements of LMOs have been considered in the NBF of Palestine.

The Protocol offers to the signatory Parties exact mechanisms to ensure obtaining, processing, transferring and deliberate releasing to the environment of any GMO/LMO by reducing or minimizing its adverse effects on the environment and risks for human health.

The State of Palestine has ratified the Cartagena Protocol of CBD on April 2, 2015. This can be considered the first significant step towards ensuring the active participation of Palestine in international cooperation in the framework of the Protocol. We hope that the present National Biosafety Framework will promote effective implementation of the provisions of the Protocol and will support addressing biosafety-related issues in Palestine.

Jameel Mtour

Chairman of the Environment Quality Authority

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List of Abbreviations

Abbreviation	Definition
AIA	Advanced Informed Agreement
ARIJ	Applied Research Institute of Jerusalem
BBI	Biodiversity and Biotechnology Institute
BCH	Biosafety Clearing Housing
BERC	Biodiversity & Environmental Research Center
BSL	Biosafety Level
CBD	Convention on Biological Diversity
CP	Cartagena Protocol
CPB	Cartagena Protocol on Biosafety
DFG	Deutsche Forschungsgemeinschaft
DNA	Deoxy Nucleic Acid
EIA	Environmental Impact Assessment
EPR	Emergency Preparedness & Response Procedure
EQA	Environment Quality Authority
FAO	Food and Agriculture Organization
GM	Genetically Modified
GMO	Genetically Modified Organism
GS	Gaza Strip
IB	Introduced Breeder
IPM	Integrated Pest Management
KM	Kilometer
LMO	Living Modified Organism
LMO-FFP	LMO for Food, Feed or Processing
MOEA	Ministry of Environment
MEC	Monitoring and Evaluation Committee
MoA	Ministry of Agriculture
MoF	Ministry of Finance
MoH	Ministry of Health
MoHE	Ministry of Higher Education
MoL	Ministry of Labor
MoNE	Ministry of National Economy
MTIT	Ministry of Telecom and IT
NARC	National Agricultural *Research* Centre
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NBFP	National Biosafety Focal Point
NBSAP	National Biodiversity Strategy And Action Plan
NCA	National Competent Authority
NGO	Non-Governmental Organization

JD	Jordanian Dinar
PA	Palestinian Authority
PCR	Polymerase Chain Reaction
PPU	Palestine Polytechnic University
PTUK	Palestine Technical University-Kadoorie
R&D	Research and Development
RAB	Regional Administrative Body
RB	Resident Breeder
RBC	Regional Biosafety Center
SP	State of Palestine
UNFCCC	United Nation Framework Convention on Climate Change
USAID	U.S. Agency for International Development
WB	West Bank

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Definitions

ADVANCED INFORMED AGREEMENT (AIA): The Advanced Informed Agreement procedures apply to the first international trans-boundary movement of GMOs for intentional introduction into the environment of the party of import. The party of import is notified of the proposed trans-boundary movement and is given an opportunity to decide whether or not the import shall be allowed and under what conditions.

AN INCIDENT: is an event that exposes human health and/or the environment to the risks associated with a GMO.

A SIGNIFICANT ADVERSE EFFECT: is measured by considerations such as:

a) long-term or lasting transition, defined as a change that can not be redressed by normal recovery within a suitable time frame.
b) The magnitude of qualitative or quantitative shifts that have a negative impact on biological diversity components.
c) The decline in the capacity of biological diversity elements to deliver products and services;
d) The magnitude of any harmful effects on human health in the light of the Protocol.

BIODIVERSITY: The variability among living organisms from all sources, including, inter alia, terrestrial, marine and other ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

BIOPHARMING: The use of genetically transformed crop plants and livestock animals to produce valuable compounds, especially pharmaceuticals.

BIOSAFETY: The avoidance of risk to human health and safety, and to the conservation of the environment as a result of the use for research and commerce of infectious or genetically modified organisms.

CONFINED USE OR CONTAINMENT: Measures and protocols applied to limit contact of genetically modified organisms or pathogens with external environment.

CONTAINED USE: Any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.

DAMAGE: an adverse effect on biological diversity protection and sustainable use, including risks to human health, that is significant and measurable or otherwise observable, taking into account, where possible, scientifically proven baselines recognized by a qualified authority, as well as any other human-induced variance and natural variation.

FOOD AND FEED FOR HANDLING: The term covers genetically modified agricultural commodities, such as GM soybeans or maize for food or feed use, or GM tomatoes.

FOOD AND FEED FOR DIRECT USE OR FOR PROCESSING: Covers genetically modified agricultural commodities, such as GM soybeans or maize for food or feed use, or GM tomatoes for example.

GENETICALLY MODIFIED ORGANISMS: Are considered the living and non-living modified organisms.

INTRODUCTION INTO THE ENVIRONMENT: refers to any non-contained application of GMOs that is subject to this Act, but does not include GMOs imported for direct use of food, feed, or refining.

INVASIVE ALIEN SPECIES: is defined by the Convention on Biological Diversity, "invasive alien species" refers to a species, subspecies or lower taxon, introduced outside its natural past or present distribution; including any part, gametes, seeds, eggs, or propagules of such species that might survive and subsequently reproduce; whose introduction and/or spread threatens ecosystems, habitats or species."

LANDRACES: These are races of crops and fruit trees that have acquired distinctive characteristics in the place where they are currently cultivated. These distinctive characteristics, which represent adaptations to that particular environment are valuable for developing sustainable agricultural systems.

LIVING MODIFIED ORGANISM: Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

LIVING ORGANISM: Any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

MODERN BIOTECHNOLOGY: Biotechnology is defined as the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

NATIONAL BIOSAFETY FRAMEWORK: A National Biosafety Framework is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

NOTIFICATION: Refers to the letter sent from the exporting parties to the National Competent Authority in the importing parties prior to any intentional trans-boundary movement of a GMO.

OPERATOR: refers to someone who has direct or indirect influence over a living modified organism as defined by this Act, such as the permit holder, individual who put the living modified organism on the market, creator, manufacturer, notifier, exporter, courier, or supplier.

RELEASE: Any non-contained application of GMO/LMO.

RESEARCH & DEVELOPMENT: Refers to investigation work, which is of actual or potential use in the development of new or enhanced materials, products, services or processes. RISK ASSESSMENT: A scientifically based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

RESPONSE MEASURES: refers to steps taken to:

a) Prevent, reduce, absorb, reduce, or otherwise avoid harm.
b) Restore biological diversity by taking the following measures in the order of preference:
i. Returning biological diversity to the state it was in before the damage, or a close approximation thereof, unless the competent authority decides that this is not possible;
ii. Restoration by, for example, replacing biological diversity loss with other biological diversity components for the same, or for a different form of application, either at the same time or, if needed, at a later time.

RISK MANAGEMENT: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed selecting appropriate prevention and control options.

RISK: Risk is defined as the probability that a substance or situation will produce harm under specified conditions. Risk encompasses impacts on public health and on the environment, and arises from exposure and hazard.

TRANSBOUNDARY MOVEMENT: The movement of a living modified organism from one party to another party, save that for the purposes of Articles 17 and 24 of the CP trans-boundary movement extends to movement between parties and non-parties.

WILD RELATIVES OF AGRICULTURAL SPECIES: These species found in uncultivated sites, such as rangelands and along road sides, are important wild relatives of currently cultivated and herbaceous and fruit tree species. Such wild relatives comprise a genetic resource that could be of critical importance for the future sustainability of agriculture.

Summary

The continuous technological progress and intensive use of natural resources have resulted, among other things, in significant human-generated impact upon biological diversity, diminishing considerably the number of species and varieties of living organisms, which inhabit our Earth. Every day one species of mammals, birds or plants disappears from the globe as the result of human activities.

After recognizing the threats to biological the international organization and governments of the worldwide nations convened an Earth Summit held at Rio De Janeiro in 1992 diversity . During the Summit, 157 countries ratified the Convention on Biological Diversity (CBD) which focused on three main objectives: (1) conservation of biodiversity, (2) sustainable use of its components and (3) equitable sharing of benefits from the use of genetic resources. The CBD articles 8 paragraph (g) and 19 paragraphs (3) and (4) provide for the establishment of a mechanism to address the issue of modern biotechnology and biosafety. Moreover, Chapter (16) of Agenda 21 (Environmental Sound Management of Biotechnology) requires that biotechnology be safely developed, applied, exchanged and transferred through the agreed procedures for risk assessment and management.

The conference of the parties to the Convention on Biological Diversity (CBD) adopted a supplementary agreement of the Convention known as the Cartagena Protocol on Biosafety on 29 January 2000. The CPB objectives in article 1 stated “In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, hand ling and use of LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on trans-boundary movements”.

The Environment Quality Authority (EQA) in Palestine since its establishment in 1997 (the Ministry of Environmental Affairs (MEnA Before) has taken proactive strides towards the conservation and sustainable use of biodiversity through the commitment to implement the CBD provisions and resolutions. In addition, EQA issues the Environmental Law No.7-for the year 1999 which includes a chapter for Nature Protection. In April 2015 EQA ratifies the CBD and the Cartagena Protocol on Biosafety (CPB), which emphasize the application of precautionary principles and aims at the conservation and sustainable use of biodiversity and natural resources.

The principle of biosafety is to apply policies and procedures to ensure proper and safe application of biotechnology, without endangering the public health, the environment, and the biological diversity of countries. Some of the adverse impacts of biotechnological products on ecosystems include the potential of invasive alien species (IAS's),weeds, and the possibility of transferring genes to wild relatives, landraces and to initiate imbalances in ecosystems, natural habitats. The development and design of biosafety policies must rely on the nations’ natural resources and biodiversity richness taking into account at the same time the agricultural policies and economic development.

The National Biosafety Framework is a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

The National Biosafety Framework varies from country to country; they often contain a number of common components:

- A Government policy on biosafety
- A regulatory regime for biosafety
- A system to handle notifications or requests for authorization
- A system for follow up such as enforcement and monitoring for environmental effects Mechanisms for public awareness, education and participation

Introduction

Biodiversity in the Mediterranean

The Mediterranean region has been widely recognized for its great richness in biodiversity. Four of the 18 “hot spots” of endemic flora defined by Myers are found in the Mediterranean ecosystems. The richness in wild species diversity of the Middle East is due to sociopolitical factors (including several anthropogenic and natural), agro-climatic, ecological, and genetic factors. The whole region has been shown to be a critical habitat of global importance for genetic resources; it comprises a wealth of more than 25000 plant species, more than 50 percent of which are endemic to the region, and a good proportion of which are relicts.

Biodiversity in Palestine

Despite its small area, State of Palestine’s nature enjoys a rich biodiversity, compared to other countries in the region, due to its distinctive location as well as its special topography and history such as Great Rift Valley and bird’s migrations etc. It contains five bio - geographical zones (Ecosystems) which associated with their climate and biodiversity (Central Highlands - Semi - Coastal Region - Eastern Slopes - Jordan Rift Valley - Gaza Strip), in addition to four phytogeographical regions (Mediterranean - Irano -Turanian - Saharo -Arabian - Sudanese/Ethiopian). It consists of two physically separated landmasses: the West Bank [WB] (including East Jerusalem) and the Gaza Strip [GS]. There are about 51,000 living species in the State of Palestine, constituting approximately 3% of the global biodiversity. There are more than 30, 848 animal species, consisting of an estimated 30,000 invertebrates, 373 birds, 297 fish, 92 mammals, 81 reptiles and 5 amphibians. The state of Palestine also hosts over than 2,076 species of plants including 54 endemic plants that do not exist in any other part of the world (Figure 1).

Flora and Fauna

Due to its location, where the Mediterranean, Irano-Turanian, Sudanian and Saharo-Arabian phytogeographic zones intermingle in an area of varying climates and soil types (Euroconsult and IWAC, 1994; ARIJ, 2002; Ali-Shtayeh and Jamous, 2003). Based on plant species numbers mentioned by several publications e.g. Piales, (1996), Boulos, (1997), AliShtayeh & Jamous (2002), Danin, (2004), Sawalha, (2005), ARIJ, (2006), and Görlach et al., (2011), it has been concluded that the records of Palestinian flora reach over than 2000 plant species and endemic flora species recorded as 54 species in SP. The most dominant families are the Asteraceae with 96 genera and 260 species, Poaceae with 87 genera and 198 species, Fabaceae with 62 genera and 268 species, Brassicaceae with 63 genera and 124 species, Lamiaceae which is famous as a medicinal plants, with 23 genera and 99 species, Lilaceae known for its beautiful flowers, with 23 genera and 97 species, the Trifolium genus which is used as a forage plant contains 40 species, Medicago genus contains 22 species, and Trigonella genus, which contains 18 species (Bregheith, 1995).

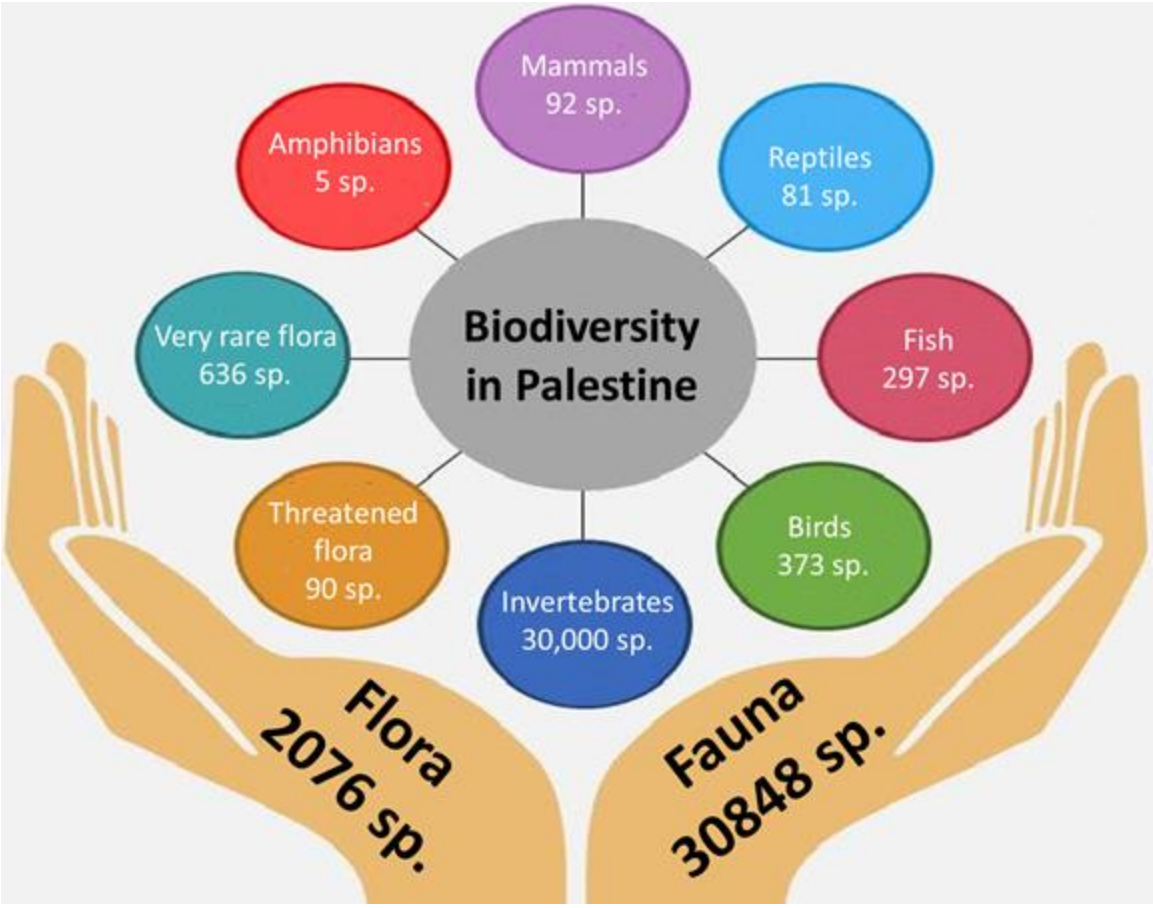

Figure 1: Biodiversity in Palestine. Numbers of species of the major living taxonomic fauna groups in Palestine. Species numbers of very rare and threatened flora species are shown.

Mammals:

Currently there are more than 92 mammals in the West Bank including east Jerusalem and Gaza Strip comprising 33 families, 28 of which are bat species. This number does not include marine mammals in Gaza Strip. Seventy-eight percent of Palestinian mammals that are described as widely distributed exist mainly in the Mediterranean region (MEnA, 1998). Many large mammals continue to exist but in diminishing numbers: Striped Hyena, Hyaena hyaena, Syrian Wolf Canis lupus syriacus, three different species of Gazelles Gazella gazelle, G. dorcas and G. arabica, and wild cats Felis silvestris, and F. chaus. The only mammal endemic in the Gaza Strip, on the other hand, is the Buxton's Jird Meriones sacramenti, originated from Saharo-Arabian desert belt, and found in the sand dunes of the southern coastal plains of the Naqap and the Gaza Strip (MEnA, 1998). Rodents and bats are the mammal orders that are most represented and contribute significantly to the local biodiversity (Qumsiyeh, 1986, 1996 and Korine et al., 1999).

Almost all of the higher mammals are on the Red Data List as threatened, extinct or rare6 . Seven species of mammals have been extinct from 50 years ago, for example, the Cheetah Acynonyx jupatus, Syrian Brown Bear, Ursus arctos syriacus, Mesopotamian Fallow Deer Dama mesopatomica, and Roe Deer Capreulus capreulus. Nowadays, there are only 200 hyenas inhabiting SP. Implementation of wildlife management plans is very difficult due to the current Israeli the occupation power in SP. Currently hunting, agricultural expansion and poverty are actual obstacles to any progress in wildlife conservation and reintroduction. On the other hand, enforcement of wildlife protection laws is weak and need to be enhancened.

Marine Mammals:

It was reported the presence of two dolphin species; the Bottlenose Dolphin Tursiops truncatus and the Common Dolphin Delphinus delphis7 . It is worth mentioning that studies on marine biota were lacking in SP. Little is documented on the status of marine mammals in the Gaza Striparea, the status of the Monk seals; Monachus monachus remains unclear (Gaza Environmental Profile, 1994).

Birds:

The number of birds identified 373 bird species in the State of Palestine (West Bank and Gaza Strip 6220 KM²), which represent 22 Orders, 64 Families, 30 subfamilies and 186 genera. (Awad, S., et al., 2015). The largest order is PASSERIFORMES which consists of 22 families 6 subfamilies, 40 genera and 160 species. The second is CHARADRIIFORMES which consists of 10 families, 10 subfamilies, 26 genera and 67 species. The third is ACCIPITRIFORMES which consists of 2 families, 15 genera and 31 species. The largest family is Sylviidae which consist of 35 species. The second is Turdidae which consist of 32 species. The third is Accipitridae which consist of 30 species. In total four birds are considered extinct species: Ostrich (struthio camelus), Brown Fish Owl (Bubo zeylonensis), and the other two extinct as breeder: Lammergeier (Gypaetus barbatus) and Lappet-faced Vulture (Torgos tracheliotus). There are 132 species of bird breeds in the State of Palestine, 52 species of which are considered as exclusively resident breeders (RB) including the three introduced breeder species (IB); namely: Rose-ringed Parakeet (Psittacula krameri), Common Myna (Acridotheres tristis) and Indian Silverbill (Lonchura malabarica), (These species spend the entire year within the borders of their breeding site with some seasonal dispersal). 38 species are considered as complex resident breeders, which are species with different categories of birding population, each exhibiting a different seasonal behavior. Further another 42 species are consider as complex summer breeders.

Amphibians:

In the State of Palestine there are only five possibly species of amphibians reported (Salman et al., 2014) but the number could climb to eight amphibians in historic Palestine. It belongs to two orders; (i) Caudata - Salamander; and (ii) Salientta - Anura with six families: (i) Salamandridae; (ii) Bufonidae; (iii) Hylidae, (iv) Ranidae, (v) Discorglossidae, (vi) Pelobatidae. Almost all amphibians in SP are endangered8 due to intensive farming, degradation of wetland habitats in the Dead Sea basin, Gaza Strip and fresh and grey water, rivers and Wadi systems. This

phenomenon is very obvious in Gaza Strip where the drying of the main wadis and intensive use of remaining water resources has not given amphibians much chance to exist. Loss of amphibian species and diversity has led to an increase in the number of disease vector insects such as mosquitoes.

Reptiles:

Reptiles are approximately 81 species, six of them are aquatic and the rest are terrestrial (Werner, 1989; Ali-Shtayeh & Hamad, 1995). One extinct species is the Nile crocodile. The highest distribution of reptiles is observed in the arid and semiarid Mediterranean and Saharo Arabian zones. The Gaza Environmental Profile (Gaza Environmental Profile, 1994) identifies the sea turtle species Caretta caretta (Loggerhead turtle) and Chelonia mydas (Green turtle) as existing in the coastal region of Gaza Strip. Turtle nesting areas of Gaza Strip are reported by The Coastal Zone Plan for Gaza Strip (MOPIC, 1996). Unfortunately, these species and their eggs are under extreme pressure from hunting and collecting.

CHAPTER I

The current situation regarding modern biotechnologies and biosafety in Palestine

Status of biotechnology and biosafety in Palestine

Biotechnology in Palestine still in early development stages, with little efforts in Palestine to catch up in this rapidly developing area, especially in the fields of food, medicine and agriculture. Several universities have recently established graduate and undergraduate programs in biotechnology or genetic engineering.

Research program in universities or biotechnology centers are using basic biotechnology, plant tissue culture, immunology, and molecular biology techniques. There is also high research interest for and a limited production of immunological diagnostic kits and animal vaccines, and drugs.

Traditional biotechnology is being used in Palestine for the production of food, drink and yeast. Some work was conducted in the area of screening for organisms that have a potential biotechnological application. Plant tissue culture has attracted high attention from public and private sectors. Several university, governmental and private research programs were conducted to optimize micro-propagation of plant tissues. Tissue culture has been used for in vitro conservation and cryopreservation, production of disease-free plants, plant propagation, selection of biotic and a biotic tolerant stocks and production of secondary metabolites. Private and governmental laboratories commercially produce regenerated plants such as ornamental and cut flowers, date palm, potatoes and banana. Animal and human cell culture is mainly centered on medical and veterinary applications such as In-vitro fertilization and embryo culture.

The biosafety measures that are implemented in the Palestinian institutions are Biosafety Level 1 and 2 (BSL-1 and BSL-2). BSL-1 is applied in laboratories that study infectious agents that do not always cause disease in healthy adults. Such measurements include the basic microbiological safety procedures that do not require special equipment or infrastructure. These procedures involve surface sterilization of working areas, hands, wearing masks, etc. Laboratories that handle moderate-risk infectious agents or toxins that could be accidently inhaled, swallowed or exposed to skin apply BSL-2. Such laboratories contain hand and eye washing stations, emergency doors, autoclave for decontamination, etc. Although BSL-3 is partially applied in few laboratories in Palestine, it is almost restricted to the use of biosafety hoods for control flow of air. Higher biosafety levels, namely BSL-4 are not implemented in Palestine.

Survey of the Institutions pertaining to Biotechnology:

The survey of the national governmental and non-governmental institutions pertaining to Biosafety in Palestine is summarized in Table 1.

Table 1: Institutions and Programs Pertaining to Biotechnology and Biosafety:

Institute/Center	Program/activities	Offered courses related to biotechnology	Community outreach services
Palestine Polytechnic University (PPU): Palestine-Korea Biotechnology Center.	Joint master program in biotechnology with Bethlehem University. The center has three research groups: Genomics and Molecular Diagnostics, Animal Health and Virology, Agriculture and Plant Biotechnology.	Business Aspects of Biotechnology, Molecular Diagnostics, Advanced Topics in Biotechnology Applications, Plant Tissue Culture, Plant Molecular Taxonomy and Diversity, Molecular Phytopathology	Genetic tests for Al-Ahli Hospital mainly in the field of personalized medicine (pharmacogenetics).
Bethlehem University: A-Medical Laboratory Sciences Department:	Joint master program in biotechnology with Palestine-Korea Biotechnology Center/PPU.	Advanced molecular biology, bioinformatics, Biotechnology instrumental and techniques, advanced topics in genomics, Social and Ethical Aspects of Biotechnology.	
B-UNESCO Biotechnology, Educational and Training Center.	Agricultural Biotech research, Biotech training courses.		Plant pathogens diagnostic and genotyping services for the farmers, ministry of agriculture and seed distributors.
C- Heredity Research lab.	Medical research/ genome methodologies		Diagnostic tests of several inherited human genetic disorders
D- Cytogenetics lab	Cytogenetic research.		Diagnostic services of chromosomal abnormalities
Arab American University: Biology and Biotechnology Department	Bachelor of Biology and Biotechnology. The same program is also offered as a minor in Education.	Genetics, Biotechnology, Plant and animal cell culture techniques, Molecular biology, recombination DNA technology & genetic engineering and Bioinformatics & computational biology.	None
Palestine Technical University-Kadoorie: Faculty of Agricultural Sciences and Technology	Bachelor in Agricultural Biotechnology.	Molecular biology, Biodiversity, Medicinal and aromatic plants, Bioinformatics, Genetically modified plants, and Training in plant biotechnology.	None

An-Najah National University: Faculty of Science	Bachelor program in Biology Biotechnology	Genetics, Plant and Animal cell culture, Microbiology, Bioinformatics, Molecular biology, Techniques in molecular biology, Protein purification, Recombinant DNA Technology, Applied biotechnology, Microtechnique, Molecular Plant Taxonomy, Animal Biotechnology, Medical Biotechnology, Molecular Genetics Diagnosis, Biofuels, and Biotechnology in Biological Control.	None
Al-Quds University: Faculty of Science and Technology	Bachelor in Food technology.	Principles of Food Science, Food Chemistry, Food Microbiology, Food Engineering, Food Analysis, Food Processing, Fats and Oil Technology, Food Toxicology, Dairy Technology, Meat Technology, Food Packaging, Industrial Microbiology, and Quality Control.	None
Hebron University: College of Agriculture. Nutrition & Food Technology Department	Biotechnology lab (Research center) Conduct research in the field of genetic engineer, mainly those related to plants and plant diseases. Bachelor of Nutrition & Food Technology.	Principles of Food Processing, Dairy Processing, Food Microbiology, Food Quality Control, Food Analysis, Processing of Cheese and Fermented Milk, Meat Science and Technology, Nutrigenomics, Food Biotechnology, Modern Genetics, Medicinal and Aromatic Plants, and Processing of Oils and Fats.	
BirZeit University Biology department	Bachelor program in Biology/minor Biochemistry.	Genetics and Molecular biology.	None

Biodiversity & Environmental Research Center (BERC). Biodiversity and Biotechnology Institute (BBI).	Conduct Biotechnology research.		
National Agricultural *Research* Centre (*NARC*)	Part of the conducted research is in the field of biotechnology.		

Ongoing biotechnology-related research in Palestine

Research activities in Palestine pertaining to biotechnology are mainly focused on agriculture mainly tissue culture with some related to endangered species, dates, wheat and Barley, Royal Irises, wild species of economic concerns, biological control of agricultural pests and insects of plants, diseases free grapes, diagnostic studies on the genetic polymorphism of the causes of pests, etc.), yeast and enzymes (plant by-products, enzyme production by bacteria, monoclonal antibodies for diagnosis, etc.), genetic engineering and their tests (finger printing of dates, GMOs, etc.), veterinary medicine and animal production (use of hormones sponges, PCR on local goats, animal feed improvements, in vitro fertilization and embryo transfer, etc., and biofertilizers such as the uses of olive cakes for biogas production, dairy cattle manures for biogas production, etc. Research work is also going on the application of new technology for animal disease diagnosis such as PCR technology.

CHAPTER II

Status of Policies and legislations on biosafety in Palestine

The Convention on Biological Diversity (CBD) is the main international instrument that addresses biological biodiversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the use of the genetic resources. The convention ensures the development of appropriate procedures for enhancing the safety of biotechnology in the context of the convention's overall goal of reducing potential threats to biological diversity. Article 8(g) of the convention called for a general framework under which contracting parties were to develop regulations to govern biotechnological advances. "Each contracting party shall as far as is possible and appropriate establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.
The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) was adopted in January 2000. This agreement aims "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements. The concept of biotechnological safety or biosafety and genetic engineering being a relatively new field with rapid and continuous developments, includes a wide range of measures, policies and procedures aimed at reducing the possible risks that biotechnology might pose for the environment and human health, to a minimum. Moreover, chapter 16 of Agenda 21, entitled "Environmentally Sound Management of Biotechnology," seeks to " to foster internationally agreed principles to be applied to ensure the environmentally sound management of biotechnology, to engender public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms, especially within developing countries, through the following activities:

- Increasing the availability of food, feed and renewable raw materials;
- Improving human health;
- Enhancing protection of the environment;
- Enhancing safety and developing international mechanisms for cooperation;
- Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology.

Palestine has not produced the specific laws for regulating biotechnology or its biosafety. Regulating biotechnology, including biosafety during development, production and transport of LMOs, is urgently needed in Palestine. The absence of such biotechnology regulations imposes difficulties and complications for importing or local production of such products. In compliance with the Cartagena Protocol on Biosafety, Palestine needs to regulate biotechnology in terms of

reducing the risks on environment, biodiversity and human health. The proposed regulations could promote biotechnology by increasing public acceptance of new developments allowing private sector mainly companies to invest in the field of biotechnology. The protection of environment, biodiversity, and human health, were implemented by many involved and competent authorities

The Biosafety Legislations and Regulations in Palestine

The Biotechnology, Biosafety concerns and genetic engineering are newly emerging discipline with rapid and continuous developments which have not considered as a high national priority issue in Palestine. Some existing national laws, decrees or regulations are indirectly related to Biosafety issues and GMO products. These laws, decrees and regulations are aimed at regulating agricultural processes, animal safety, environment and biodiversity, health protection and food safety. Although they do not contain specific provisions relating to GMOs and biosafety, Palestine has not produced specific laws that regulate biotechnology or its biosafety. Regulating biotechnology, including biosafety during development, production and transport of LMOs, is clearly needed. Lack of such biotechnology regulation could complicate importing or local production of such products. In compliance with the Cartagena Protocol on Biosafety, Palestine needs to regulate biotechnology in terms of reducing risks on environment, biodiversity and human health. Such regulations could promote biotechnology by increasing public acceptance of new developments allowing companies to invest in the field of biotechnology in Palestine.
The existing regulations and legislations that are related to biosafety in Palestine are presented in Annex 2 and for simplicity are summarized in figure 2 below.

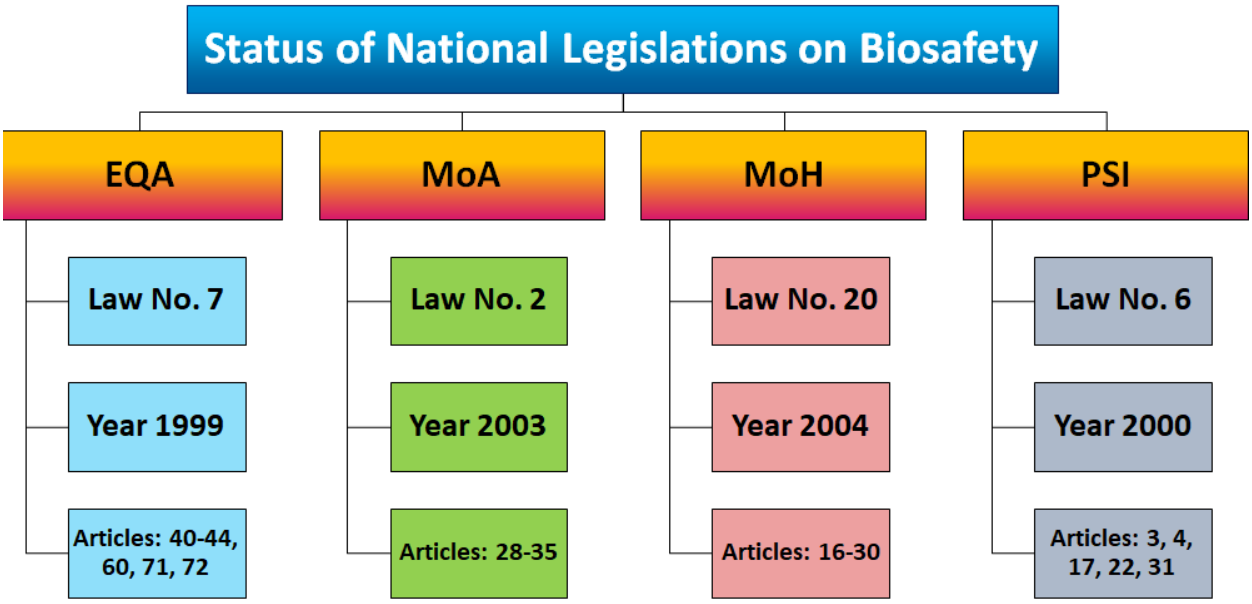

Figure 2: Existing national legislations related to biosafety.

Biosafety Policy in Palestine

State of Palestine (SP) ratified the CBD and the Cartagena Protocol on Biosafety in 2015, and is committed to the implementation of its provisions. The Environmental law didn't include any article related to Cartagena protocol on biosafety, biotechnology or Nagoya protocol on access and benefit sharing of the genetic resources. Also, SP has no additional national legislations or administrative mechanisms pertaining to biosafety and access to genetic resources. This is considered a key constraint towards achieving more meaningful biosafety measures and benefit sharing.
State of Palestine developed its National Biodiversity Strategy and Action Plan (NBSAP) in 1999 involving the main stakeholders, representatives from national institutions and other stakeholders. Biosafety issues are considered as the fourth national priority in the NBSAP. The implementation of the CBD articles was tackled among the various thematic areas discussed in the NBSAP because of the Israeli occupation which prevent the Palestinian sovereignty over natural resources, and lack of funding. In addition, improving partnerships with the private sector and local communities will be taken into consideration and will adopted by EQA in the biodiversity and biosafety conservation policies.

The legal framework In Palestine for biosafety is fundamentally composed of: The Environmental Law No. 7 for the year 1999, Public Health Law No 20 of 2004, Agriculture Law No 2 of 2003, the Palestinian Standards and Measurements Law No 6 of 2000. Other national laws just mention some food safety issues including the Decree on the Law of Industry No. 10 of 2011, and the Consumer Protection Law No 21 of 2005.

Existing Biosafety Related Policies

Despite the absence of real investigations, assessments and surveys on the presence of GMO's in Palestine, there is evidence that dealing with GMOs is being conducted at various markets and may be in some academic and research institutions mainly from Israeli resources as an occupation power that deals with Palestinians as an **experimental market**. Many agricultural products of vegetables and fruits have GMO's characteristics and introduced to Palestinian markets from Israel. It is highly probable that Palestine imports GMO components, in spite of there is to date no document outlining a national policy for biosafety or application and usage of modern biotechnologies adopted in Palestine. Existing policies on food, health, agriculture and environment may be related indirectly to GMOs or might indirectly relate to biosafety issues. Such policies are described below and are summarized in figure 3.

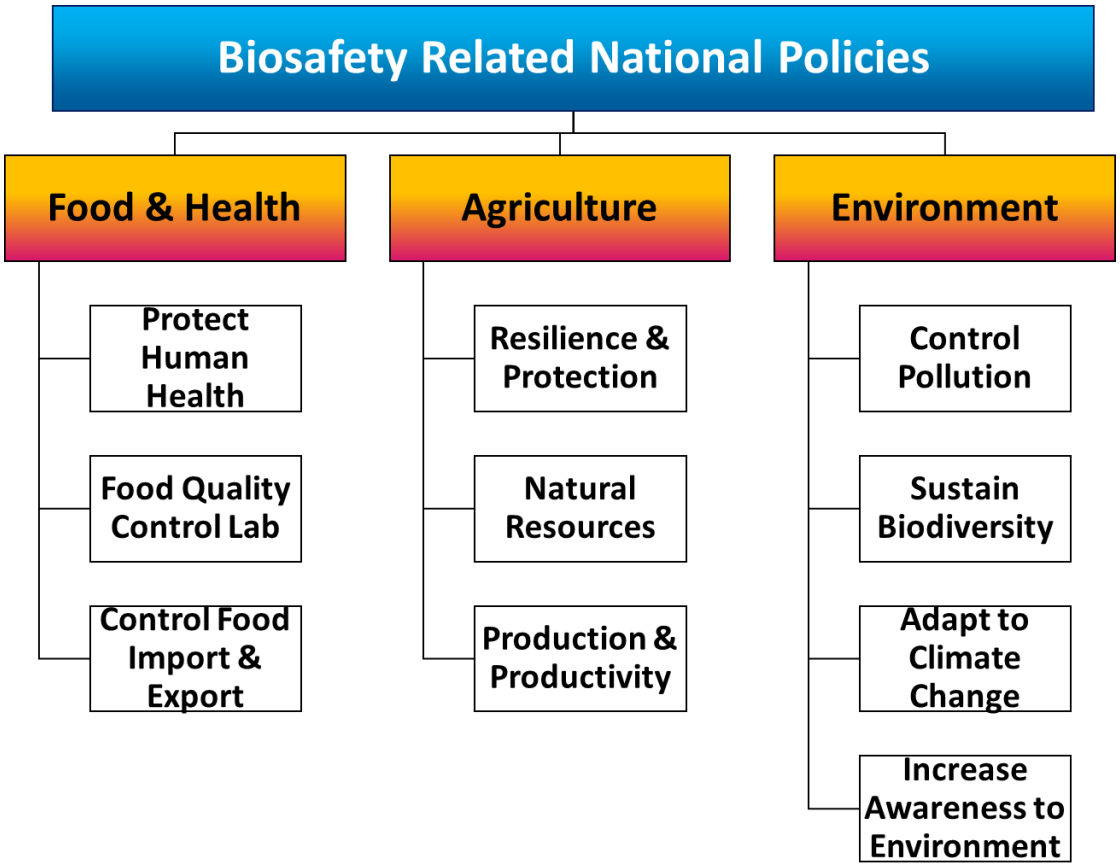

Figure 3: Existing biosafety related policies in Palestine.

Food and health policy

The national Palestinian food and health policies of different involved sectors focuses on health and food quality and safety. It involves the following:

1. Protection of human health and the consumer protection and safety;
2. Establishment of national accredited laboratories for food quality control;
3. Abide by technical rules and standards for imported and exported canned and processed food.

Taking into consideration the advances in food industry (including use of biotechnology and GMOs) and the excessive use of additives, the food safety regulations are scattered and suffering from regulatory weaknesses related to the regulatory framework for biosafety including the fragmentation of the regulatory framework governing food safety, which is based on several pieces of legislation. The legal framework is thus none-harmonized, uncoordinated and appears not to fulfill the requirements of modern biosafety and food safety legislation in line with international standards. With the aim of regulating safety food production during all its phases and ensuring a high level of consumer safety and rights, guidelines and standards for biosafety and food production will be set and risk assessment and management processes as well as food monitoring programs will be introduced.

The establishment of the Palestinian National Food and Drug Authority is an urgent national priority for the guarantee of the public health, and Environmental security achievement.

Agricultural sector policies

The Ministry of Agriculture (MOA) developed The National Agricultural Sector Strategy (2017-2022) entitled by (Resilience and sustainable development) with a vision ("Sustainable agriculture; capable of competing locally and globally; and effectively contributes to strengthening food security, the bond between Palestinians and their land as well as their sovereignty over resources, towards building an Independent Palestinian State.") .

The main national Guiding Pivots for the agricultural development are:

1. Intensifying efforts to work in Area (C) and Jerusalem
2. Addressing the impact of Israeli occupation policies and measures.
3. Facilitating access to agricultural land, water and natural resources, as well as markets,
4. Promoting investment in the agriculture sector, and strengthening public-private partnerships for this purpose.
5. Promoting innovation and adaptive solutions that mitigate the effects of climate change.
6. Strengthening and supporting farmers' organization and small-scale farmers-oriented agricultural organizations, particularly those with clear mandates and commitment to enhance the role and position of women and youth in agriculture.
7. The empowerment of the sector by MoA leadership requires common consensus and partnership amongst all on the vision and sector priorities,
8. Bringing agriculture sector to the forefront of development priorities of both government and the donor community and providing the proper budgets and support.
9. Strengthening contribution to and linkages with the Sustainable Development Goals, (SDGs) 2030
10. Joining the membership of international organizations, and ratifying international treaties and conventions

Agriculture Sector policies

The agricultural policies in SP are summarized in the Table 2.

Table 2: The agricultural policies in SP

Pillar	Strategic objective	Policy priorities
Resilience and protection	**First Strategic Objective: Female and male farmers' resilience and steadfastness on their lands enhanced**	1. Mobilize international support to restrain Israeli violations impeding agricultural developing, particularly restriction on access, and use of natural resources, borders, infrastructure demolition and uprooting of trees. 2. Institutionalize and develop technical and financial resources dedicated to the Risk Prevention and Agricultural Insurance Fund. 3. Provide suitable environment for agricultural production and development of youth and farmers in Area C, border areas and Jerusalem through continuous coordination with all parties to provide infrastructure services to farmers and producers in marginalized areas, as well as agricultural programs and projects for the poor, marginalized and women entrepreneurs. 4. Agricultural control on border crossings and the establishment of national reference laboratories. 5. Empowering farmers and producers to access different courts to get to their rights.
Natural resources	**Second strategic objective: Natural and agricultural resources sustainably managed and better adapted to climate change**	1. Establish large water facilities in arable irrigated areas through the transfer of water or water collection or wastewater treatment and increase the efficiency of the available water. 2. Provide the necessary support for land reclamation and agricultural road construction that link all agricultural land or lands that could be cultivated. 3. Take measures and arrangements to adapt with or avoid the negative impact of climate change and natural disasters,

		particularly high temperatures and fluctuating precipitation or declining rain water. 4. Intensify efforts of research and official institutions, local authorities and centers to protect the forests and natural reserves, as well as organize and develop pastures, protect agricultural biodiversity in all environmental areas in Palestine. 5. Continue the greening of Palestine as a responsibility of all institutions, local authorities, schools and universities. 6. Protect agricultural lands from urban expansion, especially in plain areas and high value agricultural lands.
Production and productivity	**Third strategic objective: Increased agricultural production, productivity, and competitiveness in local and international market, along with their contribution in gross domestic product and**	1. Guiding and supporting farmers' initiatives towards intensive and semi-intensive production systems, as well as the application of modern systems of agricultural production in line with the requirements of sustainable development 2. Strengthening the role of applied research in official research centers and universities in developing extension services for both plant and livestock agriculture. 3. Improving communication between agricultural extension

Environmental Policy

The objectives of the 2017-2022 Cross-Sectoral Environmental Strategy are:

1. Environmental pollution levels are low and controlled
2. Natural environment and biodiversity are maintained and managed in a sustainable manner.
3. Measures for climate change adaption, combat desertification, and deal with environmental disasters and emergencies are adopted and implemented.
4. The environmental legal framework is updated, activated, and integrated; the institutional framework is empowered and efficient, and the international cooperation is enhanced.
5. The level of environmental awareness, knowledge, and practice are increased and enhanced.

The policies of the strategy are:

1. Dependent on the National Environmental Policy Paper
2. Policies per each sector.
3. To draw the direction of each sector in term of Environment.
4. The responsibility is for EQA and the leading body of the sector.
5. The interventions were left to the sectors themselves to be defined.
6. They were clustered under each strategic objective as follow:

A summary of the environmental policies are summarized in table 3.

Table 3: Environmental policies in SP

1. Environmental pollution levels are low and controlled	▶ Develop and implement procedures for linking diseases and environmental pollution ▶ Regulate the usage of pesticides and manures and proper disposal of agricultural waste ▶ Support the efforts toward adopting the specifications related to communication devices ▶ Other electronic equipment so to reduce electronic waste ▶ Proper management of primary materials that are used in housing and government building projects and of building and demolition waste ▶ Adoption of regulations and initiatives that promote the usage of clean and renewable energy ▶ Adoption of regulations and initiatives that promote the usage of clean and renewable energy in transportation ▶ Enhance the control and monitoring over emissions from vehicles exhausts ▶ Encourage the use of environmental friendly transportation means. ▶ Take the necessary measures to limit pollution from shipping.
2. Natural environment and biodiversity are maintained and	▶ Enhance the implementation of sustainable production and consumption in the housing sector, infrastructure, and governmental buildings

managed in a sustainable manner	▶ Enhance the energy efficiency ▶ Take into consideration the environmental criteria and conditions related to exploring, utilizing, generating, transporting, and disposing of energy sources ▶ Ensure the protection and management of water resources in a sustainable way, manage wastewater in accordance to proper environmental and economic principles. ▶ Encourage the reuse of treated wastewater ▶ Integrated management of water bodies ▶ Develop and enhance the solid waste, and wastewater management systems including the recycling and reuse ▶ Regulate the land uses within the National Spatial Plan in a way that protect environment ▶ Enhance the values and elements of natural heritage ▶ Encourage the preservation of cultural and historical sites inside the Palestinian cities and towns and rehabilitate them in a way that respect environmental criteria ▶ Enhance the implementation of sustainable production and consumption in industrial establishments ▶ Sustainable management of natural resources ▶ Respect the elements and criteria related to green building and sustainable construction in the establishment of industrial cities ▶ Improve the efficiency of water use for agriculture ▶ Increase the use of organic agriculture ▶ implement the measures aimed at regulating fishing and preventing overgrazing to preserve bio diversity ▶ Implement the criteria and measures related to biosafety ▶ Enhance the implementation of sustainable

	production and consumption in tourism especially environmental tourism
3. Measures for climate change adaption, combat desertification, and deal with environmental disasters and emergencies are adopted and implemented	▶ Encourage green building in educational facilities and establishments ▶ Encourage green building in hospitals and health facilities ▶ Combat desertification and enhance the practices of land reclamation in an environmental-friendly way ▶ Enhance the climate change measures related to agricultural activities ▶ Take into consideration the specific environmental measures for controlling radiation broadcast ▶ Respect the requirements and technologies of green building in housing projects and government buildings ▶ Encourage the collection and use of rainwater in the housing projects, government buildings, and infrastructure ▶ Enhance climate change adaptation measures and implement the approved "Climate Change Adaptation Strategy" ▶ Improve the capabilities to deal with emergencies and catastrophic incidents.
4. The environmental legal framework is updated, activated, and integrated; the institutional framework is empowered and efficient, and the international cooperation is enhanced	▶ Implement the law as and procedures specific to the management of medical, hazardous, and solid waste, and the regulations related to radiation. ▶ implement the Arabic Health and Environment Strategy. ▶ Implement the laws and regulations related to the licensing of industrial and economical establishments in compliance with environmental criteria and conditions. ▶ Encourage issuance of green certificates for local industries to access international markets.

	▶ improve the monitoring of the compliance with environmental and public safety in working sites. ▶ Respect environmental management plans in the housing, infrastructure, and government building sector ▶ Respect environmental management plans in the construction and management of transportation infrastructure ▶ Enforce laws and regulations related to protection of environment; develop and enable institutional framework related to management of environment ▶ contribute in enhancing the environmental principles linked to human rights principles ▶ enhance the representation of Palestine in the international, and regional platforms, bodies, entities, and agreements related to environment ▶ Maximize the benefit of available opportunities in the international platforms to protect the Palestinian environmental rights, and expose the Israeli violations in this area Accomplish the environmental security for Palestine in accordance with the international human rights. ▶ Enhance the monitoring over infrastructure projects in harmony with environmental impact assessment policy. ▶ Intergrated and implement environmental criteria in the procedures of physical planning, building licensing, and infrastructure projects. ▶ Take into considerations the environmental criteria in public procurements and purchasing
5. The level of environmental awareness,	▶ Encourage and support social, and voluntary initiatives and economic empowerment projects that motivate sustainable

knowledge, and practice are increased and enhanced	environment and encourage green jobs especially for women and youth ▶ Transfer knowledge to behavior that protect the environment, and raise the awareness and knowledge of environmental issues in educational activities ▶ Focus on scientific and practical environmental research ▶ Integrate environment in curriculums of schools and universities in an integrated and organized manner; Enhance the environmental culture in the society; Integrate environmental aspects in cultural activities and initiatives ▶ Promote environmental issues through communication and information technology; -Encourage green jobs in the labor market ▶ Offer financial and taxation incentives to environmental-friendly initiatives and projects ▶ Raise environmental awareness of youth and encourage their participation in environmental initiatives and activities ▶ build and support environmental partnerships with the Arabic and International surroundings ▶ Contribute in empowering women through the participation in environmental activities and initiatives ▶ Adopt and support environmental projects and initiatives of women

Proposed national biosafety policy

The biological diversity and natural resources richness of the State of Palestine should be taken into consideration when developing the national biosafety policies;

"The objective of the national Biosafety policy and regulations is "to protect human, plant and animal health, the environment and biological diversity, by regulating the production, importation, exportation and contained use of LMOs, and the release of products of such organisms. Moreover, to ensure the regulations require that the risks posed by or as a result of modern biotechnology be identified and managed through regulating activities involving LMOs/GMO's. At the same time, the biosafety policy should not impede sound and orderly technological development/research and the promotion of modern biotechnology that may otherwise reflect positively on society."

Objectives of biosafety policy

The national biosafety policy and regulations of the National Biosafety Framework should achieve the following objectives:

Objective 1: To establish a regulatory regime for biosafety, including the management of the research, development and testing of GMOs and GM products, environmental release assessment, import and export, and use of all products resulting from modern biotechnology.

Objective 2: To establish an administrative system for the management of biosafety related issues defining clearly the mandates of National Competent Authority (NCA) and stakeholders.

Objective 3: To establish a transparent decision-making system for handling notifications or requests for authorizations for activities involving GMOs (e.g. trans -boundary movement, transit, domestic use, contained use, placing on the market, intentional release into the environment). This system should include a technical system for risk assessment and management, and specific plans for promoting access to information and public participation.

Objective 4: To establish systems for the monitoring and enforcement of biosafety measures.

Objective 5: To build and enhance the national capacity for biosafety management by developing mechanisms for promoting and facilitating public awareness, education and participation and the development of human resources for biosafety management.

The following Principles should be followed for establishing the national policy and regulations:

1)- Precautionary Principle: should entails a close monitoring of the various phases of modern biotechnology development and a containment of potential risks

2)- Research and Development: Measures will be taken to encourage, support and promote the research, development and commercialization of biotechnology, while undertaking continuous and long-term monitoring and research to minimize the potential risks and damages, taking into account the adoption of the precautionary principle.

3)- Risk Management: through the minimization of risks will be undertaken on strong scientific basis. A series of technical standards, guidelines, and procedures will be formulated. The management measures should be based on monitoring and EIA which will be strictly applied when dealing with products containing GMOs.

4)- Public Participation: GMOs, CPBs provisions and principles, and biosafety issues will be integrated in the educational curriculum and be part of national communication strategies for awareness purposes and public participation.

5)- National Regional and International Cooperation

Inter-disciplinary and inter-sectoral exchange, coordination and cooperation are considered essential to promote national interests and avoid duplication and/or fragmentation.

Targets for Biosafety policy

To assess the potential danger for human health and environment resulting from modern biotechnology and their products, including genetically modified (GMO's/LMO's) of animals, plants and microorganisms and their products, the biosafety management targets are consist of and regulated by the following risk classes which were specified for isolated systems for GMOs:

Class I: activities with negligible risks comparable to the risk of using non-pathogenic microorganisms, or without any risk (No risk);

Class II: activities with low risks comparable to the risk of using conventional pathogenic microorganisms (Low risk);

Class III: activities with moderate risks comparable to the risk of using microorganisms potentially capable to spread infections (Intermediate risk);

Class IV: activities with grave risks comparable to the risk of using microorganisms capable to spread very dangerous infections (High risk).

The Proper safety control measures will be adopted according to different risk levels as illustrated in Table 4 below.

Table 4: Risk levels and safety measures:

Risk Class	**Safety measures**
Class A (No risk)	Permitted
Class **B** (Low risk)	Precautionary approach
Class C (Intermediate risk)	Research and experimentation (Other use need special permits)
Class D (High risk)	Research and testing, Excluded from any other use

Draft Action Plan for the development of Biotechnology and Biosafety policy in Palestine

Rationale:

Palestine has signed on the convention of Biological Diversity (CBD) including the Cartagena Protocol on Biosafety (CPB) in 2015. One of the obligations to implement the protocol is to review the available national legislations and policies concerning the environment with focus on the field of biotechnology and Genetically Modified Organisms (GMOs). Another obligation is

to determine if the existing policies are adequate to regulate the modern used of biotechnology in Palestine. This process revealed that there are no policies regarding the use of modern biotechnology, GMOs and biosafety. Also, the Palestinian environment law no. 7 does not include any article related to benefits and drawbacks of the use of modern biotechnology and GMOs. Therefore, there is an urgent need to create a national action policy on Biotechnology and Biosafety. In this context, this document constitutes the first draft action policy on biotechnology and biosafety in Palestine.

Need for the use of modern biotechnology in Palestine.

The use of modern biotechnology has been enhancing the abilities of many developed countries to better compete in the growing global trade. Apparently, the integration of modern biotechnology in the various sectors including agriculture, environment, health, industry and education would contribute to the sustainable developments of these sectors, in the improvement of the Palestinian economy and its international reputation. This would also reduce the dependency of Palestine on the international donations. The implementation of modern biotechnology would ensure a nationally sustainable food security. A good example to achieve this is through the development of crops resistant to biotic and abiotic stresses. The health sector would be improved through the local production of drugs, vaccines and other pharmaceuticals. The environmental and industrial sectors would also be enhanced through the optimized utilization of bio-resources, and production of biofuels as an alternative energy source. Also, the application of biological control programs of pest would reduce the contamination of the environment due to the heavy use of hazardous pesticides. At the educational level, high quality graduates would have higher chances of establishing small and large enterprises related to biotechnology, hence opening the job market for other Palestinian graduates in this field. All of these benefits of the use of modern biotechnology necessitate the need for setting up a national biosafety action policy following the regional and international standards. As part of the Arab League, such policy should be harmonized with the available regional biosafety policies. Furthermore, as Palestine has unpretentious trade with some international countries and the country is now part of the CBD, the presence of a national biosafety policy would facilitate the biotechnology transfer, especially LMOs, with these countries.

Biotechnology and Biosafety Stakeholders

In Palestine, stakeholders of biotechnology and biosafety include the Ministry of Agriculture MoA, The Ministry of Health MoH, EQA (formerly Ministry of Environmental Affairs MOEA, PSI, private sector, NGOs, universities and schools, researchers, policy makers and implementers, farmers, and the general public.

Status of Biotechnology in Palestine

Several Palestinian universities offer an undergraduate degree in biotechnology. Other universities offer courses related to biotechnology within their undergraduates and graduates science programs. In addition, several private and governmental research centers conduct biotechnological research in Palestine. Much of the conducted research is related to the development of agriculture by means of biological control, plant tissue culture, molecular

diagnosis of pathogens, marker-assisted breeding for the production of tolerant plants, and to a few extinct production of LMOs for research purposes. Other researches are related to the public health sector mainly in the identification and diagnosis of heritable human genetic disorders. Moreover, few companies employ biotechnology in the production of organic food mainly olive oil for the local consumptions as well as for exportation. A detailed list of the involved universities, institutions, companies, and research centers has been prepared as part of developing this NBF for Palestine. Moreover, a roster of national experts in the field of biotechnology has been prepared.

Challenges facing Biotechnology and Biosafety Development

There are four main challenges facing the development of biotechnology and biosafety in Palestine (summarized in figure 4). These challenges are:

Financing of biotechnology research: The majority of the biotechnology researches that have been conducted in Palestine have been funded internationally in the form of multilateral projects. The international funders apply in many cases political restrictions that hinder the Palestinian researchers from applying to such grants. For example, the German DFG and the USAID apply political terms that alienate the Palestinian researchers from applying to such grants especially when the national regulations forbid the cooperation with Israeli research institutes. On the other hand, there are no or few national fund sources for research in general including biotechnology. Most of the available local finance resources are not adequate to establish and maintain the sufficient infrastructure related to biotechnology.

Job market: With the presence of several undergraduate and graduate degrees in biotechnology, the market is saturated with jobless graduates. There are a limited number of national biotechnological companies that cannot cope with the emerging annual graduates. Many of those graduates seek for job opportunities in other field or abroad.

Public Awareness: As most of the Palestinian population is involved to various degrees in the education process which involve teaching biotechnology at the school level, the public awareness of biotechnology is relatively elementary but probably inadequate. The public need to appreciate the role modern biotechnology could play in developing the various sectors mainly concerning the public health and food security.

Lack of legislations and ethical codes: So far, the Palestinian laws have no articles concerning biosafety, LMOs, GMOs, regulation of modern biotechnology research, and commercialization of biotechnology products. Also, there is no formal code of ethics in Palestine regarding the use and application of modern biotechnology including LMOs. It is worth mentioning that some Palestinian universities have developed their own ethical guidelines. The presence of such legislations would facilitate the acceptance of the public to the products of biotechnology.

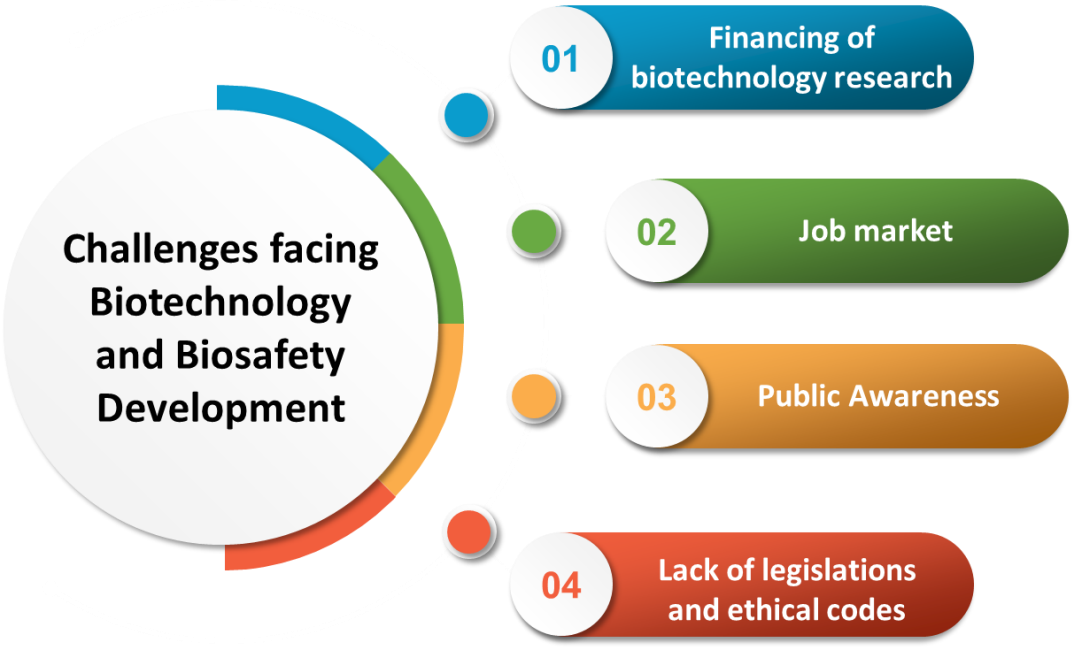

Figure 4: A summary of the challenges facing biotechnology and biosafety development in Palestine.

Guiding Principles

The intended biosafety policy shall be in accordance with the existing Palestinian laws and the national guidelines toward achieving sustainable developments of the various sectors. It should also allow the capacity building of human resources and infrastructure to face the developmental challenges in the fields of public health, food security, biodiversity and industry. This requires strong support of the cooperation among the various stakeholders of biotechnology which shall lead to the enhancement of transparency and accountability among them. Moreover, the policy should encourage the stakeholders mainly researchers and biotechnological companies to attract international and regional investments to ensure self-sustainable development in the field of biotechnology. Furthermore, the policy should ensure the safe development, application and regulation of modern biotechnology products.

Objectives of the action plan

The major milestone of the policy is to ensure the safe use and implementation of modern biotechnology in Palestine to enhance the public health, food security, economy, and biodiversity protection. Specific objectives include the followings:

1. National capacity building in biotechnology research and applications.
2. Encourage the use of biotechnology products and procedures.
3. Provide regulatory, monitoring, and evaluation mechanisms for the development of sustainable applied biotechnology.
4. Endorse ethical codes in biotechnology research and development.

Policy Statements and strategic actions

The implementation of policy will be in accordance of above-mentioned guiding principles. The objectives of the policy and the suggested strategic actions to achieve them are outlined below. Figure 5 represents a summary of these policy statements.

1. Capacity building of human resources:

Policy statement 1: Mechanisms that ensure the persistent development of well-qualified biotechnology personnel who are capable of running advanced biotechnology research will be established.

Rationale: Without the sustainable availability of well-qualified national human resources, it would be impossible to conduct advanced research or offer scientific degrees in biotechnology. In addition, the commercial use of biotechnology would be unsafe without the presence of the well-trained personnel. Therefore, the policy shall consider the continuous development of the human resources in the field of biotechnology and biosafety.

Required actions by the implementation strategies:

A. Provide technical and academic training sessions for Palestinian researcher at qualified local and international biotechnology institutes.
B. Encourage cooperation and networking among the various stakeholders as a tool to exchange expertise.
C. Encourage the universities that teach biotechnology degrees to keep updating their academic curriculum, participation of faculty in courses and conferences in advanced biotechnology, and provide their students with adequate training on biosafety.

Expected outputs:

a) Enhanced technical and skill capacities in Biotechnology and Biosafety.
b) The stakeholders are effectively utilized through coordination.
c) Advanced biotechnological tools and biosafety measures are part of the academic programs.

Responsible institutions: Universities, EQA, MoHE, PSI.

2. Infrastructure development:

Policy statement 2: To promote the development of biotechnology and biosafety in Palestine, biotechnology laboratories and research centers shall be equipped with the adequate infrastructure.

Rationale: Although several Palestinian universities and research centers are equipped with the basic biotechnological infrastructure, most of these institutes do not have the high-tech equipment, infrastructure and biosafety measures that would enhance the research quality. Most of these institutes rely on foreign institute to fulfill their research

activities. Therefore, to achieve a high quality research the national institutes shall be equipped with the adequate infrastructure that ensures the safe application of modern biotechnology.

Required actions by the implementation strategies:

A. Ensure that sufficient infrastructure facilities for biotechnology research and development are installed in the major national research centers including those affiliated to the national universities and the customs centers at the borders.
B. Implement strategies for sharing technology among the various stakeholders including the private sector.
C. Facilitate the establishment of a center of excellence in biotechnology research to coordinate the development and upgrading of the existing biotechnology academic programs.

Expected outputs:

a) Availability of national high quality, productive research centers.
b) Efficient networking and cooperation between the various sectors of biotechnology.
c) High quality academic programs in biotechnology.

Responsible institutions: EQA, MoHE, MoH, PSI, Universities, private sector.

3. Research and Development (R&D):

Policy statement 3: Research and development of biotechnology and biosafety shall be facilitated and supported in topics with national priorities such as food security, health care and proper utilization of the natural resources as water.

Rationale: During the last decade, biotechnology researches have been conducted at various national institutes. Most of these research projects were funded internationally and were selected based on the funder criteria. Fortunately, part of these criteria requires the conduction of research in topics that are of local interests. The research outcomes have partially participated in enhancing the public health and agriculture sectors. Further support of such research activities in fields of national priorities such as the safe use of reclaimed waste water in agriculture, food security, and health care shall be supported by the government by all available means. This would enhance the development of a healthy and productive nation.

Required actions by the implementation strategies:

A. Provide administrative facilities for conducting advanced biotechnology and biosafety R&D.
B. Conduct an evaluation study to determine the national research priorities.
C. Establish an online platform to facilitate meetings and discussion between the various biotechnology and biosafety stakeholders and policy makers.

D. Establish a national biotechnology R&D database and provide access to all involved stakeholders.
E. Promote biosafety standards by implementing biosafety regulations at all research centers.

Expected outputs:

a) Administrative facilities for biotechnological R&D and biosafety are implemented.
b) The national research priorities are determined.
c) An online platform for networking is established.
d) An accessible national biotechnological R&D database is established.
e) Biosafety regulations are implemented at all research centers and universities.

Responsible institutions: MoHE, PSI, Universities, NGOs, Donors, private sector.

4. Public Awareness and Participation

Policy statement 4: Set up strategies to enhance public awareness and participation in Biotechnology and Biosafety Development.

Rationale: Although the concept of biotechnology is not novel for a wide range of the Palestinian populations, people are not adequately aware of the potential benefits and risks of this branch of science. Therefore, the responsible authorities have to promote activities that would increase the public awareness to modern biotechnology and the role it could play in improving the various sectors including agriculture and public health.

Required actions by the implementation strategies:

A. Launch biotechnology and biosafety practical campaigns at schools, universities and other related sectors.
B. Provide access to information on biotechnology and biosafety to the public and the private sector through the various communication media.

Expected outputs:

a) Public awareness to biotechnology and biosafety has dramatically improved.
b) The private sector is actively participating in biotechnology awareness campaigns.

Responsible institutions: EQA, MoHE, PSI, Universities, Schools.

5. Industrial Application and Commercialization

Policy statement 5: The government will facilitate national and international investments leading to broader application and commercialization of modern biotechnology.

Rationale: In Palestine, biotechnology is applied in limited industrial sectors. These include particularly nationally commercialized dairy products and internationally commercialized organic plant products mainly olive oils. To improve the national

economy, biotechnology should be utilized in a wider range of industries including the production of pharmaceuticals, plant somatic propagation, biological control pests, etc. This requires governmental facilitation and support to promote the private sector to invest in this area.

Required actions by the implementation strategies:

A. Encourage investment in biotechnology through supporting existing and planned national enterprises and companies by providing facilitated licensing process and incentives.
B. Ensure that proper biosafety measures are implemented in all industrial stages of production and commercialization of biotechnology products.

Expected outputs:

a) The number of biotechnological enterprises and companies has increased.
b) Biosafety measures are implemented at these companies.

Responsible institutions: EQA, government, MoH, MoA, PSI.

6. Bioethics and Biosafety

Policy statement 6: Appropriate mechanisms will be established to ensure that the use of biotechnology follow the national and international code of ethics and biosafety measures.

Rationale: To be acceptable by the public and compatible with the international standards, application and commercialization of biotechnology have to comply with the social morals and ethics and the international biosafety measures. A national code of ethics and biosafety instructions shall be established and implemented to deal with any possible prospective unethical practice during the application of biotechnology.

Required actions by the implementation strategies:

A. Create a national code of ethics related to the use of biotechnology.
B. Make mechanisms to ensure the proper implementation of the code of ethics in biotechnology R&D.
C. Ensure the appropriate labeling of GMOs for national and international commercialization.
D. Increase the public awareness of the code of ethics through the biotechnology education and practical campaigns.
E. Establish a protocol for decision making concerning biotechnology application and commercialization.

Expected outputs:

a) Ethical standards are accomplished and implemented.
b) Public awareness of the code of ethics concept concerning biotechnology has increased.
c) GMOs are labeled according to the international standards.
d) Decision on the application and commercialization of biotechnological products follow the established procedures.

Responsible institutions: EQA, MoA, MoH, PSI.

7. Risk Assessment

Policy statement 7: Establish and maintain mechanisms for the regulation, management and control the risks associated with the use of modern biotechnology particularly the release of LMOs and commercialization of GMOs.

Rationale: Although GMOs and LMOs are not common in the Palestinian market and environment, the country may have to produce, import or commercialize them in the future. Possible motives for the prospective introduction of GMOs into the local market or LMOs into the environment might be related to economical, health or environmental issues. This necessitates the establishment of proper mechanisms for risk assessment of GMOs and LMOs to help the responsible authorities reach into the best decisions.

Required actions by the implementation strategies:

A. Establish a mechanism for the assessment of the possible effects of GMOs on human health.
B. Establish a mechanism for the assessment of the release of LMOs into the environment.
C. Provide the related sectors with access to the risk assessment process.
D. Establish a decision maker committee for issues related to GMOs and LMOs. This committee should include expertise in biosafety and methods of risk assessment.

Expected outputs:

a) Risk assessment mechanisms for the use of GMOs and release of LMOs are established.
b) Risk assessment process is accessible to all concerned sectors.
c) A specialized committee for making decisions on use of GMOs and release of LMOs is established and functioning.

Responsible institutions: EQA, MoA, MoH, PSI, NBC.

8. Networking and Partnerships

Policy statement 8: Promotion of strategic partnerships and networking among the national biotechnology related sectors as well as with the concerned regional and international organizations to facilitate the execution of this policy.

Rationale: After signing on intentional agreements on the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety, the development of biotechnology and biosafety in Palestine can be enhanced through networking between the related national and international institutions and organizations. Therefore, establishing partnerships among these sectors shall be encouraged.

Required actions by the implementation strategies:

A. Promote networking and collaboration among the public and private sectors involved in biotechnological R&D.

B. Encourage universities to establish biotechnology academic programs and practical courses jointly with international institutes.

C. Provide incentives and facilities for the establishment of multinational biotechnological enterprises and companies.

Expected outputs:

a) Collaborative national and multinational biotechnology research is functioning.
b) Joint biotechnology academic programs are established and functioning.

Responsible institutions: Government, Universities, public and private sectors.

9. Biodiversity Conservation and Utilization

Policy statement 9: Promotion of the use of biotechnology in enhancing the conservation and utilization of the national natural resources.

Rationale: Several factors have produced a huge biodiversity of flora and fauna in Palestine. These factors include the diversified climates and soil types. Biotechnology could be applied to conserve this biodiversity by through the conservation of the genetic resources. In addition, biodiversity could be better utilized in enhancing the national economy. Through the use of modern biotechnology, the natural recourses could be utilized in improving the agricultural, health and industrial sectors. As an example, the establishment of stress-tolerant plants through gene transfer from wild to cultivated plants.

Required actions by the implementation strategies:

A. Apply molecular biology to evaluate the potential use of indigenous flora and fauna for medical and economical applications.
B. Utilize biotechnology for the conservation of national genetic resources.
C. Encourage biotechnological research for the utilization of national biological resources.
D. Establish or update the legislations aiming at the conservation of biodiversity.

Expected outputs:

a) Gene banks and taxonomic databases are established.
b) Research-directed utilization of the national bio-resources.
c) Legislations for the conservation of biodiversity are updated and applied.

Responsible institutions: EQA, universities, research centers.

Policy implementation

Responsibilities:

The implementation, monitoring and regular review of this policy is the responsibility of the government represented by the EQA and in cooperation with the related sectors. For these

purposes, sustainable implementation mechanisms and committees shall be established by EQA. By default, the implementation committee shall include the EQA for issues related to the CBD, and the NBC for matters related to biotechnology and biosafety. EQA is the sole governmental liaison with the CBD and is responsible for coordinating data exchange with them. The NBC is a formal consultancy committee encompasses experts in biotechnology and biosafety as well as ability to evaluate the risks and benefits of the use of biotechnology. The NBC has to be involved in the implementation of this policy. Supported by the EQA, the NBC is responsible for reviewing and approving the national biotechnology research and development activities.

The implementation of this policy is also the responsibility of other sectors involved in biotechnology and biosafety. For example, the MoH is responsible for the safe production, development, and application of biotechnology involved in pharmaceuticals and nutrition products. The MoA is responsible for all activities involving agricultural biotechnology. EQA is responsible for the protection of biodiversity. Commercialization of biotechnological products including GMOs is a shared responsibility of EQA, MoA, MoH and MoNE. The MoL is responsible for the safety of the biotechnology workers. The MTIT is responsible for the communication infrastructure and services. All of these responsibilities shall be coordinated by the EQA.

Financing:

Funding of the development of biotechnology through the implementation of this policy shall be the responsibility of all related sectors. Attracting funds through collaborative research activities are also encouraged. Additionally, the MoF shall allocate an annual budget of biotechnological R&D. The breakdown of this budget shall be designed in cooperation with EQA, the NBC and representatives of research centers. The government shall also attract donations to support the implementation and periodic review of this policy.

Monitoring and evaluation

Following the conditions of this policy, the NBF being established by EQA will include a monitoring and evaluation system for biotechnology and biosafety development. Indicators to monitor the execution of the various activities of this policy will be set up. Methods of collection and analysis of information will be developed. A monitoring and evaluation committee (MEC) has to be established and shall include the EQA by default. The MEC shall ensure the proper implementation of this policy. Collectively, the performance of the biotechnology sector will be constantly monitored based on measurable parameters following the regulatory system of the NBF.

EQA will periodically evaluate the influence of the conducted actions and activities on the implementation of this policy. Based on the collected data and performance indicators, EQA will also measure the efficacy of the implementation strategies and evaluate them.

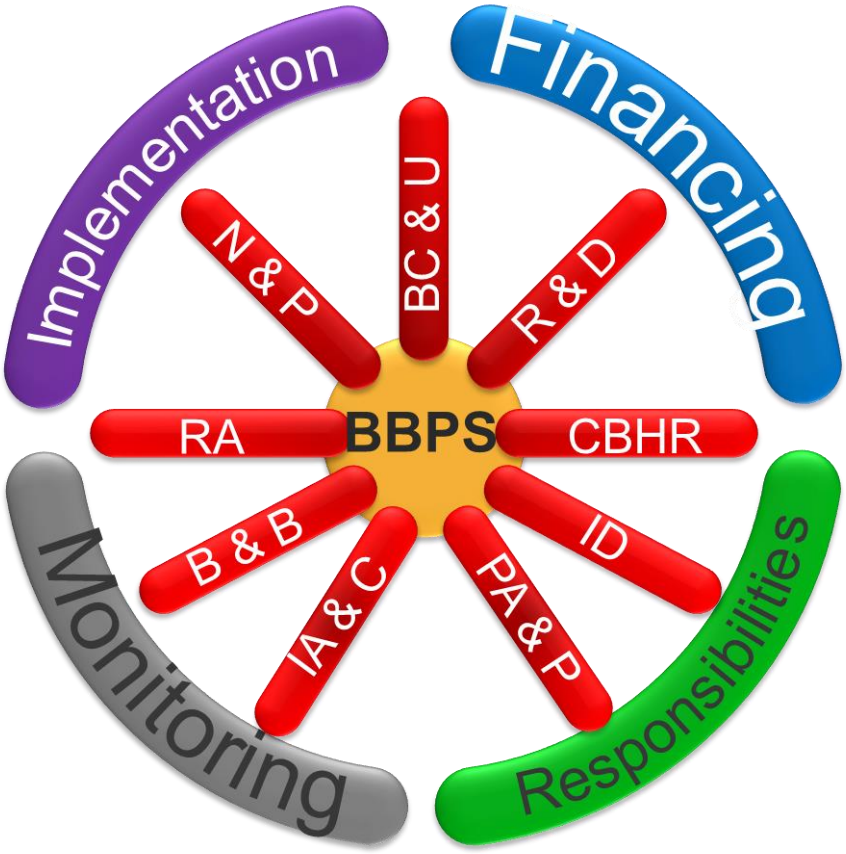

Figure 5: A summary of the Biotechnology and Biosafety Policy Statements (BBPS). The implementation and monitoring for the policy require financing resources and defining the responsible authorities and committees. CBHR: capacity building of human resources, ID: infrastructure development, PA&P: public awareness and participation, IA&C: industrial application and commercialization, B&B: bioethics and biosafety, RA: risk assessment, N&P: networking and partnership, BC&U: biodiversity conservation and utilization, R&D: research and development.

Mainstreaming biosafety into relevant sectoral policies and strategies

Background:

With the advancement in the modern biotechnologies, particularly LMOs and GMOs, there is a need for raising the awareness to the biosafety and seriously consider its implementation into relevant sectoral policies, legislations and strategies. The recent increasing utilization of LMOs

in agriculture, sustainable food, biofuel and fiber production, fisheries, and for climate change involves the cooperation of all relevant sectors. Therefore, the conference of the parties serving as the meeting of the parties to the CPB (COP-MOP) encourages the integration of biosafety framework into the policies, action plans and strategies of all relevant sectors including the biodiversity strategies in line with the national circumstances and priorities. There is no doubt that such integration would additionally reinforce national coordination mechanisms to implement the CBD and CPB. In fact, the main obstacle against the full implementation of the CBD is the inadequate integration of the CPB in the relevant sectorial policies and strategies. Consequently, the COP-MOP also urges the parties to assign satisfactory human and financial resources to accelerate the mainstreaming of biosafety and the execution of the sectoral and national strategic plans.

Rationale for integration

1. CPB is an integral and essential part of the CBD. Integration of CPB facilitates the implementation of the CBD. This will help in the conservation and sustainable use of biodiversity and enhance food security and human health by achieving the provisions of the CPB (figure 6), which ensure the safe movement, release and contained use of LMOs. The integration of CPB could influence several biodiversity targets including control of invasive alien species, sustainable agriculture and production, maintaining genetic diversity, ecosystem restoration, and raising the public awareness.

2. Integrated implementation increases productivity and lead to efficiency savings. The national mechanisms to implement the CPB and CBD such as the capacity building and public-awareness raising activities are mutually supportive. In addition, the research and academic activities and their facilities could be shared. Needless to say that several procedures and guidelines of the CPB are applicable to other topics covered by the CBD. For example, the risk assessment and risk management principles and guidelines of the CPB can be helpful for the implementation of CBD Articles related to alien invasive species as Art. 8(h). Another example is the sharing of information through the BCH, which applies to all issues of the convention. The effective integration of the CPB into relevant sectors would facilitate its implementation with the minimum efforts and enhance coordination among the various sectors.

3. To obtain better financing. Integration would facilitate allocating governmental and international funds such as the Global Environment Facility GEF funds.

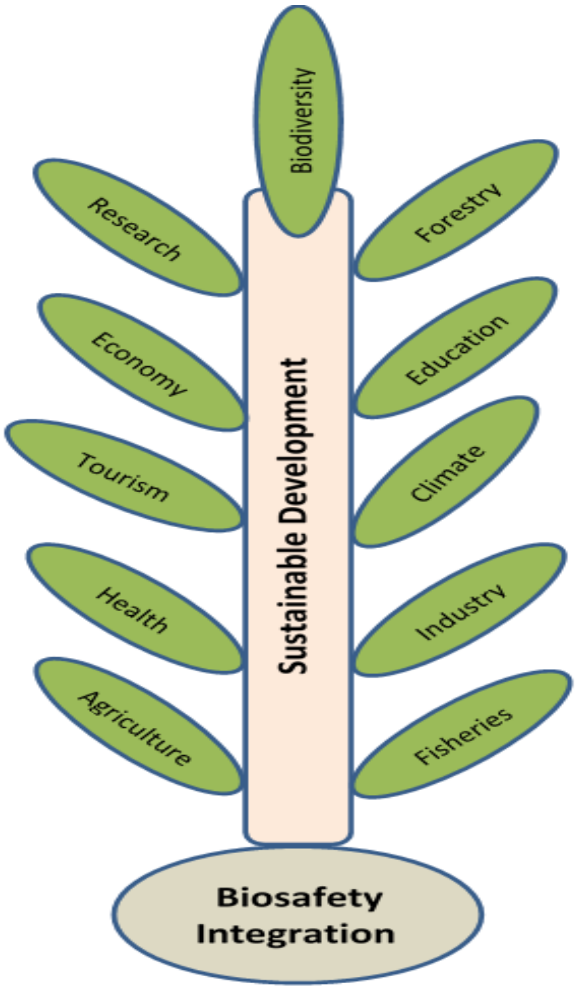

Figure 6: Mainstreaming biosafety into relevant sectorial policies and strategies facilitates the sustainable development of these sectors.

The mechanism of mainstreaming biosafety

The biosafety-mainstreaming strategy involves a number of steps as summarized in figure 7. First, objectives and outcomes of the mainstreaming should be established. Second, identify and prioritize the mainstream targets, also called entry points (the priority sectors and policies, etc). Third, determine the mainstreaming tools. Finally, design the integration strategy (could be a timetable of events). The conduction of these steps necessitates cooperation among the related sectors. This could be achieved through inter-sectorial committees and joint activities. In addition, the integration strategy shall identify the required research activities on biosafety and the needed capacity building for mainstreaming including developing the capacity of the sectoral officials. This would help the policymakers achieve better decisions. Furthermore, indicators for success shall be established to assess the mainstreaming process. Examples of such indicators include the number of activities on biosafety, adequate representation of the ministries in the committees, and the number of national plans and policies that integrate biosafety measures. To gain support for the mainstreaming process, public awareness activities all relevant stakeholders

should be involved in the process. This could be achieved through the public awareness activities as well as the direct communication with the stakeholders.

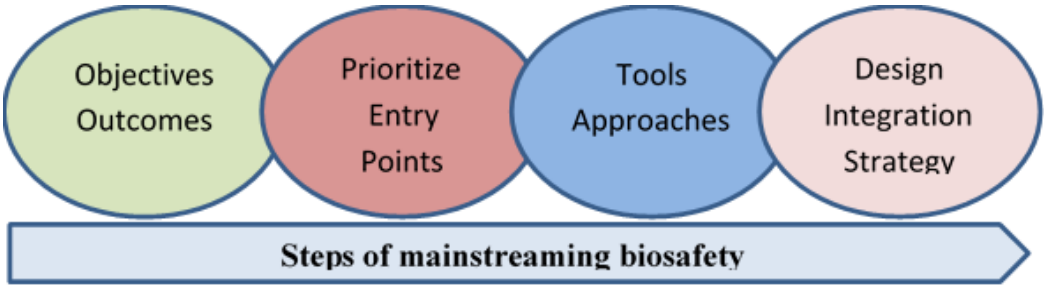

Figure 7: Mechanism of mainstreaming biosafety into relevant sectors.

What are the feasible entry points for mainstreaming?

The entry points for mainstreaming biosafety include the National Biodiversity Strategies and Action Plans (NBSAPs) as well as the national spatial planning, economic and development, education, and mitigation of the climate change. Moreover, the entry points may also include the national strategies and policies for sustainable development, poverty reduction, trade and international cooperation.

Sector prioritizing for mainstreaming

When selecting the sectors as targets for mainstreaming of biosafety, the priority should be given to the sectors that meet all of any of the following conditions. First, if there is a clear linkage between biosafety and sustainable development of that sector. Second, if the absence of biosafety integration is potentially associated with negative impacts. Third, if the decision makers of that sector are willing to adopt the integration. Finally, if the timing is appropriate for mainstreaming. Examples of suitable timing for mainstreaming include times when strategies and policies are being revised, budgets being prepared, change of government, after crises and disasters, etc.

Approaches and tools of mainstreaming

There are various approaches and tools for mainstreaming depending on the target sector. The following are examples of common tools to integrate biosafety:

- Environmental Impact Assessment (EIA).
- Strategic Environmental Assessment (SEA), which identifies and appraises the potential consequences of policies and plans before their implementation.
- Economic and financial tools such as incentives, taxes, etc.
- Ecosystem approach: reach into decisions that sustain biodiversity and enhance human health.
- Useful practices and guidelines.
- National spatial planning.

Regional biosafety harmonization policy

Background:

Although, Arab countries share a common language and cultural values, there are huge variations among these countries in term of the scientific research capacities, including the field of biotechnology, as well as the agricultural and natural resources which are reflected on the disparate economic status of these neighboring countries. Proper utilization of such diversified resources and expertise through cooperation and networking would result in mutual benefit for all of the involved countries.

During the last two decades products of biotechnology mainly living modified organisms LMOs and LMOs-FFP, those intended for direct human food, animal feed, or processing, have been subject for scientific and public controversies in regard to their potential risk on the human health and biodiversity. Cartagena Protocol on Biosafety CPB has been established internationally to ensure the development of policies and procedures that should reduce possible risks of LMOs, public fear and assign precautionary approaches when scientific ambiguity exists.

Several Arab countries have signed the CPB and some of those countries have already developed National Biosafety Frameworks independently. Palestine is in the process of developing a NBF. An important criterion that is being considered is to harmonize the intended Palestinian NBF with those of the sub-regional countries. To accomplish this task, the existing sub-regional NBFs has been reviewed and in accordance this policy of biosafety harmonization has been prepared.

Importance of the biosafety harmonization policy:

Pragmatic uniform regional biosafety policies would facilitate the trade of agricultural products among the Arab countries. Also, harmonization of the policies should lead to the development of a shared legislative and regulatory framework, common protocols and guidelines that would allow the sharing of human and agricultural resources among the sub-regional countries at a favorable socio-economic cost. It is expected that such harmonization would improve the scientific risk assessment and the cooperative capacity building among the neighboring countries leading to a smaller burden on the poor, less developed countries. The policy would allow an effective mutual sharing of personal and institutional expertise as well as governmental finance support through easiness of exportation/importation. Furthermore, it would reduce the chances for uneven innovation and investment climate in the region. With comparable levels of technology adaptation in the field of biotechnology and biosafety, several underexploited agricultural areas would thrive and participate in the improvement of the socio-economic status of the less-developed countries of the region.

The objectives:

1. To attain a practical, effective and flexible biosafety protocol for Palestine and the sub-regional countries.
2. The protocol has to be established based on the actual common risks and should possess the public confidence.

3. The protocol should reduce possibilities of uneven innovation and enhance the chances of equal investment opportunities in the region in the field of agricultural biotechnology.
4. To be functional, the protocol should be approved/signed by the participating countries.

Principles of Policy Harmonization:

The intended biosafety policy will allow for the sovereign rights of the participating countries as well as the individuals' human rights. Also, the biosafety system and the legislative and regulatory frameworks should be flexible, adapted to the needs of participating countries, agile and continuously updated based on the growing local and international scientific knowledge and experiences especially in regard to risk assessment of LMOs and socio-economic analysis. The flexibility of the biosafety system ensures that the biosafety regulatory system and the decision making concerning introduction of LMOs into the environment shall be at the country level on a case by case basis. By default, the regulatory system has to include the EQA, the National Biosafety Committee (NBC) and the MOA (quarantine authorities). However, decision making on the use of LMO-FFP shall be made in coordination with all the participating countries to facilitate the import/export processes. To ensure transparency, the process of decision making shall be conducted through clear communications and have to be published at the biosafety clearing housing BCH. The policy shall take into account that the biosafety regulations of biotechnology products will not unjustifiably hamper the biotechnology innovations, investment and prospect economic success when possible.

The regulatory systems should also include national guidelines to regulate the institutional biotechnology research and LMOs in containment (in a laboratory or a greenhouse), and a one-time permit for LMOs at the country level as well as a common permitted list of LMO-FFP published at the regional BCH. A reference regional laboratory should be established to support the regulatory system of each country in the monitoring, routine testing and capacity building. A unified system of labeling of LMOs and LMO-FFP shall be established. It may follow the international voluntary negative labeling where the critical level of negative labeling is at 5% LMO content. In general the labeling information could be positive i.e food contain GMOs or negative i.e, GMO-free. The labeling is mandatory in some countries as EU, Japan, Australia and Brazil and voluntary in others as in South Africa. This contention stems from two different GMO regulatory approaches followed in the different countries. The first is process-based precautionary approach that consider labeling as risk management tools. While the other is product-based approach according to the theory of substantial equivalence, which worry that labelling may hamper trade (Figure 8). CPB obliges the parties to identify GMOs and LMOs by proper labeling. This is because consumers have the right to know what they are purchasing, should be protected from misleading practices and to get education on possible human and environmental health hazards.

It is worth mentioning that all the biosafety information should be published at the regional biosafety clearing house to ensure the harmonization between the national biosafety and administrative systems. These include the online administration and follow up of the various prospect stemming applications among the countries.

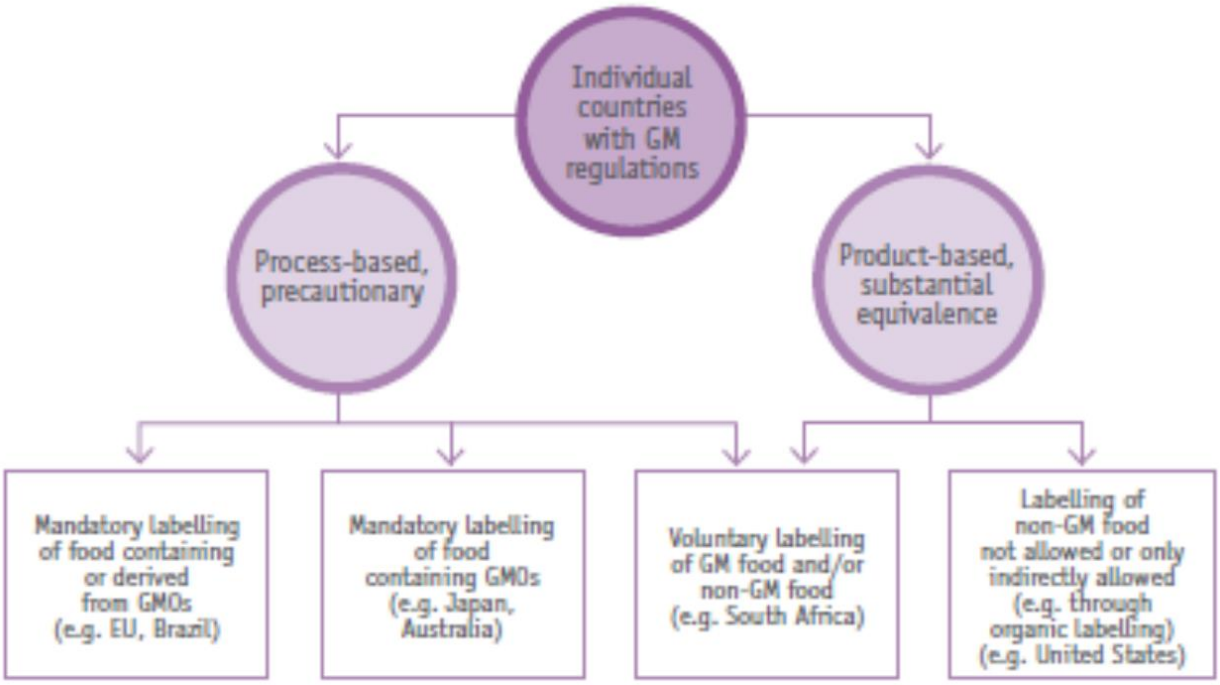

Figure 8: Classification of labeling regulation. Courtesy, Biosafety resource book, legal aspects, FAO, Rome, 2011.

Proposed Mechanism of Regional Harmonization of biosafety Implementation in Palestine and the sub-regional countries.

In this section, mechanisms for regional harmonization of biosafety implementation in Palestine are proposed for LMOs intended for intentional introduction into the environment, LMO-FFP, LMO-FFP labeling, LMOs for contained use, and LMOs in transit (Figure 9).

A. Regional harmonization of LMOs intended for intentional introduction into the environment

A regional administrative body RAB and a regional biosafety center RBC must be established to house the regional BCH and to coordinate the following activities and tasks;

1. Processing of applications for import of LMO following Cartagena protocol.
2. Inform the national BCH of LMOs intended for intentional introduction into the environment.
3. Maintain a roster of experts from related disciplines.
4. Maintain a list of registered institutional biosafety committees to facilitate networking.
5. Compose scientific risk assessment commission to support national decisions.
6. Support the decision making body.
7. Ensures that all national decisions are made within the specified timeframe.
8. Provide access to all parties of the documents, decisions and a list of approved LMOs and LMO-FFP through the BCH.
9. Coordinate the development of common guidelines and the public education programs.
10. Support regional research and educational programs in the field of biotechnology.

Although, the harmonization will include all of the above mentioned tasks, decision on LMOs, the implementation of the decisions, labeling of LMOs and providing permits will be the responsibility of the national regulatory system at the country level in coordination with the national EQA, Ministry of agriculture and Ministry of health. The national regulatory system will be also responsible for monitoring the borders to prevent the intended and non-intended introduction of LMOs into the environment.

B. Regional harmonization of biosafety systems for LMO-FFP

LMO intended for human food, animal feed or processing have no or low risk to the agriculture since they are not intended for release into the environment. Therefore, the risk assessment of LMO-FFP and the regulations of their use may follow the national food security guidelines and legislations. However, to facilitate the trade between the participating countries, such regulations, risk assessments, scientific procedures, and decision making process should be shared through the regional BCH.

C. Regional harmonization of labeling of LMO-FFP

The voluntary negative labeling system will provide the consumer with the option of buying unlabeled products for cheap prices. This will be good for those who don't care whether the product is LMO-FPP or not. Consumers who prefer a labeled product to eliminate the chance of consuming a LMO-FPP may have to spend more money for their choice. On the other hand, the mandatory system of labeling will increase the prices of all products. This is because labeling of LMOs necessitates extra procedures from the farmer such those ensuring the separation of normal and LMO crops during cultivation, storage, processing and shipping. Following the voluntary negative labeling, imported LMO-FFP would be equivalent to non-LMOs. The participating countries in this harmonization policy should decide on a labeling system that is associated with less health risk to their people. It is worth mentioning, that a 5% LMO content have been recommended by other regional policies for certification practices. Needless to say, that the labeling LMO-FPP shall be implemented by the food security department of the national Ministry of Agriculture.

D. Regional harmonization of Biosafety Framework for LMOs in contained use

Reasoning:

For several reasons, the Biosafety Framework and legislation must be able to handle application for contained or confined use of LMOs. This is important to support national and sub-regional modern biotechnology research including those aiming at development of LMOs. Also, this will allow the laboratory testing of LMOs before their commercial release into the environment or even their export to other laboratories for further scientific research as in the case of LMO seeds.

E. Regional harmonization of Biosafety Framework for LMOs in transit

Sometime LMOs might be transited through Palestine or any of the sub-regional countries to the destination country. To avoid unintended introduction of LMOs in non-destined environment, proper packaging and labeling of LMOs must follow the guidelines of Cartagena protocol and the common standards of the transit country.

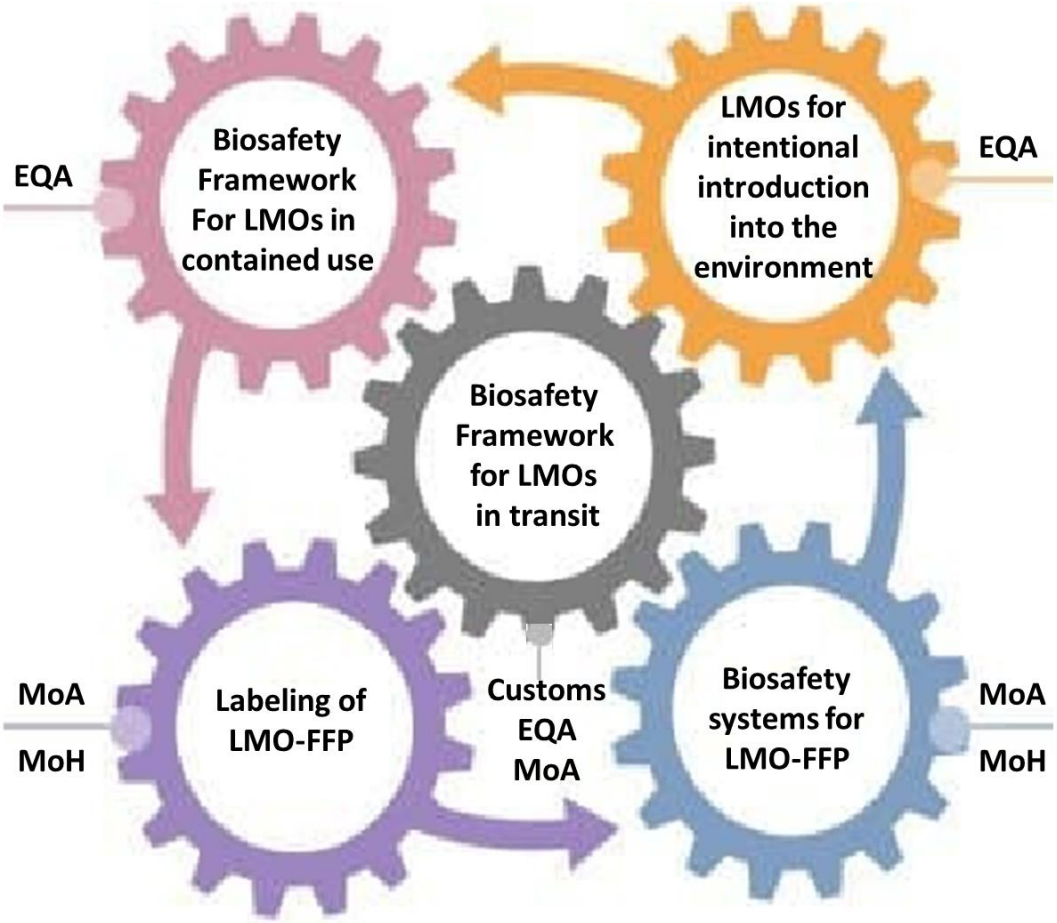

Figure 9: Proposed regional harmonization mechanism of biosafety implementation in Palestine. Candidate responsible authorities for the biosafety implementation are shown.

Policy guidelines

All institutions, research centers or companies intended to work with LMOs in a contained setting must be registered by the biosafety administration system of that country. Institutions could apply for registration through the regional BCH against a fee. Following signing a harmonized agreement and fulfilling the regional pre-developed guidelines, the institution will authorized to work on LMOs under the monitoring of the regulatory system. The release of LMOs to the environment requires application, evaluation, risk assessment and decision making a national level. Still sharing such processes through the regional BCH would help create uniform biotechnology developmental chances among the participating countries.

Liability and redress

The participating countries (Palestine and sub-regional countries) should develop agreed common methods for Liability and Redress based on the Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

CHAPTER III

Biosafety regulatory regime and administrative system (guidelines) for LMOs in Palestine

The status of Biosafety policy in Palestine

The Palestinian authority (PA) has been established since two decades, Israel as an occupying power is still occupying and controlling the majority of the lands, especially those as known as area C, that shall belong to the state of Palestine according to the international agreements. This area is of great agricultural and environmental importance. It encompasses protected areas (nature reserves), rich indigenous flora and fauna, cultivated areas, and underground water reserves. Since its establishment, PA has introduced the environmental law No. 7 and has signed several international agreements related to the environment and conservation of biodiversity including the CBD. However, there are still no legislations, policies and laws to regulate the safe use of biotechnology products specifically GMOs and LMOs. Represented by the EQA of the Ministry of Environment, the Palestinian government promotes the use of biotechnology in Palestine to improve the population economy and lifestyles. On the other hand, the government ensures and supports setting up regulatory framework and policies that aim at minimizing the risks associated with biotechnology products mainly LMOs to the public health and biodiversity at all stages of the process including their transport, handling, and use.

To achieve the government goals, a set of national priority actions on biosafety have been recognized by the EQA. These include establishing a regulatory framework for biosafety and a technical system for risk assessment of LMOs/GMOs. The risk assessment procedures of LMOs shall include criteria for analyzing their potential risks, for classifying the levels of the risks, as well as for the biosafety monitoring in the field. Other national priority actions are supporting the scientific research on biosafety and increasing the public awareness of biosafety through education, media, local and international training, workshops and other feasible means.

Regulatory Framework for Biosafety

This is the first draft national regulatory framework for the safe use of biotechnology in Palestine following the provisions of Cartagena Protocol. It is prepared by EQA through consultancy with a national expert and a couple of workshops involving the concerned stakeholders. The draft regulatory framework deals with the management of LMOs/GMOs transportation, labeling, and risk assessment throughout the phases of the biotechnology development program in Palestine (Figure 10). Technical and advisory committee will be established to conduct these tasks. Mechanisms for the harmonization of the intended framework with regional and sub-regional

countries have been put in place. The biosafety regulatory system will include a national By-law on biosafety, specialized biosafety regulations, and procedural regulations such as assessment procedures and technical guidelines (Figure 10). A National Biosafety Committee (NBC) has been established by EQA to review these regulatory policies concerning the safe use of biotechnology in Palestine.

For the sustainable improvement of the national regulatory framework for biosafety, several values have been considered (Figure 10). First, Biotechnology/biosafety research, cooperation and coordination among the national stakeholders, and public participation in the management and supervision of biosafety are continuously encouraged and supported. Second, follow up with the international biosafety activities and protocols and updating the local frameworks accordingly. Third, the regulatory system and its risk assessment and monitoring procedures should be solely based on scientific evident. Finally, the monitoring procedures should be applied at all stages of biotechnology development so that the identification of the potential risks biotechnology products are detected at the very early stages of the process following the rule prevention is better than treatment. Following these values and considerations, two application forms have been established to regulate the process (see annex 6).

Figure 10: A summary of the components, purpose, and responsible authorities of the Biosafety Regulatory Framework (BRF).

For import/export of LMOs intended for the release into environment for the first time, the CPB has an Advanced Informed Agreement (AIA) that describes the process of notification and approval (Figure 11). The aim of the AIA is to prevent possible unfavorable effects on the environment and biodiversity.

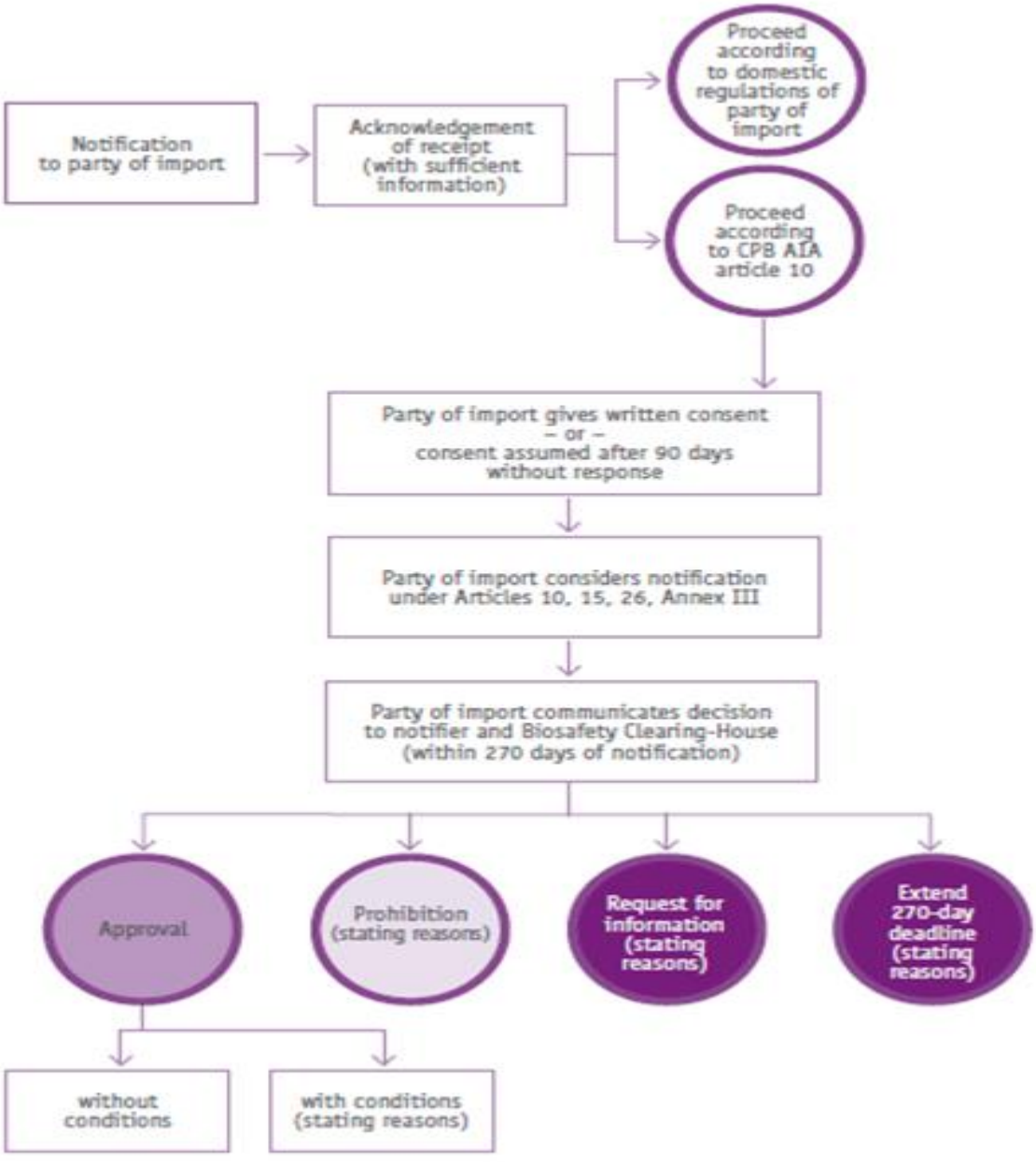

Figure 11: The AIA process. Courtesy, Biosafety resource book, legal aspects, FAO, Rome, 2011.

Administrative System

The structure of administrative system for biosafety is summarized in figure 12 and consists of the followings bodies:

1. National Biosafety Focal Point (NBFP).
2. National Biosafety Committee (NBC).
3. Technical advisory sub-committee.
4. Relevant authorities and stakeholders.

The administrative system is the authority responsible for the proper implementation of the policies related to LMO and biosafety. This include assuring the safe use of modern biotechnologies in Palestine and the biosafety of the environment and human health taking into consideration the cultural and ethical impacts. This system should achieve these milestones according to the formal policies, regulations, legislations, by-laws and proposed activities of this NBF. The administrative system should assign technical advisory committees and consultants on a case-by-case basis. Moreover, the system is responsible for promoting the scientific research related to LMOs and inspect for the applied biosafety measures, as well as to raise the public awareness and involvement in the decision making regarding the use of LMOs.

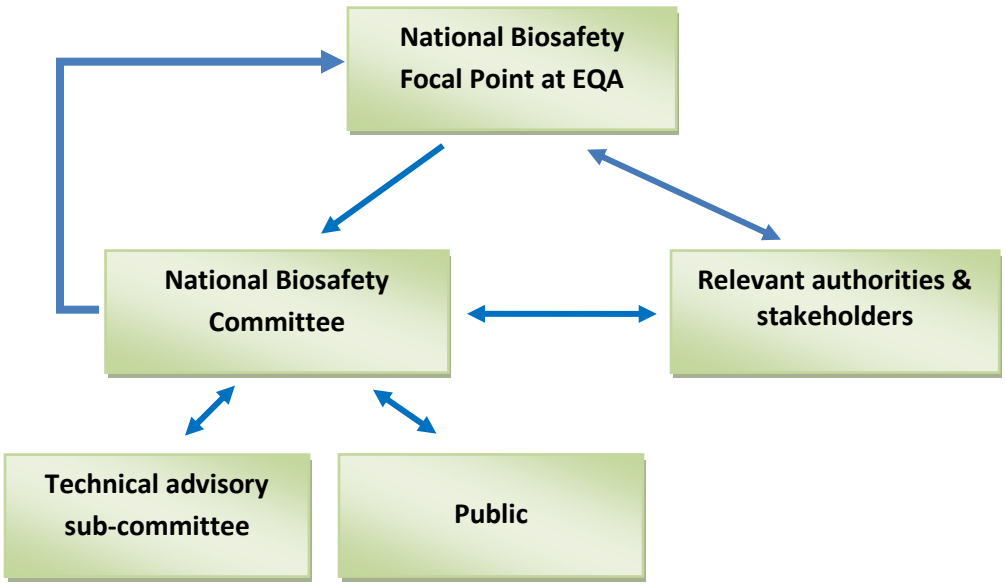

Figure 12: structure of the biosafety administrative system.

The National Biosafety Focal Point

The National Biosafety Focal Point should be part of the EQA and is responsible for the following tasks:

1. Receive, review and coordinate the process of approving or rejection of all applications related to LMOs/GMOs and related research. This include passing the applications to the NBC, publishing the related biosafety information to the public and related stakeholders through a formal accessible database, and informing the applicant of the decision.
2. Networking with the national, regional and international relevant stakeholders and authorities including the BCH and the secretariat of Cartagena protocol.
3. To maintain an updated rosters of national experts in the field of biotechnology and biosafety as well as of GMO products in Palestine.
4. Supervise the implementation of the biosafety measures and act following the emergency response procedures in cases of damage or accidents related to LMOs.
5. To announce through the BCH about GMO or products thereof that might be subjected to a risk assessment.

The National Biosafety Committee (NBC)

The first step in developing appropriate policies, regulations and procedures for the regulation of biotechnology is to establish a National Biosafety Committee (NBC) under the supervision of the Environment Quality Authority (EQA). The NBC should then move quickly to establish policies and procedures to govern the use of modern biotechnology and its products in Palestine.

NBC responsibilities

The NBC Responsibilities and Powers are to:

- Formulation of the national biosafety policy and guidelines;
- Updating, development, and execution of the national biosafety legislations and regulations;
- Applications approval or rejection for importing, exporting and/or using LMOs and their products;
- Leading the national authorities and co-ordinate the efforts in an emergency created by the release, whether intentional or unintentional, of a LMO into the environment, and/or of an unintentional trans-boundary movement of a LMO;
- Guiding the capacity building of governmental authorities and institutions that are responsible for biosafety and for the development of modern biotechnology in the country;
- Periodically assess biosafety criteria and review decisions on import, export and/or domestic use of LMOs and their products;
- Monitor domestic handling and use of LMOs and their products and assure appropriate application of all procedures;
- Provide the national focal point for the Biosafety Clearing-house with all information on its decisions on import and domestic use of LMOs and their products and any other information required; and disseminate information on biosafety issues at the national level;
- Inform the public of planned releases of LMOs and their products, promote public participation in decision-making concerning GMOs, and generally promote public awareness of biosafety issues;

- Report at least annually to the Government.
- Providing guidance for safe use of modern biotechnology;
- Establishing and monitoring the implementation of policies and procedures for the purpose of handling LMOs; and
- Assesses any risks posed by LMOs and products of LMOs;
- Determining the classes of Biosafety Levels (BSL) for contained use activities for the purpose of modern biotechnology research and development and decides on all applications and matters relating to the release and import of LMOs as well as notifications in relation to export, contained use and import for contained use of LMOs;
- Promotes research, development, educational and training activities relating to biosafety;
- Establishes mechanisms to facilitate the collection, storage and dissemination of data relating to biosafety; and performs, or provide for the performance of, obligations arising from agreements, conventions or treaties relating to biosafety to which Palestine is a party, if directed by the Minister to be harmonized with national legislations.

Members of the NBC

The NBC consists of the following members and representatives:

- Environment Quality Authority (Chairman)-headed by the Minister
- the Ministry of Agriculture (MOA);
- the Ministry of Health (MOH);
- the Ministry of finance and planning
- the Ministry of National Economy
- the Ministry of Higher Education
- the Ministry of Education
- the Ministry of Interior
- Palestine Standards Institution
- National Agricultural Research Center (NARC)
- Agricultural Engineering Association
- Consumers Protection Association
- Union of Agricultural working committees (UAWC
- Palestine Polytechnic University (PPU):Palestine-Korea Biotechnology Center
- Bethlehem University: A-Medical Laboratory Sciences Department, and B- the UNESCO Biotechnology, Educational and Training Center.
- Arab American University: Biology and Biotechnology Department
- Biodiversity & Environmental Research Center (BERC). Biodiversity and Biotechnology Institute (BBI).

Technical advisory sub-committee

The NBC have the authorities and rights to establish other technical advisory sub-committees, as needed, to review all technical activities regarding LMOs. These sub-committees should include and consist of experts from various science-based and other relevant disciplines experts including but not restricted to the following fields:

- Molecular Biology.
- Animal and/or plant biotechnology.
- Animal and/or plant breeding.
- Genetics and genetic engineering.
- Food and/or environmental microbiology.
- Biosafety.
- Agronomy and/or crop physiology.
- Biochemistry.
- Virology.

Relevant authorities and stakeholders

These include the environment police, borders' customs, experts of risk assessment and biosafety, Ministry of Agriculture and Ministry of Health. These authorities have to cooperate with NBFP of the EQA to implement and accomplish the following tasks:

1. Control and inspect the movement of LMO, GMO and product thereof through the borders and inform the NBFP of such events and violations if any.
2. Inspect for the unintentional release of LMOs into the environment and inform the NBFP of such events.
3. To implement risk assessments of LMOs, GMO or products thereof when requested by the NBFP or the NCB.
4. To assist the NBFP in the inspection of the compliance of biosafety measures at the research institutes, companies, the markets and fields handling LMO, GMO and products thereof.

Risk Assessment

The major milestone of this assessment is to recognize and asses the possible negative outcomes of LMOs release into the Palestinian environment on the protection and maintaining of biodiversity and public health. This risk assessment is intended to help the authorities in reaching into solid and informed decisions related to import, use and release of LMOs.

Principles of the risk assessment

1. Transparency: the assessment should be conducted based on well-defined scientific facts and should consider the well-known international guidelines and relevant expertise. In cases where the scientific knowledge are not present, assessment of risk should not be conclusive whether as risky, acceptable risk or no risk unless enough data are provided.
2. Individuality/privacy: Each case should be evaluated separately depending on the kind of LMO, its intended use and kind of genetic modification, etc.

3. Comparison to negative control: assessments of LMOs and other biotechnology products including GMO-FPP should be compared to the risks of their unmodified parental organisms in the receiving environment.

Assessment procedure/guidelines

1. Collect all the available data regarding case under evaluation. Use the application Forms 1 or 2 for this purpose. Depending on the case, ask for additional needed data if not available and provide the applicant with an acceptable frame of time to obtain the requested information. In other cases, disregard irrelevant information. The additional data may include part or all of the followings:
   a) Identity, origin and host range of the vector.
   b) Name, sequence and function of the inserted nucleic acid.
   c) Knowledge on the biological differences between the LMO and the parental organism.
   d) Location, geographical, climatic, ecological characteristics of the receiving environment.
   e) Biodiversity of the receiving environment if available.

2. In addition to the basic information requested in the previous point, the following steps should be followed to help achieve a comprehensive evaluation of the risks:
   a) Recognition of any unique genotypic and phenotypic characters associated with the LMO that may have possible unfavorable effects on biodiversity and public health in the receiving environment.
   b) Evaluation of the possible consequences and thereof estimation of the overall risk of these negative effects on the public health and the biodiversity of the receiving environment.
   c) Provide advice on the level of the identified risks and propose relevant approaches to manage and control them.
   d) If the level of risk can't be precisely determined, additional relevant information should be requested from the applicant and an in-filed monitoring and risk assessment strategies should be applied.
   e) The applicant should provide when available, reliable methods for the detection or identification of the LMO.

Monitoring and Enforcement

Principles of Monitoring

A successful monitoring of LMOs should have definite objectives and scientifically-based design. Adequate knowledge on the receiving environment and the released LMO must be

utilized to build the monitoring plan. In addition, the monitoring process should be implemented during and after the release of the LMO and should last from 5-15 years depending on the life cycle of the released LMO. Moreover, the monitoring should ensure that genetic modifications will not be transferred from the LMO to their wild or cultivated relatives.

Providing that several monitoring methods are available internationally, the selection of the appropriate method should be based on its practicability, cost, applicability, reproducibility and convenience. It should be pointed out that different LMOs necessitate the implementation of different methods based on the LMO nature and intended application. Although the monitoring process could be carried out by the user of LMOs or any other governmental or non-governmental body, the EQA should supervise and manage the process. It is the responsibility of the monitor to detect and report on any unintentional or unsafe outcome of the monitored LMO on biodiversity and human health to the supervisor. The EQA supported by the NBC should provide the monitor with the effective measures to control such impacts.

Technical Methods for Environmental Monitoring

The most applied monitoring methods for different LMOs are summarized in table 5 below:

Table 5: A summary of the methods for environmental monitoring of LMOs.

Technical method	**Genetically modified organism**			**Details of method**
	Animal	**Plant**	**Micro-organism**	
Direct observation		✓		Morphological, physiological, biochemical & microbiological identification.
Biological sampling		✓		Genetically modified plants are surrounded by cultivated native plants to prevent the escape of transgenic pollens.
Indirect method		✓		Are used to measure the dispersion of transgenes based on the distribution of gene types in the population used to deduce the possible model of gene flow.
Sampling	✓			A population of natural species is captured & tested for LMOs or transgene escape.
Genetic test	✓	✓	✓	Marker-assisted molecular or phenotypic detection of LMOs or transgenes.
Microscopic examination			✓	Identify the modified microorganism under the microscope.
Numeration			✓	board numeration, maximum possible numeration

CHAPTER IV

Emergency Preparedness and Response Procedures for Disaster Involving Genetically Modified Organisms in Palestine.

Background

Within the auspices of the United Nations Environment Programme, the Convention on Biological Diversity was adopted in 1992. The Convention aims to ensure that the earth's natural resources are not depleted to the point that they can no longer replenish themselves. Biological diversity directly contributes 40% to the global economy. On September 11, 2003, the Protocol to ensure the safe care, transport, and use of living modified organisms (LMOs) arising from modern biotechnology went into effect. It seeks to ensure their proper care and use with appropriate environmental and human health safeguards. The Protocol, effective since 2003, is an international document that supplements the Convention on Biological Diversity. The United Nations Environment Program has urged all Parties to take action to carry out their commitments under the Protocol.

Palestine, as a Convention member, is also a signatory to the Cartagena Protocol. This requires any operator to do business in the country as long as it complies with the rules. In addition, clear guidelines on how to handle accidents that involve LMOs should be available.

Objectives

The Biosafety Emergency Response Procedures act as a checklist for dealing with LMO-related disasters. They are designed to guide operators in the case of an accidental incident that may be hazardous to the atmosphere or human health.

The Emergency Response Strategy

The stages of the emergency response strategy from the preparedness through the response and recovery to the rehabilitation are explained below and summarized in Figure 13.

1. **Preparedness**

Preparing for emergencies means identifying high risk or critical danger points in the LMO's flow and compiling a list of potential accidents. Readiness for emergency also employs compiling a complete list of appropriate departments to be contacted in the event of an incident, as well as their contact information. It also requires defining all appropriate equipment/facilities and inspecting them on a regular basis to ensure they are in good shape to respond to emergent situations.

2. **Response**

The protocol to implement in the case of an incident should include immediate warning of appropriate parties and protections of life and property. In addition, it should involve immediate

and long-term evaluation of the location where the incident/damage happened and reporting to the relevant authorities.

3. **Recovery**

In the case of an accident, all potentially hazardous materials must be reclaimed. This involves determining the scope of the spread, mapping the affected area, rescue material as possible with the risk control strategy and reporting to the appropriate authority.

4. **Mitigation or Rehabilitation**

Based on the results of the response and recovery measurements, actions should be planned to initiate a quick or long-term mitigation/rehabilitation process. This might necessitate the involvement of the relevant stakeholders and the requirement for various resources. By the end of this stage, a full report of the event including evaluation of the undertaken Emergency Response Procedures (ERP) should be prepared and submitted to the NBFP.

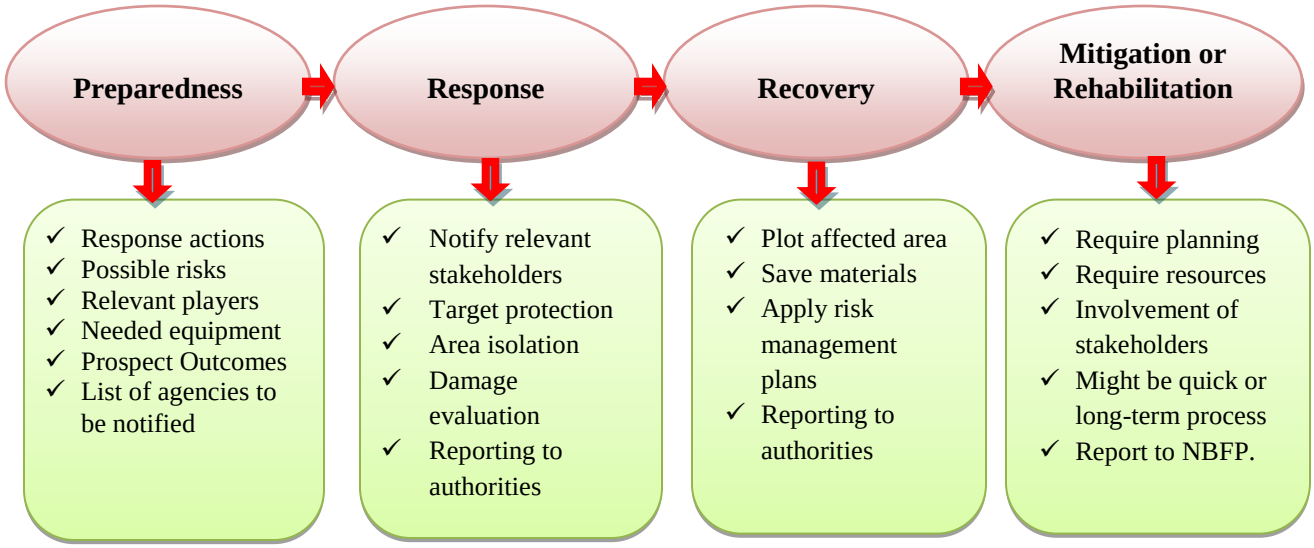

Figure 13: Stages of the emergency response strategy.

Emergency Response Procedures

The Cartagena protocol and its Regulations require that various Emergency Response Procedures be followed in the different cases involving a GMO. For each of the following cases, a suitable ERP is recommended:

- GMOs for confined field trials (CFTs)
- GMOs for release into the environment
- GMOs for import, export and transit
- GMO intended for food, feed and for processing
- Unintentional release into the environment

Having an emergency response strategy/procedure by the operator or the biosafety stakeholder is a prerequisite before starting any of the above events in Palestine. The NBFP/EQA is responsible

for monitoring the implementation of the operator's procedures described below. An emergency inspection checklist to follow up such cases is attached as annex 3.

Upon completion of any of the procedures described below, the EQA will analyze the collected information and provide the operator with recommendations to avoid similar accidents in the future. The EQA may ask the operator to pay any or all of the costs incurred because of the accident.

EPR for confined field trials

Preparedness Plan

a) The operator must provide a practical training for his staff on the safe use of GMO, how to respond to emergencies and utilize the appropriate equipment as well as how to implement the standard operating procedures. The staff should be able to distinguish GMO from natural organisms. Staff members should be aware of their roles in cases of accidents.
b) The operator and his staff should identify and properly store the equipment needed for handling emergency events.
c) Ensure that adequate security is in place including fencing and security personnel to restrict access to the area in case of accidents.
d) All GMO related products including seed and harvest must be stored in a secure defined area.
e) Identify the shortest route for the transportation GMO and products thereof.
f) The operator should regularly identify and monitor high-risk point.

Response Plan

a) Inspect the site immediately and provide the NBFP at EQA within one hour with the following information:
    i. The nature and possible causes of the accident.
    ii. The identity and quantity of the GMO.
    iii. The possible impacts of the accident on public health or the environment.
    iv. Possible measures to be conducted.
b) Instantly evacuate everybody and close off the affected area.
c) Inform related emergency authorities of the accident.
d) Apply the available emergency measures.
e) Submit a detailed report to the EQA.

Recovery Plan

a) Determine the geographic range affected by the accident and rate of spread.
b) Collect the contaminant GMO material as possible and store it in a safe place until proper disposal.

Mitigation Plan

a) Improving security if the incident was a result of inadequacy of the security system.
b) Holding any suspicious people or animals under quarantine until they are declared clean and free of contaminant GM content.
c) Analyzing the incident report in order to enrich the emergency response strategy.

ERP for GMOs/LMOs for release into the environment

Preparedness Plan

a) Train the relevant stakeholders, particularly the local authorities and farmers, on the identification of GMOs from natural organisms.
b) Provide accessible facilities and equipment to store and contain released GMO.
c) Maintain a contact list of all relevant stakeholders for emergency cases.
d) Maintain appropriate farming measures to prevent contamination or mixing of non-GMO and GMO plants. Keep adequate distance between the two farms.
e) Establish and maintain an appropriate record of your data.

Response Plan

Follow the same responses indicated for contained field trials (above).

Recovery Plan

a) Determine the geographic range affected by the accident and rate of spread.
b) Cooperate with the local relevant stakeholder in the recovery process.
c) Contain the GMO, prevent further spread and store it in a safe place until proper disposal.

Mitigation Plan

a) Properly dispose the collected GMO.
b) Perform a health survey of all involved beings.
c) Monitor the area of incident for 3-4 months.
d) Submit a detailed report to the NBFP and utilize it to enrich future preparedness plans.

ERP for Import, Export and Transit of GMOs/LMOs

Preparedness Plan

a) Identify the shortest route for the transportation GMO. Ensure all utilized vehicles are legal, safe, insured, GMO-labelled and have accessible maintenance record.
b) All consignments must have an import permit and other relevant documents.
c) Drivers should be informed on risks associated with the consignment and should be trained on responding in cases of emergencies/accidents.
d) Maintain a contact list of all relevant stakeholders for emergency cases.
e) Operator should have a tracking system for the vehicles along the transportation route.

Response Plan

Follow the same responses indicated for contained field trials (above). Additionally, the operator should conduct all possible short, medium and long-term measures to prevent the prospected drawbacks of the accident. He should also set a plan to pursue any missing product.

Recovery Plan

Follow the same recovery plan describe above for GMOs/LMOs for release into the environment.

Mitigation Plan

a) Clean the accident site and properly dispose the collected contaminants.
b) It is the operator responsibility to compensate any affected party.
c) Submit a detailed report to the NBFP and utilize it to enrich future preparedness plans.

ERP for GMOS Intended for Food, Feed and for Processing

Preparedness Plan

a) The operator shall maintain a traceable record of the GMO or products thereof.
b) The operator shall have a system to ensure the separation of GMOs and non-GMOs during the processing, packaging, transportation and storage.
c) Trained personnel and needed equipment for handling shipped GMO shall be identified.
d) Maintain a contact list of all relevant stakeholders for emergency cases and a system for the dissemination of emergency information to relevant stakeholders.
e) Maintain procedures for disposing waste by products emerging from GMO processing.
f) The operator shall have a storage facility for GMO waste by products until disposal.

Response Plan

Since GMO-FFP might constitute health risks to human and animals, the response plans of the operator might not be adequate. In such cases, the EQA shall interfere and apply all or part of the following measures:

a) Prevent the placing on the market or use of the suspected food or feed.
b) Inform all affected parties about the product including retailers and consumers.
c) Removing the product from the market.
d) Any other proper temporal measure.

These measures might be canceled or extended as soon as the emergency case is no longer valid. EQA shall publish a justification for conducting any of these measures through their website or other media tools.

If GMO and non-GMO products were not properly separated, monitoring through testing shall be conducted to eliminate chances of contamination.

If the operator suspect that the consignment does not fulfil the related safety obligations, he shall activate the process of withdrawing the product from the market and inform the EQA and consumers for the reason of his act.

Recovery Plan

Determine the affected areas and collect all distributed GMO-FFP.

Mitigation Plan

Properly destroy the GMO and follow steps b and c of the mitigation plan of the ERP for Import, Export and Transit of GMOs/LMOs.

ERP for Unintentional Release into the Environment

Sources of GMOs that unintentionally released into the environment include GMOs from laboratories, storage and contained facilities, theft, escaped due to fire or structural instability, and invasive GMO, as well as those released during transportation or by terrorists.

Preparedness Plan

g) Operator should inform relevant stakeholder of possible risk associated with his GMO.
h) The conditions of the handling facilities should be suitable for the GMO and periodically inspected and evaluated.
i) The operator and his staff should identify, properly store and have access to the equipment needed for handling emergency events.
j) Ensure that adequate security is in place including fencing and security personnel to restrict access to the area in case of accidents.
k) Identify the shortest route for the transportation GMO. Ensure all utilized vehicles are labelled.
l) Maintain a contact list of all relevant stakeholders for emergency cases.
m) The operator should prepare risk assessment tools including protective equipment and safety data sheets.
n) Provide access to this preparedness plans to your staff and all relevant stakeholders.

Response Plan

Follow the same responses indicated for contained field trials (above). Additionally, provide the NBFP/EQA with the site of accident and an evaluation of the degree of damage. If the operator is not yet known by the EQA, the police and related authorities should identify the operator, assess the damage and inform the EQA which in turn shall:

o) Define the proper response measures and contact the operator to implement them instantly.
p) If the operator refused to implement the response measures, the EQA has to do that on the expense of the operator.

Recovery Plan

Follow the same recovery plan describe above for GMOs/LMOs for release into the environment.

Mitigation Plan

Clean the accident site and properly handle and dispose the collected contaminants.

Awareness on the emergency response procedures

The EQA will make every effort to make these protocols known to all operators and other related stakeholders. Stakeholders must domesticate relevant sections based on their planned GMO operations and create their own emergency response plans, which they must submit to the EQA. Stakeholders will be expected to ensure that their employees are qualified/trained on emergency response plans.

CHAPTER V

Raising public awareness, education and participation.

Background

Palestine is a highly rich biodiversity region compared to other countries. This enormous biodiversity is associated with the presence of 5 climate zones, more than 25 soil types, and being on a cross road among three continents. The Palestinian biodiversity has been threatened by several factors including urbanization, Israeli settlements, overgrazing, etc. According to the Convention on Biological Diversity (CBD), the public should not be only aware of the potential risks to biodiversity but also shall participate in the protection of these valuable genetic resources. With the advance of biotechnology, the release of LMOs into the environments has been identified as a potential risk factor to biodiversity. On the other hand, the emerging practical benefits of the use of LMOs should not be neglected. For example, bio-control agents and genetically modified crops for resistance of agricultural pests have reduced the use of pesticides, contamination of underground water, as well as the cultivation costs. On the other hand, the high yield associated with such modified crops has relatively increased topsoil erosion and drought. Therefore, raising the public awareness on biotechnology, biosafety and biodiversity through educational programs as well as providing the public with access to the relevant information would facilitate their participation in the process to achieve the best choices on the use of modern biotechnology and maintain the national biodiversity. Particularly, this would also facilitate the evaluation process concerning the release of LMOs into the environment.

Scientists have addressed two main concerns about the release of LMOs. First, there is a possibility that the recombinant genes might be transferred from the LMOs to their native counterpart species. Second, native species might become endangered since they would be most likely less competent commercially compared with LMOs. These two factors would negatively affect the national biodiversity. Therefore, the release of LMOs should be accompanied by national programs that ensure the protection of the biodiversity of the native species. This could be achieved by prohibiting the release of LMOs into areas of wild relatives and areas of high biodiversity and restrict their release into restricted areas under governmental control.

Components of the public (stakeholders)

The public or stakeholders include all citizens, groups, NGOs, organizations, government and the private sector that might be concerned or affected by implementing the Cartagena Protocol of the CBD in Palestine (Figure 14). Participation of the stakeholders involves all the processes leading to decision making including consultation, designing and reviewing strategies, as well as direct engagement in the project. The main goal of such participation is to reach into the best decisions concerning the safe use of biotechnology particularly LMOs and GMOs in the country following CBD regulations. The components of the public are categorized below:

- **Government:** include the agencies that are directly involved in implementing the CBD and those who might be affected by its implementation.
- **Private sector:** include the private industrial sector and investors. This category might help implement this convention to improve their economic status through investments applying advance biotechnological techniques.
- **Community:** this is the largest category and includes individual citizens, politician, religious, municipalities, academic and researchers, agricultural NGOs and unions as well as media. This category is enriched with experts in biotechnology such as researchers and members of NGOs who could participate in the evaluation and implementation of this convention. Other members, i.e. media can participate in data collection and publishing to be available to all other stakeholders.
- **International donors and NGOs:** this category has been actively involved in the Palestine. It includes donors with special interest in the Palestinian biodiversity.

Figure 14: Components of the public (stakeholders).

Justification of public involvement

The public categories described above show that most of the Palestinian population could be positively or negatively affected by implementing the CBD in Palestine. Therefore, all impacts of the convention on the environment, flora, fauna and people must be identified and evaluated through discussions involving all stakeholders. Moreover, the socioeconomic impacts including public health, lifestyles, and economy shall not be neglected. Altogether, stakeholders could better cooperate to evaluate the prospective impacts, put in place monitoring mechanisms and assist in decision making. In general, the involvement of the public in the implementation of the CBD could be justified by three reasons. First, as a democratic society, all Palestinian citizens have the right to participate in this convention. Second, the international standards as well as the CBD require the involvement of the public in such conventions. Needless to say, that such step would facilitate attracting funds to implement the conventions and would also reflect the transparency of the Palestinian authorities worldwide. Third, public participation would lead to better decisions and smooth and safe implementation of the convention.

Benefits of public participation:

Public participation in the implementation of the CBD convention is a win-win situation. The benefits to the government include; first, the recognition of the public priorities, concerns, and benefits as well as a comprehensive identification of the threats to the convention. Second, avoid conflicts with the public by increasing their accountability to the decisions. Third, decrease chances of inferior decisions that would increase the costs of implementation. Fourth, promote community development and democratic values, a shared benefit with the public. On the other hand, the public will benefit in several ways including; first, get access to all information about the convention and the associated impacts. Second, acquire participation skills and practice their right in decision making. Third, diminish the drawbacks of implementing the convention through active participation and presentation of their opinions, fears and values. These benefits are summarized in figure 15.

Figure 15: A summary of the benefits of public participation.

Faces of public participation

The involvement of the public in the convention could be conducted at three levels; education, consultation to collect ideas, and participation in the decision making process. Stakeholders could be informed about the convention through media (TV, radio, newspapers), newsletters, brochures, and lectures at schools, universities and municipalities. Valuable ideas could be collected from the stakeholder through workshops, interviews, surveys, and public meetings. Finally, advisory and monitoring committees could be assembled to review and evaluate the decisions.

Indicators of success

Listed below are some indicators of the success of public participation in the implementation process of the convention.

- Public participation including their concerns, values, comments, and advises should be reflected on the outputs of the national biosafety system.
- Females, persons with physical disabilities, and illiterate persons should not be excluded from participation.
- A transparent process provides all stakeholders with access to all information and decisions.
- Stakeholders should have enough time to read and discuss the information and present their views.
- Feedback and responses to the public shall be provided when requested.
- Times and places of educational and other activities shall suit the majority of the stakeholders at the lowest possible costs to the participants. Ensure that affected groups are participating.
- Do not ignore the opinions of the others even if their views cannot be adopted. Make sure to scientifically and logically explain to them the negative impacts of these views without hurting their pride.

Mechanisms for public participation

As a summary, public participation could be optimized by three means as shown below and in figure 16:

1. Education: strengthen the public awareness. This could be achieved through the use of the various media such as TV and radio programs, newspapers, brochures, etc. Also, the facilities at the municipalities, universities, schools, NGOs, unions, and clubs could be utilize to accommodate seminars, workshops, brain storming and practical sessions on biosafety. Social media and governmental websites particularly that of EQA could also be utilized to outreach the public through publications, animations and recorded demos. Furthermore, sessions on biosafety should be integrated in the universities schools curricula.

2. Providing the public with access to biosafety information. The public should be informed about the various activities related to the CBD and have access to this information. This could be facilitated through media announcements, EQA website, and official newspapers. A formal Biosafety newsletter could be established by the EQA and published periodically. The local communities could be outreached through their municipalities. Additionally, concerned stakeholders shall have an access to the data published at the BCH.

3. Integration of public input into decision making particularly in issues concerning release of LMOs and use of GMOs. Public suggestions, comments and advises could be received through the EQA website feedback button that shall be established and by building a database for concerned stakeholders. Feedback on public input could be announced in the formal newspapers.

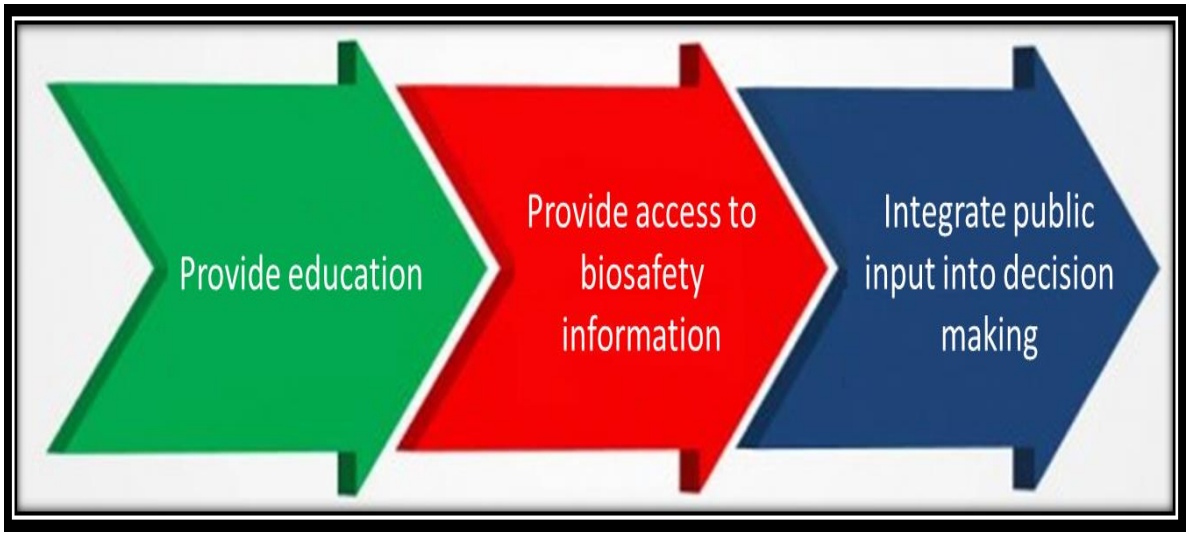

Figure 16: Mechanisms of public participation.

Annexes:

Annex 1: Rosters of National Scientists Involved in Biotechnology Research in the West Bank & Gaza strip/Palestine

Sector	Researcher Name	Address	Degree and Rank	
1. Genetic Engineering and Molecular Biology	Yamen Hamdan	Faculty of Agricultural Science and Technology/ Palestine Technical University-Kadoorie (PTUK). y.hamdan@ptuk.edu.ps	Ph. D	Associate Professor
	Bilal Ghareeb	Biology and Biotechnology Department/ Arab American University Bilal.ghareeb@aaup.edu	=	=
	Munqez Shtaya	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University	=	=
	Rezq Salimia	Department of Plant Production and Protection Hebron University rezqbasheer@hebron.edu	=	=
	Hani Al-Ahmad	Department of Biology & Biotechnology/ An-Najah National University alahmad@najah.edu	Ph. D	Assistant Professor
	Rana M. Jamous	Biodiversity & Environmental Research Center-BERC/Till rana.jamous@berc.ps	=	=
	Sami Yaish	Department of Biology & Biotechnology/ An-Najah National University syaish@najah.edu	=	=
	Heba Al-Fares	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University heba-alfares@najah.edu	=	=
	Imad Matook	Faculty of Science & Technology/Al-Quds University	=	=

		imatook@staff.alquds.eud		
	Omar Hamarsheh	Faculty of Science & Technology/ Al-Quds university ohamarsheh@gmail.com	=	=
	Siba Shanak	Biology and Biotechnology Department/ Arab American University Siba.shanak@aaup.edu	=	=
	Rolla Jadallah	Biology and Biotechnology Department/ Arab American University Rolla.jadallah@aaup.edu	=	=
	Mohannad M. Khader	Faculty of allied medical Sciences/ Arab American University	=	=
	Fadel A. Sharif	Faculty of Science, Islamic University of Gaza fsharif@iugaza.edu.ps	Ph.D	Professor
	Salah Y. Abu-Jadallah	Faculty of Science, Islamic University of Gaza sjadalla@iugaza.edu.ps	=	Assistant Professor
2. Veterinary Medicine and Animal Production	Jamal Abo Omar	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University aboomar57@najah.edu	Ph. D	Professor
	Jihad Abdallah	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University jmabdallah@najah.edu	Ph. D	Associate Professor
	Rateb Othman	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University r.othman@najah.edu	=	=
	Adnan Fayyad	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University adnanf@najah.edu	Ph. D	Assistant Professor
	Maen Helmi Samara	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University samaram@najah.edu	=	=
	Hatem Atalla	Faculty of Agriculture and	=	=

		Veterinary Medicine/ An-Najah National University hatematalla@najah.edu		
	Nimer Khraim	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University nkhraim@najah.edu	=	=
	Sameh G. K. Abuseir	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University sameh.abuseir@najah.edu	=	=
	Robin Abu Ghazaleh	Palestine-Korea Biotechnology Center/PPU Robin.abughazaleh@ppu.edu	=	=
	Ibrahim Alzuheir	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University ibrahimzuhair@najah.edu	=	=
3. Solid Waste and Wastewater Management	Issam Al-Khatib	Institute of Environmental and Water Studies/BirZeit University ikhatib@birzeit.edu	Ph. D	Professor
	Rashed Al-Sa`ed	Institute of Environmental and Water Studies/BirZeit University. rashed.alsaed@gmail	=	=
	Maher Al-Jabari	Department of Environmental Engineering Technology/PPU mjabari@ppu.edu	=	=
	Maher Abu-Madi	Institute of Environmental and Water Studies/BirZeit University abumadi@birzeit.edu	Ph. D	Associate Professor
	Nidal Mahmoud	Institute of Environmental and Water Studies/BirZeit University nmahmoud@birzeit.edu	=	=
	Alfred Abed Rabbo	Water & Soil Environmental Research Unit/Bethlehem University abedrabo@bethlehem.edu	=	=
	Khaldoun Rishmawi	Applied Research Institute Jerusalem	Ph. D	Assistant Professor

		rishmawi@umd.edu		
	Ahmed A. Abu Shaban	Faculty of Agriculture & Veterinary Medicine, Al-Azhar University, Gaza ahmedschaban@gmail.com	Ph. D	Associate Professor
	Jamal Mohamed Safi	Faculty of Agriculture & Veterinary Medicine, Al-Azhar University, Gaza eprigaza@palnet.com	Ph. D	Professor
4. Bioinformatics	Yaqoub Ashhab	Palestine-Korea Biotechnology Center/PPU yashhab@gmail.com	Ph. D	Associate Professor
	Fouad Zahdeh	Faculty of Science/Bethlehem University	Ph. D	Assistant Professor
5. Genetics and Human Heredity Disorders	Moien Kanaan	Heredity Research Lab/Faculty of Science/Bethlehem University mkanaan@bethlehem.edu	Ph. D	Professor
	Hisham Darwish	Department of Medical Laboratory Sciences/Arab American University Hisham.darwish@aaup.edu	=	=
	Hashem Shahin	Faculty of Science/Bethlehem University hshahin@bethlehem.edu	Ph. D	Associate Professor
	Mahmoud Srour	Department of Biology and Biochemistry/Birzeit University msrour@birzeit.edu	=	=
	Maysa Azzeh	Medical Research Center/ AlQuds University	Ph. D	Assistant Professor
	Suhair Hamameh	Faculty of Science/Bethlehem University slolas@bethlehem.edu	=	=
	Ramez Zaid	Basic Medical Sciences Department/ Arab American University Ramez.Zaid@aaup.edu	=	=
	Abdalla Asaf Abed	Faculty of Science, Islamic University of Gaza aabed@iugaza.edu.ps	=	=
	Mahmoud Sirdah	Faculty of Science, Al-	Ph. D	Professor

		Azhar University, Gaza sirdah@alazhar.edu.ps		
	Basim M. Ayesh	Faculty of Medical Sciences, Alaqsa University, Gaza bm.ayesh@alaqsa.edu.ps	Ph. D	Associate Professor
6. Biological Control and Integrated Pest Management (IPM)	Mazen Salman	Palestine Technical University m.salman@ptuk.edu.ps	Ph. D	Professor
	Yacoub Battah	AnNajah National University	=	=
	Radwan Barkat	Hebron University radwanb@hebron.edu	=	=
	Ruba Abu Amsha	National Agricultural Research Center	Ph. D	Assistant Professor
	Tawfiq Qubbaj	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University agri@najah.edu	=	=
	Mohammed Mahassneh	Environment Quality Authority	Ms.C	
7. Cytogenetics	Mazin Qumsiyeh	Faculty of Science/Bethlehem University mazinq@bethlehem.edu	Ph. D	Professor
8. Plant and Environmental Biotechnology	Mohammed S. Shtayeh	Biodiversity & Environmental Research Center-BERC/Till shtayyeh@gmail.com	Ph. D	Professor
	Omar Dar-Issa	UNESCO Biotechnology Research and Educational Center/Bethlehem University odarissa@bethlehem.edu	Ph. D	Associate Professor
	Raed Alkowni	Department of Biology & Biotechnology/ An-Najah National University ralkowni@najah.edu	=	=
	Abboud Y. El Kichaoui	Faculty of Science, Islamic University of Gaza akichaoi@iugaza.edu.ps	Ph.D	Assistant Professor
	Tarek El-Bashiti	Faculty of Science, Islamic University of Gaza tbashiti@iugaza.edu.ps	=	=
9. Marine	Kamal Jadallah Elnabris	Faculty of Science, Islamic University of Gaza	=	=

Biotechnology		elnabris@iugaza.edu.ps		
10. Molecular Microbiology	Ghaleb Adwan	Department of Biology & Biotechnology/ An-Najah National University adwang@najah.edu	Ph. D	Professor
	Ahmad Amro	Faculty of Pharmacy /Al-Quds University aamro@pharm.alquds.edu	Ph. D	Associate Professor
	Sabri Naser	Department of Biology & Biotechnology/ An-Najah National University sabri.mnaser@najah.edu	Ph. D	Assistant Professor
	Walid Basha	Faculty of Medicine and Health Sciences/An-Najah National University wbasha@najah.edu	=	=
11. Food Science and Technology and Medicinal Plants	Hilal Zaid	Biology and Biotechnology Department /Arab American University Hilal.zaid@aaup.edu	Ph. D	Professor
	Monzer Fanun	Department of Food Science, Faculty of Science and Technology/ Al-Quds University. fanunm@gmail.com	=	=
	Jamil Harb	Department of Biology and Biochemistry/ BirZeit University jharb@birzeit.edu	=	=
	Ibrahim M. Abu-Reidah	Biology and Biotechnology Department /Arab American University	Ph. D	Assistant Professor
	Claude ElAma	Department of Food Science, Faculty of Science and Technology/ Al-Quds University. elama@staff.alquds.edu	=	=
	Ibrahim Afaneh	Department of Food Science, Faculty of Science and Technology/ Al-Quds University. iafaneh@staff.alquds.edu	=	=
	Ghadeer Omar	Department of Biology & Biotechnology/ An-Najah National University ghadeeromar@najah.edu	=	=

	Saleh Sawalha	Department of Food Science, Faculty of Science and Technology/ Al-Quds University. ssawalha@ccba.alquds.edu	=	=
	Suleiman Alloussi	Department of Food Science, Faculty of Science and Technology/ Al-Quds University. loussi@staff.alquds.edu	=	=
	Ziad Ayyad	Department of Food Science, Faculty of Science and Technology/ Al-Quds University. ziad.ayyad@staff.alquds.edu	=	=
	Ola Anabtawi	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University ola.anabtawi@najah.edu	=	=
	Mohammad Sabbah	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University m.sabbah@najah.edu	=	=
	Manal Badrasawi	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University m.badrasawi@najah.edu	=	=
	Samer Mudalal	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University samer.mudalal@najah.edu	=	=
	Sabri Saghir	Nutrition and Food Technology Department/Hebron University sabrisaghir@hebron.edu	=	=
	Mohammad Altamimi	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University m.altamimi@najah.edu	=	=
	Adnan Ibrahim Al-Hindi	Faculty of Science, Islamic University of Gaza ahindi@iugaza.edu.ps	Ph.D	Associate Professor
12. Plant Tissue Culture	Hassan Abu-Qaoud	Faculty of Agriculture and Veterinary Medicine/ An-Najah National University	Ph. D	Professor

		hassan@najah.edu		
	Rami Arafeh	Palestine-Korea Biotechnology Center/PPU arafeh@ppu.edu	Ph. D	Assistant Professor
	Nasser Sholi	Faculty of Agricultural Science and Technology/ Palestine Technical University-Kadoorie (PTUK). n.sholi@ptuk.edu.ps	=	=

Annex 2: Status of National Regulations & Legislations on Biosafety

1)-Environment Quality Authority

Palestinian Environmental Law No. (7) for the year 1999 AD

The Environmental law No.7- for the year 1999 in Palestine urgently needed to be updated and modified to b harmonized with the international treaties and agreements and should provides the EQA with the authority and responsibility to control the intended release of GMOs in Palestine. This law lacks many environmental themes that should be adopted Examples of the absent themes in law no. 7 include the biosafety and biotechnology issues related to Cartagena Protocol and its provisions, the Nagoya Protocol and its provisions, and the climate change agreement (UNFCCC). Generally, the Legislation in Palestine governing the Biosafety related to GMOs/LMOs has not been included in the Palestinian environmental laws till now.

Article (5)

This law shall guarantee:

A. The right to every individual to live in a sound and clean environment and enjoy the best possible degree of health care and welfare.

B. Protection of the country's natural fortunes and economic resources, besides the preservation of its historical and cultural heritage without any harms or side effects that are likely to occur sooner or later as a result of the variant industrial, agricultural or constructional activities, with an impact on the quality of life and basic ecosystems such as air, water, soil; marine resources, animals and plants.

Chapter 5

Protection of Natural, Historical and Archaeological Areas

Article (40)

The Ministry, in coordination with competent agencies, shall prescribe bases and standards for the protection of natural reserves and national parks, monitor and declare them, and establish and designate the national parks and supervise them.

Article (41)

It is prohibited to hunt, kill, or catch the birds, marine and wild animals, and the fish specified in the bylaw of this law. Moreover, it is prohibited to possess, transport, walk with, sell or offer them for sale neither dead nor alive, or to damage their nests or the eggs.

Article (42)

The Ministry, in coordination with the competent agencies, shall specify the conditions necessary to guarantee the preservation of bio-diversity in Palestine.

Article (43)

The Ministry, in coordination with the competent agencies, shall set the bases and standers that determine the plants, wild and woodland are forbidden by these standards to be, temporally or permanently, picked up, harvested, damaged or cut off to ensure their endurance and continuation.

Article (44)

It shall be forbidden for any person to conduct activities or perform any action that may cause damage to the natural reserves, forests, public parks or archaeological sites, or affect the esthetical aspects of such areas.

Article (60)

If, as a result of violation to the provisions of this law or any regulations or resolutions issued thereupon, an epidemic illness spreads out, and that the violator could have - in the extent possible - expected such a nuisance, he/ she shall be subject to imprisonment of a period not less than 5 years and a fine of not less than ten thousand Jordanian Dinars, or one of the two penalties.

Article (71)

Any person violates the provisions in Article (41) of this law shall be punished by a fine of not less than 20 and not more than 200 Jordanian Dinars or the equivalent thereof in the legally circulated currency, and the imprisonment for period not less than three days and not more than tow weeks, or one of the two penalties.

Article (72)

Any person violates the provisions of Article (44) of this law shall be penalized by paying a fine of not less than 20 and not more than 200 Jordanian Dinars, or the equivalent thereof in the legally circulated currency, and the imprisonment for a period not less than three days and not more than one month, or one of the two penalties.

2)- Agricultural Law for Palestine No. (2) for the year 2003

Decree-Law No. (14) of 2018 regarding the amendment of the Agriculture Law No. (2) of 2003, as amended

Article (10)

Article (76) of the Original Law shall be amended to read as follows:

1. The Ministry specifies and circulates standard specifications for agricultural, animal and vegetable products, both imported From them or locally produced, in accordance with the provisions of the law.

2. It is prohibited to import or transfer plant or animal agricultural products or agricultural production inputs to the State of Palestine, unless they fulfill the conditions stipulated in the legislation in force.

3. The Minister may take a temporary decision prohibiting the entry or transfer of any agricultural plant or animal products, based on the report of the technical committee formed by the Minister for this purpose.

4) Subject to what is stated in the legislation in force, if it is proven after examination that the animal or vegetable agricultural products or agricultural production inputs that were brought into the State of Palestine, whether smuggled or restricted from them, are spoiled products, they are destroyed by a decision of the Minister, at the expense of the violator The case of the damage is proven in an official report, and the file is referred to the competent court. 5) It is permissible, by a decision of the Minister, to destroy the prohibited or restricted agricultural materials if they are sound in specific cases he deems appropriate. 6) The Minister may issue a decision to destroy or sell for the benefit of the public treasury in the event that animals, products and animal wastes intended for human consumption, as well as not intended for human or animal consumption, enter in an illegal manner, at the expense of the animal owner.

Article (15)

A new article shall be added to the original law bearing Article (15) bis number, stating the following:

1. The Ministry, in coordination with the concerned authorities, may prepare sanitary and phytosanitary measures, approve, apply and review them, in order to protect the health of animals and plants from pests and diseases that may be transmitted to them or harm that may affect them from animal and plant products or from agricultural production inputs.

2. The Ministry shall, together with the competent authorities, prepare and implement sanitary and phytosanitary measures that ensure that disease is not transmitted to humans through plant and animal products and agricultural production inputs, without prejudice to any authority related to food inspection established for any government agency under the legislation in force.

Chapter II agricultural genetic resources

Article (27)

Agricultural genetic resources shall be deemed to be a property of the state and shall be subject of the principle of national sovereignty. The state shall also respect the individual property rights in the common local strains.

Article (28)

In coordination with other competent authorities, the Ministry shall conserve the agricultural biodiversity and use it in conformity with the public policy in the following manner: 1. List local genetic strains and origins. 2. Preserve and protect genes and genetic origins. 3. Adopt particular sources and mechanisms to reproduce genetic origins and strains.

Article (29)

In coordination with other competent authorities, the Ministry shall define the components of agricultural biodiversity which require urgent protection measures. In this regard, the Minister shall issue forth decisions that regulate the following issues: 1. The mechanism of preserving and regulating the database. 2. Define methods and conditions of the taking of data. 3. Define the appropriate technologies. 4. Define the processes and activities which involve or may lead to negative effects on the conservation of agricultural biodiversity as well as its permanent use

. Article (30)

The launching of living beings which are modified through biotechnologies and which pose a danger to the health of humans or animals or bear a negative impact on the environment or which may threaten the agricultural biodiversity, shall be prohibited

. Article (31)

Any material of a vegetative, animal or germinal origin or other origins which contains genetic origins may not circulated, sold, exported or disposed of without a licence from the Ministry.

Article (32)

The agricultural material, components and goods which are modified through biotechnologies may not be imported, exported, held or circulated except by a licence from the Ministry.

Article (33)

In accordance with the provisions of the Law, scientific research may not be developed and implemented nor shall the transference of biotechnologies based on genetic resources take place except by permission from the Ministry.

Article (34)

In implementation of the provisions of this Law, the Ministry shall be entitled to conclude agreements and exchange information in regard of genetic resources, agricultural biotechnologies and relevant patents. In addition, the Ministry shall have the right to exchange scientific and technical information with the signatory countries as well as develop and implement joint cooperation programs in respect of obtaining various resources and assistance thereon in a manner that does not violate the protection of intellectual rights.

Article (35)

The Minister shall issue forth instructions on the regulation of the management of agricultural biological resources in order to preserve, protect and use them in sustainable development; the conditions on obtaining licenses for the importing and transportation of genetic resources and biotechnologies; and the form of the license and payable fees. The Minister shall also be entitled to define the types, varieties and strains which are threatened of extinction.

Chapter IX penalties

Article (78)

Unless contradicting any graver penalty provided by another law, each person who contravenes the provisions of Chapters I and IV under Title One, Chapter II under Title Two, Title Three, Chapter III under Title Four, and Chapters I, II, IV and VIII under Title Five shall be punished with either or both confinement for a period not exceeding three months and financial fine not exceeding three hundred Jordanian Dinars or its equivalent in the legally circulated currency.

3)- Public Health Law for Palestine No. (20) For the Year 2004 AD

Chapter Four
Food Safety

Article 16

The Ministry demands the following from the factory or the importer of foodstuff, within a period he specifies:

1. Its chemical composition and structure.
2. Details about how they are used and exchanged.
3. A sample of these products for analysis and examination.
4. Any other information pertaining to public health.

Article 17

The Ministry, in coordination with the competent bodies, shall be responsible for the inspection of food during the exchange process, in addition to inspecting the:
1. imported food at arrival to customs and not allowing its entrance until the Ministry approves
2. locally produced foods, in their places manufacturing or preparation.

Article 18

It is forbidden to deal with foods if:
1. They were in violation with the specified standards and specifications.
2. They were hampered with in a manner that changes their nature.
3. They were not appropriate for human consumption, or hazardous to human health.

Article 19

Foods shall be deemed inappropriate for human consumption in the following cases:
1. If there was a change in its structure or natural characteristics with respect to taste or smell or shape.
2. If the analysis proved that there was a change in the chemical structure or any forbidden chemical additions that created food contamination by any chemical, biological or radial means.
3. If its expiry date stated on it, has elapsed.
4. If they were transported in unhealthy conditions or methods.

Article 20

Foods are harmful to human health in the following conditions:
1. If they were contaminated with radioactive materials or microbes or fungi or pesticides in a manner that would lead illnesses in humans
2. If they were produced from an animal infected by an illness transferable to humans or from a dead animal.
3. If their packaging or containers contain materials harmful to health.
4. If they contained hazardous chemical materials or heavy metals in excess to what is allowed that would cause diseases for human beings.

Article 21

There should be a commitment towards the specifications and conditions determined in the obligatory technical instructions issued by the standards institute in coordination with the Ministry.

Article 22

It is forbidden neither to deal with special foods nor to advertise them before their registration and the attainment of a permit from the Ministry to deal and to market them.

Article 23

1. The importer shall bear the costs of sample analysis when its entering the country.
2. The food factory shall bear the costs of sample analysis that is taken during the manufacturing process

Article 24

It is not permissible to license any individual infected with any infectious disease, to work as a food or beverage vendor.

Article 25

1. The specialized staff assigned by the Ministry have the right to examine the food samples during the exchange process
2. the samples mentioned in the previous article shall be taken according to the special instructions that are issued according to the law.

Article 26
The samples shall be analyzed and examined in laboratories determined by the Ministry. The concerned person shall be informed about the results within a period not exceeding fifteen days from the date the sample was taken.
Article 27
If, according to the apparent examination or sample analysis, it was guaranteed that the sample does not have the specifications and characteristics required, harmful to human's health, inappropriate for human consumption or cheated, the Ministry will take the needed actions in cooperation with the competent bodies, to destroy the foodstuff from which the sample was taken from on the cost of the responsible.
Article 28
For all those who deal with foodstuff, they should provide the specialized employee assigned by the Ministry with all the information and samples he/she needs in order for him/her to complete their mission in accordance with the law.
Article 29
It's not permissible that the employee assigned for inspection in a certain area to be related directly or indirectly to any foodstuff business.
Article 30
It is forbidden to hide or deal with any foodstuff seized according to law by any means possible.

4)- Palestinian Standards and Measurements Law No. (6)

Second Chapter

Article (3)
The Institute aims at achieving the following goals:
1. The adoption of certain systems for standards and measurements which are based on modern scientific basis and in line with the scientific developments in the field of standards, measurements and quality control.
2. Participating in providing the health, environmental, economical protection for the consumer through the adoption of the Palestinian standards and measurements and the issuance of the conformity marks and certificates.
3. Supporting the national economy and the economical development plans and participating in developing and rehabilitating the industry in coordination with the related institutions and bodies in Palestine.

Article (4)
The Institute shall have the following functions and powers:
1. Prepare and adopt the Palestinian standards and measurements related to goods, materials, services and other items and reviewing such standards and measurements and amending or replacing in addition to publishing them. Human and veterinary medications, vaccines and serums shall be excluded from the Institutes' scope of powers and functions.
2. Developing a national measurement system.

3. Unifying and developing the measurement methods in addition to calibrating and adjusting the measurement tools.
4. Issuing the conformity marks and certificates which are approved by the Board.
5. Adopting the national main measurement references for the calibration of measurement tools in order to stamp or brand them.
6. Approving the testing and calibration laps which are qualified and specialized in conducting the tests and analyses on goods and other materials in order to apply the related standards and measurements.
7. Approving the products' labels.
8. Cooperation with the local governmental bodies and scientific institutions in order to achieve the Institute's goals and carry out its functions and duties.
9. Support and encourage the research conducted in the approved testing and examination labs in areas related to standards, measurements and quality control, in addition to holding training sessions and programs related to the Institutes scope of work.
10. Enter into agreements with Arab, regional and international agencies, related to the mutual recognition of conformity marks and certificates, provided that such agreements include an agreement on the previous and continuing testing of the material included in the agreement, in order to make sure that it confirms with adopted technical standards and conditions.
11. Cooperating and coordinating with Arab, regional and international institutions which work in the standard and measurements field and joining such institutions.
12. Publish and distribute the publications related to standards and measurements issued by the Institute or other Arab, regional or international related bodies.

Article (17)
1. It is prohibited to import any commodity or material and enter it into Palestine or produce it in the country unless such commodity or material does confirm with the standards'' requirements specified in the mandatory technical instructions for such commodity. The Institute's President in coordination with the competent minister may exempt any commodity from the provisions of this article in special instances.

Article (22)
The Institute issues its own conformity certificates and marks and it may give any product or commodity or material inside or outside Palestine a permission to use such certificate or mark according to a regulation which shall be issued for such purpose according to the provisions of this law.

Sixth Chapter
Penalties
Article (31)
Without prejudice to any more severe penalty stipulated in any other law:
1)-. Any person who commits one of the following acts , shall be punished by imprisonment for a period not less than one month and not more than one year or by a fine not less than one thousand Jordanian Dinars and not more than ten thousand Jordanian Dinars or its equivalent in the legally circulated currency or by both penalties :

a) Manufacturing or selling or tampering with any measurement tools, with the intention to commit fraud.

b) Using any measurement tools which are not branded or stamped by the competent authorities.

c) Prevent or obstruct any of the officials who are duly authorized by the provisions of this law from finding any illegal measurement tools whether such tools belong to him/her or to anyone ells.

d) Deny any of the duly authorized officials entry to any factory or commercial store or warehouse or any other place for the purpose of inspection and monitoring.

e) Tampering with any stamp or report or certificate used by the competent authority or issued by it.

f) Tampering with the weights and sizes of materials with the intention defraud.

g) Offering materials which do not comply with the mandatory technical instructions in the markets or commercial stores.

h) Tampering with the information stated in the product's label with the intention to defraud.

i) Using the phrase "confirms with the Palestinian standards and measurements" on any commodity's label or using such phrase in any way without acquiring the Institute's written consent.

j) Any actions that would lead to defrauding or deceiving the consumers such as the misleading announcement related to the commodity or material such person may import or manufacture or offer for sale.

2)-. In case of repetition the penalty shall be doubled.

3)-. The competent authority shall have the power to publish the information of the non confirming commodities in the various media outlets.

Annex 3: Development of National Biosafety Framework for Palestine

Following the signing of the state of Palestine on the convention of Biological Diversity (CBD) including the Cartagena Protocol on Biosafety (CPB) in 2015, several achievements, activities and events have been conducted by the Palestinian Environment Quality Authority (EQA) to fulfill the requirements of the CBD and CPB. One of those obligations, yet to be achieved through this consultancy mission, is to develop a National Biosafety Framework (NBF) for Palestine and the fourth national report on Biosafety. Dr. Omar Darissa was assigned to assist in accomplishing these tasks.

As part of developing the NBF for Palestine, this short questionnaire is designed to help us collect information on the status of biotechnology research including Living Modified Organisms(LMOs)and the followed biosafety regulations at your institute.

We kindly ask you to pass this short questionnaire to the authorized offices at your institute (i.e Dean of research, Biotechnology chairperson, head of research center, etc), fill it and send back to omarissa75@gmail.com.

We thank you in advance for your help.

Name of your institute: _____

Kind of institute: ____Academic _____Research Center, ____Other; specify_____

Questions	**Yes**	**No**	**Specify**
Do you offer Biotechnology as an academic program at your institute?*			
Do you offer biotechnology **practical** courses (including molecular biology, genetics, tissue culture, etc) for your students?			
Do you conduct modern biotechnology related research at your institute? If yes, please specify the name of researchers and the title of projects they conduct.			
Do you cooperate with other international or regional institutes in the field of biotechnology?			
Did you publish any research paper in related to biotechnology or biosafety?			
Is your team well-trained/skilled to do biotechnology research?			
Is your institute well-equipped and have the infrastructure to conduct biotechnology research? Name the main equipment			

that are available at your institute.			
Do you apply recombinant DNA technology or genetic transformation in your research activities?			
Do you produce, import or host GMOs/LMOs at your institute?			
If you have GMOs/LMOs, are they contained**?			
If you have GMOs/LMOs, are they commercialized?			
If you have GMOs/LMOs, do you have a permit or license from any national or international organization to use them?			
Do you have the capacity to identify LMOs?			
Do you handle LMO-FFP at your institute?***			
Other than first aid, do you have/apply biosafety or biosecurity regulations?			
Are the regulations home-made or adopted from elsewhere?			
What level of biosafety (BLS) do you have? BLS1- BLS4.			
Is your institute part of any planned or ongoing National Projects for capacity building related to the safe use of biotechnology? If yes please specify.			

*Specify whether undergraduate or graduate program, major or minor.
**Contained in a greenhouse, field or in the laboratory.
***LMO-FFP: LMO- intended for direct use as food, animal feed or processing.

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Annex 4: Proposed by-law on biosafety

PROPOSED BY-LAW ON BIOSAFETY UNDER THE ENVIRONMENTAL Law NO.-7 CHAPTER-5

SECTION ONE

Objective, Scope and Definitions

ARTICLE 1

1) This By-Law aims at developing and incorporating a biosafety scheme to avoid possible threats from genetically modified organisms and their products acquired by modern biotechnological means within the framework of scientific and technical advancements; to protect human, animal, and plant health; and to safeguard and ensure the long-term use of the environment and biological resources.
2) The current By-Law controls and oversees all practices involving Genetically Modified Organisms and their products, including but not limited to research, production, marketing, monitoring, utilization, importation, exportation, transportation, protection, packaging, and storage.
3) This By-Law would not apply to human or veterinary medicinal products and cosmetics that have received a license or permission from the Ministry of Health.

Definitions

ARTICLE 2

1) The definitions of the terms used in the present Law are as follows:

i. **Unique identification:** A numerical and alphanumeric encoding scheme that assigns a code to each GMO, along with the code for each transferred gene it contains.
ii. **EQA:** Environmental Quality Authority.
iii. **Simplified procedure:** A simplified decision-making procedure based on current evidence and prior risk assessments showing that there is no risk that a GMO or its substance poses to human, animal, or plant health, biological diversity, or the environment.
iv. **Biosafety:** Conducting GMO-related operations in a way that protects human, livestock, and plant health, biological diversity, and the environment.
v. **Biosafety information exchange mechanism**: A framework will be developed to promote the exchange of science, technological, and practical information and documents to inform the public and facilitate their participation in national and international decision-making processes on GMOs and products thereof.

vi. **Biosafety system:** The administrative, legal, and institutional framework that ensures biosafety, as well as all activities related to it.

vii. **Biodiversity:** Intra- and interspecies differences, as well as ecosystems' variations.

viii. **Contaminants:** are materials that are not intentionally applied to food and feed but are found in the food as a result of contamination at the primary stage of manufacturing, refining, preparations, packing, packaging, delivery, or storage, or contamination from the environment.

ix. **Living organism:** Biological species that can replicate or transmit genetic material as microorganisms and sterile organisms as well as active biological objects as enzymes, viruses, virion, and viroids.

x. **Experimental release into the environment:** experimenting with a GMO in a confined area and under stable conditions to avoid contact with the surrounding environment.

xi. **Genetically Modified Organism (GMO):** Any living organism (except humans) acquired by advanced biotechnological methods of gene transfer.

xii. **GMO-derived products:** Products that are partially or entirely derived from GMOs but do not contain or consist of GMOs.

xiii. **GMOs and products thereof:** Products derived in part or entirely from GMOs and still contain or consist of GMOs.

xiv. **Interested party:** Stakeholders who are involved in practices such as research, production, marketing, control, utilization, importation, exportation, transit, transportation, preservation, packaging, and storage of Genetically Modified Organisms.

xv. **Process:** Any procedure that substantially alters the original state of a GMO or products thereof in order for them to be used as food, feed, or other uses.

xvi. **Monitoring:** All types of observation, surveillance, testing, and monitoring activities carried out at all stages of the production and delivery chain of a GMO or products thereof since it has been determined that it poses no danger to human, animal and plant health, and the biological diversity.

xvii. **Contained use**: Any activity involving GMOs that is carried out in a controlled facility or laboratory with biological, chemical, and physical safeguards in order to eliminate any possible harmful effects on human, animal, and plant health, and biological diversity.

xviii. **Decision:** Following experimental risk analyses and socio-economic assessments, the NBC made a decision on an application for a GMO or product thereof.

xix. **NBC:** The National Biosafety Committee.

xx. **Scientific committee:** The NBC appoints committees to carry out the scientific evaluations.

xxi. **Modern biotechnology:** is the use of in vitro nucleic acid techniques to enable direct transformation of cells and organelles with recombinant deoxyribonucleic acid (rDNA), or interspecies cell hybridization to surmount the natural reproductive obstacles of breeding.

xxii. **Handling:** Any operation involving genetically modified organisms, including but not limited to packaging, labelling, transfer, transportation, and storage, while taking into account the precautions necessary to protect human, animal, and plant health, as well as the biological diversity.

xxiii. **Placing on the market:** placing any of the products covered by the current Law on the market, either for a fee or for free.

xxiv. Protocol: Cartagena Biosafety Protocol to the UN Convention on Biological Diversity.

xxv. **Risk assessment:** is a four-step process that includes identifying, determining characteristics, identifying risk elements, and evaluating threats and risk sources that GMOs and product thereof can pose to animal, human, and plant health, biological diversity, and the environment using scientific methods such as experiments, evaluations, and trials.

xxvi. **Risk communication:** refers to the collaborative sharing of knowledge and views among risk assessors, risk managers, and other interested parties about hazards and threats, risk-related causes, and risk expectations during the risk analysis process, including the interpretation of risk assessment results and the rationale for risk management decisions.

xxvii. **Risk management:** is the practice of evaluating, selecting, and applying appropriate alternate preventive and control solutions in coordination with interested parties to ensure that GMOs and product thereof are used and managed in compliance with the purposes and rules defined based on the risk assessment findings.

xxviii. **Socioeconomic assessment:** Scientifically based evaluation and studies (evaluated before a decision is taken on the application) to determine the consequences and socioeconomic costs associated with the environmental release of GMOs and products thereof on biodiversity, the consumer, and the farmer.

SECTION TWO

Fundamental Principles

Application, Evaluation & Decisions

ARTICLE 3

1) Importation, exportation, experimental release into the environment, placement on the market of GMOs and products thereof, and contained use of GMOs are legitimately allowed following the results of scientific risk assessments that ensure the protection of human, animal, and plant life, as well as the conservation of the environment and biological diversity. Issued decisions on applications that are proved risk-free are valid for ten years.
2) All applications, whether by private or corporate citizens, for the importation or production of GMOs and products thereof must be submitted to the EQA. The application must be submitted before importation, release into the environment, or placing on the market of the GMO or product thereof. The content and the purpose of using the GMO or products thereof must be specified in the application. Separate applications could be submitted for multipurpose usage of GMOs and products thereof.
3) The decision on one application has no influence on the decision of another.
4) The EQA forwards all received applications to the NBC. The NBC informs the EQA whether the application is approved or rejected, as well as all other observations, within two months. Thereinafter, the applicant will be notified of the decision via the EQA within two weeks. This timeframe does not include the time it takes to present additional

information and documents. Under any situation, the time to inform the applicant of the decision shall not exceed 6 months from the time of application.

5) Applications for approval of GMOs and products thereof will be refused if the one or more of the following conditions is/are met:
   a) It poses a threat to the environment, biological diversity, and health of humans, animals, and plants.
   b) It restricts the consumers' freedom of choice.
   c) It intrudes or adversely affect the natural ecological balance of the environment.
   d) Where there is a chance of a GMO to propagate itself in the new environment unless approved by the scientific committee.
   e) It jeopardizes biological diversity's long-term viability.
   f) If the applicant lacks adequate technological ability to carry out the biosafety measures.
6) Following a formal written request by the applicant and an approval by the EQA, certain items of the application will kept confidential. However, the following information can never be considered confidential under any situation. The applicant's/importer name and address, the purpose(s) of use, attributes, identification details of GMO or product thereof, common and scientific names, the donor organism of the transferred gene, the country of origin of the receptor and donor species, description of the transformation method, emergency procedures and risk assessment.
7) Applications must contain a document approving that the GMO or products thereof is licensed for release into the environment or placing on the market for consumption in the country where it was produced or developed. The license shall be valid and the use of GMO or product thereof is still ongoing in the country of origin. The related authorities of the country of origin must specify the time since the GMO or product thereof has been on the market.
8) For each transit passage of GMOs and product thereof, a permit from the EQA is required. The EQA shall refer to the laws/regulations of the Customs, Ministries of Health and Agriculture before issuing the permit.
9) Authorized universities or research institutes must have apply for a permit from the EQA for importing, conducting scientific research and contained use of GMOs or products thereof. The whole process must be conducted according to the terms of the permit including the containment requirements and the precautions to be taken in the event of an unintended release into the environment. It is mandatory to keep the EQA up to date on the experimental work and its outcomes.
10) The NBC ensures that the scientific risk assessments and socioeconomic appraisal reports for applications for GMO or products thereof are available for the public consultation via the biosafety information exchange mechanism. The NBC must submit the evaluation report to the EQA within thirty days of their first meeting. The report must include all of the comments received during the public consultation, the favorable judgment, along with all signatures and reasons for any possible contrary votes. The NBC's decisions take effect after they are published in the official newspaper.

11) In the case that the application is rejected, the EQA will notify the applicant in writing. If new evidence becomes available that justifies a change in the decision, the applicant can request the EQA to reconsider the decision. In this situation, the NBC reviews the decision within two months, taking into account the additional evidence submitted, and notifies the EQA of the outcome for conveyance to the applicant and the public.
12) When the NBC reject the Sub-committee's recommendation, the reasons must be declared.
13) The following points have to be included in the decision:
    a) The validity period.
    b) The formalities of importation.
    c) The purpose(s) of use.
    d) Data required for risk management and market surveillance.
    e) Conditions of monitoring, documentation and labeling.
    f) Packaging, transportation and storage regulations.
    g) Requirements for waste disposal.
    h) Safety precautions and emergency procedures.
    i) Annual reporting method.
14) The applicant may apply to the EQA to extend the validity period at least one year before its expiration. The NBC evaluates the request and notifies the EQA of the outcome, who then inform the applicant of the decision. If the decision on the extension cannot be achieved within a year, the duration of the previous approval will be temporarily extended until a new decision is made.
15) A legislation establishes the protocols and principles for the execution of the present Article.

Risk assessment, socioeconomic evaluation, and risk management

ARTICLE 4

1) Each GMO or product thereof that is the subject of an application under the current Law is subjected to a risk assessment and socioeconomic evaluation based on scientific principles. If the submitted data are insufficient, the applicant may be asked to provide further research work, measurements, analysis or tests. The applicant is responsible for all costs associated with the risk and socioeconomic assessments.
2) Risk assessment will be conducted for each application independently. The applicant must submit the information needed for the assessment when requested. Such information may include nutrient analysis, toxicity and allergy tests, and field trials including laboratory, greenhouse, and field tests.
3) A socio-economic assessment have to be made to determine the impact of GMOs on the conservation of biological diversity, as well as on consumers and users. This assessment will be considered in the decision-making process.
4) Based on the outcomes of risk and socio-economic assessments, a comprehensive risk management plan for each submitted application will be prepared. Provided by general

risk management principles from the EQA, the applicant is responsible for the preparation and execution of this plan.

5) A legislation establishes the protocols and principles for the execution of the present Article.

Prohibitions
ARTICLE 5

1) The following activities involving GMOs and products thereof are prohibited:
    a) Placing GMOs and products thereof on the market without prior approval.
    b) Using or allowing others to use GMOs and products thereof in violation of NBC decisions.
    c) The development of genetically engineered plants and animals without approval.
    d) Using GMOs and products thereof for purposes and areas other than those specified by the NBC decision.
    e) Using GMOs and products thereof in baby food and formula, or in dietary supplements for babies and children.

Simplified Procedure
ARTICLE 6

1) Applications might be subjected to simplified procedures based on available prior risk and socio-economic assessments that states a GMO or product thereof poses no risk to human, animal, or plant health, the environment, and biological diversity.
2) In order to be able to apply for a simplified procedure, the application must meet the following requirements:
    a) The taxonomy and biological information of the donor and receiver organisms as well as the source of transferred gene must be known.
    b) Satisfactory knowledge about the potential impacts on human, animal, and environmental health, as well as biological diversity, should be accessible.
    c) The interaction of the GMO's with other living species must not result in any adverse effect as proven by the preceding risk assessment.
3) Detailed method for the detection of the recombinant nucleic acid in the GMO must be provided.
4) A legislation establishes the protocols and principles for the execution of the present Article.

Procedures following the decision
ARTICLE 7

1) Following the placing of GMOs and products thereof into the market, the EQA monitors and oversees if the decision's requirements are met, and whether any unexpected consequences on human, animal, and plant health, the environment, and biological diversity occur. The EQA has nominated laboratories to carry out the tests needed for this purpose.

2) In the event of a violation of the conditions specified in the decision, or the advent of new scientific evidence regarding any risks relevant to the GMO or products thereof, the NBC may rescind the decision. The GMO or product thereof in question is removed from the market after the decision is revoked. Those discovered to have harmful effects on human, livestock, plant, environmental, or biological diversity are immediately confiscated and eradicated, while those found not to have negative effects are conveyed to the public. The costs for the EQA's actions to be taken in accordance with the present paragraph, as well as other expenses, are obtained from the interests. The costs for the EQA's actions to be performed according to this paragraph are obtained from the interested parties, taking into account the tort and responsibility.
3) To guarantee traceability, declarations must be sent to the EQA, appropriate records must be kept, a copy of the decision must be made available, and labeling laws must be followed during the entry and circulation of GMOs and product thereof in the country. Each GMO and product thereof is given a unique identifier and must be registered. Documents relating to registered GMOs and products thereof must be saved for at least 20 years.
4) All GMO and products thereof must be labelled as containing GMOs.
5) Should a new risk or risk suspicion about GMOs or products thereof come to their notice, interested parties must immediately inform the EQA.
6) A legislation establishes the protocols and principles for the execution of the present Article.

SECTION THREE

Duties & Authorities of the EQA; NBC & scientific committees

ARTICLE 8

1) The EQA's responsibilities and authorities are:
   a) Providing comfortable working arrangements for the NBC and performing the NBC's secretarial functions.
   b) To collect the information and documents, as well as to perform or supervise the conduct of the research tests, field trials, and inspection and report the results to the NBC.
   c) To confirm the execution, prevention of unintended GMO contamination, monitoring, control and inspection of the procedures and formalities stated in the present Law.
   d) Empowering individual or corporate experts to carry out work on GMOs and products thereof, when needed, and supervising those empowered persons.
   e) Formulate and implement national biodiversity and genetic resource protection and utilization policies.
   f) Using the biosafety information exchange mechanism to confirm that the public is informed and participates in the decision-making process.
   g) To develop procedures and principles governing the actions of the NBC and the scientific committee.

h) To collaborate with the NBC to discourage the flow and use of GMOs and products thereof that are not covered by this Law.
i) To formulate and execute emergency response procedures, as well as to identify methods for dealing with unexpected situations affecting human, animal, and plant health, the environment, and biological diversity.
j) To develop procedures and principles for labeling of GMOs and products thereof.

2) The EQA shall collaborate with the relevant stakeholders, institutions and Ministries on the execution of this law.
3) To safeguard human, animal, and plant health, the environment, and biological diversity, the EQA is allowed to take precautionary steps and dispositions regarding products covered by the current Law, including expropriation, return of the product to its source, product disposal, prevention of supply to the market, etc.

National Biosafety Committee (NBC)

ARTICLE 9

1) The NBC is established to assess applications involving GMOs and products thereof, as well as to carry out the other responsibilities outlined in this article.
2) The NBC is made up of 15 members as follows:
   a) One representative from of each of the following Ministries; Agriculture, Health, Higher Education, Education, Finance and Planning, and National Economy.
   b) One representative from the following institutes/associations/Centers; Palestine Standards Institution, National Agricultural Research Center (NARC), Agricultural Engineering Association, Union of Agricultural Working Committees (UAWC), Consumers Protection Association and EQA.
   c) Two representatives from the Palestinian universities.
3) The Head of EQA appoints the President of the NBC. In his absence, the President of the NBC appoints a delegate to act in his place.
4) President and members of the NBC cannot be assigned for more than four years.
5) Members of the NBC shall have at least an undergraduate degree and shall have at least three years of experience in the fields covered by this Law.
6) If the NBC or any of its members are unable to fulfill their duties due to serious sickness or disability, or if they act in violation of this law, the EQA has the right to terminate their term of office.
7) The President and members of the NBC, as well as their spouses and family members up to second-degree relatives, cannot have any commercial activity or owning stock market instruments related to activities or sectors on which the NBC may make decisions. The Head of EQA immediately terminates the term of office of those that violate the provisions of this Sub-Paragraph.
8) Members of the NBC are entitled to a daily attendance fee of $100 for each meeting they attend, up to a limit of ten meeting days per year. In situations where a per diem is due, EQA is responsible to pay it following the regulations of the Ministry of Finance.

Working Principles of the NBC

ARTICLE 10

1) In carrying out its responsibilities, the NBC is independent. No entity or individual can issue orders or instructions to the NBC to influence its decisions.
2) On the President's invitation, the NBC meets with a predetermined agenda. The President of the NBC prepares the agenda for each meeting and distributes it to the members at least one week before the meeting. The conference is not deemed adjourned until any of the agenda issues have been discussed.
3) A proper meeting requires a quorum of seven members, and resolutions must be approved by a majority of five votes. The decisions are written down in the meeting minutes and signed.
4) People who miss three sessions in a calendar year without a legitimate explanation are considered resigned from the organization, and this fact is noted by a NBC vote. Members who refuse to sign the NBC resolutions in a timely manner, despite the fact that they were present at the meeting and did not cast a vote of opposition, or who fail to submit the basis of their vote of objection in writing, would be written warned. If this happens three times in a calendar year, the member is considered resigned. Such conditions must be noted and voted upon in the third meeting that the delegate missed, and the EQA must be informed.
5) Members of the NBC are prohibited from participating in discussions or voting on matters including their parents, adopted children, and consanguineous and families including second degree relations.

Duties and authorities of the NBC

ARTICLE 11

1) The NBC's responsibilities and powers are as follows:
    a) Compiling a list of experts.
    b) Creating science NBCs, whose participants are chosen from a selection of experts.
    c) For each submission, selecting members of the science committees from a selection of specialists.
    d) Making decisions as a NBC of Directors based on risk assessments and socioeconomic performance analyses.
    e) Based on the monitoring data, making recommendations to the EQA about penalties such as partial or full revocation of the decision, prohibition, and recall.
    f) Establishing the ethics committee

Formation, Duties & Authorities of the Scientific Committees

ARTICLE 12

1) A risk management committee, a socioeconomic appraisal committee, and, if appropriate, other scientific committees are formed for each application by the NBC. These commissions are made up of eleven people.

2) Members of universities and the Palestinian Scientific and Technological Research Council, as well as those serving in fields considered appropriate by the NBC, are included on the list of specialists.
3) The committees' responsibilities and powers are as follows:
    a) To decide if the knowledge given for risk management in applications submitted under the current Law is scientifically sufficient.
    b) Evaluate the assessments, studies, trials, reviews, and other actions that are needed, as well as request additional information if necessary.
    c) To write papers on risk management and socioeconomic appraisal.
    d) To shape a scientific judgment based on the evaluation of both recent evidence and knowledge that emerges or becomes available after decisions have been made.
    e) To conduct scientific evaluations, advise the NBC, and write reports.
4) The scientific assessment reports prepared by the committees are considered restricted records and cannot be shared with anybody other than the NBC. Committee members cannot be found liable for the scientific assessment results they prepare, with the exception of illegal actions.
5) In carrying out their responsibilities, the commissions are self-contained. The committees cannot be given orders or directives by any organ, office, entity, or individual.
6) Members of the committees are entitled to a regular attendance charge of US$100 for each meeting day they attend, up to a limit of 6 meeting days per year. In situations where a per diem is due, EQA is responsible to pay it following the regulations of the Ministry of Finance.
7) Members who refuse to attend two meetings on the same application without a legitimate explanation after being invited are considered resigned and replaced by a new member chosen by the NBC.

Obligation

ARTICLE 13

1) Personnel from the EQA, as well as members of the NBC and commissions, are prohibited from disclosing classified records, records, or trade secrets obtained in the course of their duties to someone other than the agencies approved by statute to do so, and they are prohibited from using them for their own or third-party gain.

SECTION FOUR

Civil Responsibility, Administrative Sanctions & Penal Clauses

Basic Principles of Responsibility

ARTICLE 14

1) Except if they have received licenses under the current Law, those who engage in actions involving GMOs or their products are responsible for damages to human, animal, and plant health, the climate, and biological diversity. This duty applies even though no harm is caused by a GMO or its substance, and is described as failing to meet the requirements specified in the application and judgment.
2) Those who engage in practices such as contained use, putting GMOs on the market for fuel, feed, refining, or use, importing and transiting GMOs and goods without a permit, and those who release GMOs into the atmosphere and manufacture GMOs are responsible for all losses arising from their actions.
3) To add a harm to GMOs, the harm must be caused by the organisms' new traits, their replication or alteration, or the transition of the organism's changed substance to other organisms. If the damage in question stems from genetic alteration in agricultural, forestry, fruit, and feed products, it is taken into account when determining blame for the damage.
4) All who cause or aggravate damages as a result of treating GMOs put on the market for some reason whatsoever in a way counter to the decision's requirements or otherwise, as well as those who commercially manufacture, process, sell, or market them, are jointly and severally liable for these damages.
5) Those that put GMOs and their goods on the market, commercially produce them, distribute them, or advertise them are required to warn one another of the potential for harm and liability.
6) Many that manage GMOs are responsible for covering the costs of the steps that must be taken in response to the risk assessment's findings in order to avoid or mitigate any potential environmental damage. Those that cause destruction are often liable for the costs of restoring degraded or lost environmental elements to their original state or replacing them with equivalent elements of comparable value.
7) The right to seek restitution for harm incurred by GMOs and GMO goods lasts for two years until the suffering party becomes aware of the harm and the name of the responsible party, and in every case for twenty years after the incident that caused the damage occurs.
8) If it is concluded that the destruction was caused by natural causes such as storm, hail, avalanche, or earthquake, or by the gross incompetence of people who sustained the damage or third parties, the above liability dispositions do not apply.

Administrative sanctions and penalties

ARTICLE 15

1) Those who contravene this law by illegally importing, producing, and releasing genetically engineered plants or animals into environment face jail sentences of five to twelve years and judicial penalties of up to 2,000 JD.

2) Under the provisions of this law, those who import, process, use, put in the market, sell, purchase for trade purposes, accept, transport, hand over GMOs or GMOs product thereof or products obtained from GMOs, are subject to prison sentences ranging from three to five years and judicial penalties of up to 3000 JD.
3) Many who obtain approval under this statute by including misleading documents in their applications are sentenced to one to three years in jail, provided that no other offense has been committed that warrants a harsher punishment. Obtaining a judgment for the importation, collection, use, placing on the market, sales, handing over, receiving, shipping, or keeping of GMO, GMO and products thereof, and products acquired from GMOs on the basis of false knowledge is punishable by the penalties mentioned above.
4) If the actions specified in this Article are performed in the course of a corporate body's operations for the benefit of the corporate body, the corporate body is subject to an administrative fine ranging from 10,000 to 40,000 JD, depending on the seriousness of the act. Security measures unique to the business body can also be implemented.
5) Applicants who refuse to meet their obligations under Article 7 of the current Law face an administrative fine ranging from 2,000 to 6,000 JD for each violation, given their acts are not liable to any other abuse.
6) Those that use GMOs and their goods in a contained use in violation of the law are liable to an administrative Fine of 2,000 JD if their activities are not subject to any other abuse.
7) The court is responsible for determining administrative penalties under paragraph 4 of article 15, and the general prosecutor is responsible for determining administrative sanctions under paragraphs 5 and 6 of article 15. The administrative Fine imposed by the law must be collected within one month of notice.

SECTION FIVE

Regulations & Final Dispositions

ARTICLE 16

1) The EQA must issue the guidelines relating to the enforcement of this Law within three months of the Law's publication date.

Effectiveness

ARTICLE 17

1) The current law becomes effective six months after its publication date.

Execution

ARTICLE 18

1) The Council of Ministers is in charge of carrying out the rules of the current legislation.

Annex 5: Emergency inspection checklist

Name of Party: ……..……..

Name of Reporting Officer: ……

Designation: ……..…….

Date of Incident: ……..

Type of GMO/LMO: ……..

GM Permit Number…….

1. Does the Party have a valid GMO Permit?

2. Was the incident reported on time to the EQA?

3. Were other agencies informed?

4. Was there any unintended release?

5. Was there any non-compliance recorded?

6. Has the public been informed?

7. Were follow up measures taken?

8. Has the incident report been submitted?

Date of Inspection: ……...

Name of Inspector: ……

Signature: ……..

Annex 6: Applications forms for permission to import LMOs and for the use of GMOs.

Form 1: Applications for Permission to Import LMOs for Intentional Introduction into the Environment

Name of applicant	
Exporter address & contact details	
Importer address & contact details	
Name & identity of LMO	
Domestic biosafety level of LMO if any	
Intended date of arrival to boarders	
Common name of LMO	
Scientific name of LMO	
Center of origin/genetic diversity of LMO	
Description of the suitable habitats of LMO	
Common name of donor organisms	
Scientific name of donor organisms	
Center of origin/genetic diversity of donor organisms	
Description of the suitable habitats of donor organisms	
Description of genetic modification present	
Intended use of LMO	
Quantity and quality of LMO to be transported	
Provide country of origin risk assessment reports	
Intended methods for the safe handling, storage and transport. Include information of packaging, labeling & disposal procedures.	
Regulatory status of LMO at country of export	
I declare that all the mentioned information is literally correct	

Form 2: Application for intended direct domestic use of GMOs as Food, Feed or Processing

Name of applicant	
Contact details of applicant	
Responsible authority/contact details	
Name of GMO	
Identity of GMO	
Description of genetic modification	
Common name of GMO	
Scientific name of GMO	
Center of origin/genetic diversity of GMO	
Common name of donor organisms	
Scientific name of donor organisms	
Approved uses of this GMO	
Provide country of origin risk assessment reports	
Intended methods for the safe handling, storage and transport. Include information of packaging, labeling & disposal procedures.	
I declare that all the mentioned information is literally correct	