Assessment of Existing National Capacities for Biotechnology and GMOs Detection in Lebanon

Prepared for FAO by

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Foreword

This manuscript has been prepared in the context of a national assessment consultancy for the current status of biotechnology, GMOs and biosafety issues in Lebanon within the TCP/RAB/3202 project "Strengthening capacities towards the establishment of a regional platform for the detection of genetically modified organisms".

This assessment has been based on the available national reports related to biotechnology and biosafety as well as on direct contact with the relevant ministries and institutions. The updated data has led to a comprehensive presentation of major aspects related to biotechnology and biosafety in Lebanon, identified existing gaps and suggested subsequent recommendations.

Gratitude is expressed to the Food and Agriculture Organization of the United Nations (FAO) and its Plant Production and Protection Division (AGP) for providing us with this great opportunity to contribute in this active issue that is aiming at setting the appropriate priorities for each country in the region towards further actions for enhancing its existing capacity in the field of modern biotechnology as well as to develop a national plan of action and to enhance the implementation of the conventions relevant to biotechnology and biosafety.

Acknowledgment is also addressed to the Lebanese Agricultural Research Institute (LARI) and to its Director General for having hosted and supported me during the preparation of this report.

Finally, deep thanks are extended to involved institutions for their valuable contributions.

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Introduction

Lebanon is a small country of 10 452 km², located in the Near East Fertile Crescent region, which is considered as an important center of diversity in the world and where plant domestication started ten thousand years ago. Topographical, climatic and landscape diversity create diverse agro-ecosystems ranging from semi-arid to humid that allow for a large number of plant genetic resources ranging from temperate to subtropical crops to live and flourish. The main crops grown in Lebanon are olives, fruit trees and cereals each representing over 20% of the total cultivated area in the country, followed by tubers and fruity vegetables. About 36% of Lebanon is cultivated land, of which 7% is covered by forests and 57% is non-cultivated land or temporary pasture. In 2007, the cultivated area was about 277 000 Ha out of which 135 000 Ha is irrigated. Also, more than 30% of the population is entirely dependent on agriculture.

Modern biotechnology, synonymous with genetically modified organisms or GMOs, is today a main contributor to sustainable agriculture in the developed world, and in several developing countries in South America and the Far East. However, one can not say the same for the developing countries in the Near East and North Africa region. In such countries, conventional germplasm improvement programs are conducted largely by government institutions. Some of them have recently started to incorporate modern biotechnology tools in their programs. Nonetheless, failing to adopt biotechnologies places such developing countries at the risk of becoming markets for biotechnologyrelated products and renders their markets dependent on industrialized nations.

Although modern biotechnology has many advantages, it is not totally safe. There are many concerns regarding the impact of the products of modern biotechnology on the environment, human health, and animal health. Some of the adverse impacts of biotechnological products on ecosystems include the potential of weediness and the possibility of transferring genes to wild relatives. Moreover, the stability of the transfered genes is doubted. In this context, risks associated with GMOs fall into the categories of food safety, environmental and ethical.

Conscientious about the conservation of its natural resources and agro-environment, Lebanon has ratified the Cartagena Protocol on Biosafety (October 2008) that provides a guidance to the rational management of the risks associated with the use of modern biotechnologies and allows establishing an advanced informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to import GMOs into their territory.

The implantation of Cartagena Protocol in the country requires the development and application of reliable methods for GMOs detection and analysis, together with capacity building on the base of appropriate sampling strategies and methods that are indeed essential for the application of the related biosafety regulatory aspects. Advanced techniques in molecular biology are for ensuring GMOs detection and analysis, both for trade and imports and for safeguarding the rich agro-biodiversity in the region.

In this report we will address the current status of agricultural biotechnology in Lebanon and the existing capacities for GMOs detection in line with Cartagena Protocol requirements.

1. Status of Biotechnologies in Lebanon

Presently, there is no official policy or strategy for biotechnology in Lebanon and, despite their limited capacities, biotechnology has been included in the structure and agenda of agricultural research institutions since the nineties.

1.1. Plant Biotechnology

- Production of certified plant material (true-to-type and virus free) of economically important crops by using tissue culture techniques. Mersitem culture ± thermotherapy has been successfully used for potato, prunus, strawberry, caper and ornamental species to produce virus free material. This sanitation procedure was usually followed by micropropagation in order to achieve mass production of certified seeds/plants. In this context, a national cooperative project aiming at producing potato seeds is currently conducted at the Ministry of Agriculture in collaboration with an NGO in order to test the feasibility of the local production of potato seeds in Lebanon. The preliminary results are very encouraging. Another large scale application is the production and distribution of planting materials of fruits species root stocks that is predominantly carried out by the Ministry of Agriculture, the Lebanese private sector and CIHEAM Italy.

- Characterization of plant genetic resources of olive, fruit species and several leguminous by using molecular markers. Microsatellite markers associated to morphological descriptors are very helpful in assessing the diversity of the Lebanese patrimony and to determine the genetic distances and the cases of homonymy and synonymy among accessions.

- Virus detection and identification of new diseases by using conventional and RT-PCR. In this context, a long list of plant viruses, viroids and phytoplasm were identified in many crops cultivated in Lebanon such as *Candidatus* Phytoplasma phoenicium recently identified in the Lebanese almond trees, *Candidatus* Phytoplasma trifolii found to be associated with diseases of solanaceous crops (pepper and tomato), American Plum Line Pattern Virus detected on Lebanese cherries, two Fig leaf mottle-associated viruses found in the Lebanese fig trees.

- Immunodiagnostic of viruses using polyclonal antibodies developed against recombinant coat protein for producing antiserum for diagnosis of *Prune dwarf virus*.

- Link with breeding programs: Only few breeding activities have been carried out in Lebanon. They have been based on traditional crossings and were limited to wheat, barley, chickpea and lentil. Regarding fruit species, breeding activities are restricted to some clonal selection activities that have been recently conducted for stone fruits and grapevines. Only one single program relevant to Marker Assisted Selection (namely

QTL's) was used by a special project funded by the EU (Improvement of water use efficiency in durum wheat), however, the work was carried out by ICARDA because of the absence of the facilities and know how in the Lebanese institutions.

1.2. Animal and Veterinary Biotechnology

- Diagnosis of animal diseases such as avian influenza virus by using conventional and Real Time PCR techniques. In this context, thousand of tests have been done through the Ministry of Agriculture in the framework of an investigation of epidemic studies. A similar study will be started in the coming months for diagnosing Blue Tong virus.

- Identifying to the molecular level the ethiologic agents that are involved in economic diseases of animals by using Real Time PCR, sequencing, electrophoresis, direct fluorescence, including the mycoplasma, viruses, bacteria and their plasmids. This program is undertaken through regional projects funded by the private sectors in developing countries.

1.3. Microbiolgical Biotechnology

- Identification of candidate genes of *Bacillus thuringiensis* in the aim of production of biopesticides. This activity is undertaken in collaboration with Tunisian Institution.

- Identifying pathogens species of fungus such as *Aspergillus, Penicillim* and *Fusarium* responsible of mycotoxins species (Afla- and Ochratoxins, Don) by using microbiological analytical techniques including Real Time PCR. These activities are undertaken through a research collaborative program between two national institutions within the framework of food quality and safety control applied on cereal grains.

- Detection and identification of pathogens in food products such as *Salmonella*, *Listeria*, *Escerichia*, by using microbiological analytical techniques including Real Time PCR.

- Isolation and characterization of microorganisms with high lipase activity.

1.4. Others

Other activities based on the use of molecular biology tools and related to basic sciences, food safety and health are conducted on different public and private academic institutions and hospitals. The examples are many:

- Basic sciences programs related to cell and molecular biology, DNA testing, cell differentiation, cancers, inflammation, and protein nucleic acids interaction are conducted by using molecular biology tools.

- Detection of myco-toxins in food by using chromatography techniques.

- Detection of melamine in milk and dairy products by using chromatography techniques.

2. Physical Facilities Dealing with Biotechnology

2.1. Involved Institutions

Research centers and academia are the major contributors to the agricultural biotechnology sector in Lebanon as shown in Table 1. They are:

2.1.1. Lebanese Agricultural Research Institute (LARI)

Based on decree 16766-1957, LARI is a governmental organization under the Minister of Agriculture supervision (NARS). The Institute conducts applied and basic scientific research for the development and advancement of the agricultural sector in Lebanon. In addition the Institute keeps close ties with the farmers and tries to develop research activities aiming at solving their problems. Seven centers located at different sites throughout Lebanon conduct research in crop production, crop protection, plant breeding, plant biotechnology, agro-biodiversity and genetic resources, medicinal plants, pomology, pasture and forage production, soil fertility, biology and biochemistry, animal health, poultry nutrition, ruminant production, irrigation and agro-meteorology, food technology and quality.

LARI houses four departments that are actively involved with biotechnologies:

- The Department of Plant Biotechnology that was established in 1997 is well equipped with tissue culture facilities and since 2006 with molecular biology tools such as conventional and Real Time PCR. Its main duties comprise the production of high quality plants of different species by using tissue culture techniques and the assessment of germplasm and diversity characterization for many fruit species by using molecular markers.

- The department of Phytopathology is commonly using the molecular tools for detecting and identifying plant pathogens.

- The Department of Food Safety for analytical and microbiological test methods that is seeking for accreditation ISO 17025.

- The Department of Animal Diseases (biosafety level III) that is well equipped with molecular tools such as Real Time PCR. It is currently working to fulfill the ISO 17025 accreditation requirements process.

At the national level, official conventions for collaboration in research and development already exist between LARI and the Lebanese academia. Undergraduate and graduate students are regularly joining the LARI laboratories for training and thesis preparation.

2.1.2. American University of Beirut (AUB)

Chartered in New York State in 1863, the AUB was established in 1914 in Lebanon. It is an institution of higher learning founded to provide excellence in education, to participate in the advancement of knowledge through research, and to serve the peoples of the Middle East and beyond. The AUB regroups many faculties such as Faculty of Agricultural and Food Sciences, Faculty of Medicine, Faculty of Health Sciences, Faculty of Arts and Sciences... Since its origin in 1952, the Faculty of Agricultural and Food Sciences has been a leader in the agri-food industry in Lebanon and the Middle East. Actually, two departments are mostly involved in agricultural biotechnologies and well equipped with molecular biology tools: the Department of Agricultural Sciences (Laboratory of Plant Pathology established in 1960) that provides education and preparation of graduates for productive careers in agricultural technology, natural resources management, and agribusiness; the Department of Animal and Veterinary

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Institutions / webpages	Year established	Departments/Laboratories dealing with Agricultural Biotechnology	Mission	Main Programs / Activities	Equipments	Funds	
Lebanese Agricultural Research Institute (LARI) (main NARS institution) www.lari.gov.lb	1957	Department of Plant Biotechnology	Research & Development	 Production of certified plant material (true- to-type and virus free) of economically important crops. Diversity assessment and characterization of plant genetic resources of olive and fruit species by using molecular markers. 	Plant Tissue Culture facilities DNA facilities Real Time PCR	National funds. International funds through bilateral and multilateral projects. Donation.	
		Department of Phytopathology	Research, Development & Vulgarisation Research Development &	Pathogens detection and identification of new diseases. Monitoring Food Quality Identifying	DNA facilities		
		Accreditation for microbiological test methods ISO 17025 in process.	Vulgarisation	pathogens species of fungus.		-	
		bepartment of Animal Diseases (biosafety level III). Accreditation ISO 17025 in process.	Vulgarisation	- Detection and prevention of animal diseases - Investigation of epidemic studies.	DNA facilities		
American University of Beirut (AUB)	1914	Department of Agricultural Sciences, Laboratory of Plant Pathology	Education, Research & Development	Agricultural technology Natural resources management Agribusiness	DNA facilities	Internal funds. International funds through bilateral and multilateral projects.	
www.aub.edu.lb		Department of Animal and Veterinary Sciences	Education, Research & Development	Animal science Animal Biotechnology Basic medical sciences	DNA facilities		
		Department of Biology Medical Center	Education, Research & Development	Cell and molecular biology Cell differentiation, Cancers, etc	DNA facilities		
Saint Joseph University (USJ)	1875	Department of Science	Education, Research & Development	 Diversity Assessment of endemic plants by using molecular markers. Animal biotechnology. 	DNA facilities	Internal funds. International funds through	
www.usj.edu.lb		Department of Food Safety	Education, Research & Development	- Identification of candidate genes of <i>Bacillus thuringiensis</i> in the aim of production of biopesticides.	DNA facilities	bilateral and multilateral projects. Donation.	
		Medical Centers	Education, Research & Development	Basic medical sciences, Hereditary sickness, Microbiology, Toxicology.	DNA facilities		
University of Balamand (UOB) www.uob.edu.lb	1988	Department of Biology (2001)	Education, Research & Development	Biochemistry, Molecular Biology, Immunology, Microbiology, Experimental Plant Biology, Biotechnology, DNA testing Medical sciences.	DNA facilities	 Internal funds. International funds through bilateral and multilateral projects. Donation 	
American University for Science and Technology (AUST) Faculty of Health Sciences www.aust.edu.lb	2000	Laboratory of Molecular Biology This laboratory has been designated by the Lebanese Ministry of Economy and Trade as a testing center for GMOs in imported goods. Accreditation ISO 17025 is in process.	Education, Research & Development	Molecular biology, Forensic DNA testing, Toxicology, Medical sciences.	Conventional PCR Real Time PCR Micro arrays DHPLC Genetic analyser	 Internal funds. International funds through bilateral and multilateral projects. Donation. 	
Industrial Research Institute (IRI) www.iri.org.lb	1997	Accredited Laboratories of Chemistry and Microbiology (ISO 17025)	Monitoring Food Quality	 Detection and identification of pathogens in food products. Detection of myco-toxins in food. Detection of melamine in milk and dairy products. 	Conventional PCR Real Time PCR HPLC GC MS	 National funds. International funds through bilateral and multilateral projects. Donation. 	

Table1. Lebanese Institutions and functional laboratories dealing with biotechnology.

Sciences aiming at producing qualified graduates in all areas of animal science as well as in the basic medical sciences. On the other hand, molecular biology is commonly used in other departments such the Department of Biology within research programs on basic sciences related to cell and molecular biology, cell differentiation, cancer, inflammation, and protein nucleic acids interaction.

2.1.3. Saint Joseph University (USJ)

Founded and administered by the Compagnie de Jésus since 1875, the USJ is a Lebanese private university. It aspires to be an active member among the university institutions of the world, a pole of excellence and distinction in the Arab world in basic and applied scientific research and in its renewal and creativity in learning and teaching. Additionally, the USJ University houses the hospital of Hotel Dieu of France and many centers and laboratories that are well equipped with molecular tools and facilities and devoted to research within programs on basic sciences, medical sciences, heredity, microbiology, toxicology, hereditary sickness, plant and animal biotechnologies.

2.1.4. University of Balamand (UOB)

Based on decree 4885-1988, the University of Balamand is a private educational institution of higher learning, it has now nine faculties and hosts over 3500 students and 500 employees. Established in 2001, the Department of Biology is directly involved in biotechnologies. Its primary mandate is to provide excellence in teaching at the undergraduate and graduate levels. The undergraduate three-year curriculum introduces students to modern studies in general, molecular, cell, and environmental biology. It also emphasizes active, hands-on experience with modern technology, for the development of the intellectual and technical skills. The Department offers a two-year graduate program leading to the Master of Science (M.Sc.) degree in Biology and provides training in many areas with particular strengths in Biochemistry, Molecular Biology, Immunology, Microbiology, Experimental Plant Biology and Biotechnology. A primary component of the degree is a thesis embodying the results of original research. The Department's laboratory facilities are well equipped for graduate training and research in a wide variety of biological sciences such as Real Time PCR. The resources are further extended by association with other faculties, including the Faculty of Medicine and Medical Sciences and the Faculty of Health Sciences.

2.1.5. American University of Science and Technology (AUST)

Based on decree 3585-2000, the AUST is a private non sectarian coeducational institution of higher learning. The Faculty of Health Sciences Resolution 677-2007 houses state-of-the-art Molecular Biology and Analytical Toxicology laboratories that conduct several specialized testing services such as forensic DNA testing (paternity testing, human identification, missing individuals, etc...), GMO testing, screening for Inborn Errors of Metabolism in addition to teaching and training services. These laboratories are well equipped with Real Time PCR, microarrays, DHPLC, that were given as a donation from QUALEB (Quality EU funded program in Lebanon).

The Lebanese Ministry of Economy and Trade in the collaboration with QUALEB have designated AUST as a testing center for Genetically Modified Organisms in imported food and feed. The AUST is currently working to fulfill the ISO 17025 accreditation requirements process. The necessary paper-based and managerial (Standard Operation Procedures) requirements for accreditation have been completed. The technical and analytical procedures for GMOs and amino acid analysis are currently conducted by one Ph.D. scientist and one biologist. The application for accreditation is expected to be submitted to The Hellenic Accreditation System (ESYD) accreditation body in Athens, Greece by the end of 2009.

Except the administrative link with the Ministry of Economy and Trade, the AUST doesn't have yet any official linkage with other national or regional programs dealing with agricultural biotechnology.

2.1.6. Industrial Research Institute (IRI)

Established in 1953, and linked to the Ministry of Industry by Law n° 642/1997, IRI is a not-for-profit institution, with administrative and financial autonomy. The IRI is accredited for studies, industrial research and scientific testing and analysis by the Deutsches Akkreditierungs system Prüfwesen (DAP), including physical-chemical and microbiological analysis of water for human consumption, food and feeding stuff, microbiological analysis of cosmetics, wet wipes and baby diapers, chemical, physical-chemical, rheological and preparative-gravimetric analysis of grain and flour. The laboratory is well equipped with molecular biology tools and is opened for any kind of molecular testing upon request.

2.1.7. Other Institutions dealing with Biotechnologies

Other private academic institutions such as the Notre Dame University (NDU), Lebanese American University (LAU), the University of Saint Esprit of Kaslik (USEK) and the Lebanese University are housing laboratories equipped with molecular biology tools, for educational purposes within graduate programs. These academic institutions offer a two-year graduate program leading to the Master of Science (M.Sc.) degree in Biology, Biotechnology or other disciplines and provide training in many areas with particular strengths in Biochemistry, Molecular Biology, Microbiology, and Biotechnology. Actually, these laboratories don't have well defined research axes in terms of the use of biotechnology.

More recently, **the Lebanese University (public sector)** is undertaken actions for establishing "AZM Center of Biotechnology" which will be affiliated to the Faculty of Sciences (Tripoli, Lebanon North). This center will be operational by the end of 2011 for conducting both research and education activities in environmental, pharmaceutical and microbiological biotechnologies, bioinformatics and biomedical engineering. At least, 10 PhD and 10 MSc holders are expected to be involved in biotechnology activities.

2.1.8. Lebanese National Council for Science Research (LCNRS)

Based on decree 12765-1963, the LCNRS is a governmental institution having a role in the preparation and updating of the national science policy and programs, promoting capacity building and national and international cooperation in the scientific field, and allocating funds and grants to research development. Noted here are the considerable efforts of the LNCSR to serve as a link between academia and researchers in this sector and the government, industry and public. However the limited funds available to LNCSR have considerably hindered such activity.

2.2. Additional Information

The personnel most involved in hands on biotechnology work are MSc and BSc holders (90%) with adequate technical background, while few PhD's (10%) are actually involved in ongoing laboratory work.

The number of human resources involved in biotechnology is not really precise. Actually, each laboratory devotes one Ph.D., one to two M.Sc. or B.Sc engineer for the molecular biology work. However, this staff is regularly strengthened by the undergraduate B.Sc. and M.Sc. students/trainees that are joining the biotechnology laboratories to prepare their thesis.

Funding for biotech-related projects in Lebanon is mostly sponsored by countries of the European Union and amounting to slightly more than 45% of the total funding. United States-based funding is a distant second with about 30%, and the remaining is from national agencies. Note worthy here is that at the national level there are three main funding sources for biotech-related research and these are LNCSR, LARI and AUB.

Several biotech-related projects are fruit of partnerships with American and Europeanbased institutions. The national universities and institutions have established collaborative work with internationally recognized academic or development-oriented institutes. Of the international funding agencies, the major European ones are, and not in any order of significance, International Centre for Mediterranean Agronomic Studies (CIHEAM), Deutsche Forschungsgemeinschaft (DFG), European Union (EU, Tempus), Institut National de la Recherche Agronomique (INRA) France, Project CEDRE France, and University of Patras Greece. The American-based funding agencies are: United States Agency for International Development (USAID), Mercy Corps, United States Department of Agriculture (USDA), and to a limited extent the National Institute of Health (NIH). Other sources of biotechnology research funding are coming from international organizations such as FAO and ICARDA.

Access to information remains difficult at the national level, but this problem is often overcome through the regional and international trainings. For example LARI staff has regularly the opportunity of access to information and technology transfer through regional and international training courses under the umbrella of the Ministry of Agriculture.

Lebanese research papers on biotechnology are available in both regional and international levels (on line for each institution) on a wide range of subject. However,

peer reviewed papers on GMOs production and GMOs detection are not yet available. Only one abstract regarding the GMOs production in Lebanon is published (cf. References).

3. GMOs Research and Development

3.1. GMOs Production

Only one single study relevant to GMOs research has been declared in Lebanon. It was conducted during the period 2003-2007 at the Laboratory of Plant Pathology of AUB (abujawyf@aub.edu.lb) within a collaborative program with Arab and American institutions. It was entitled: "Development of genetic transformation of tomato in order to improve their tolerance to viruses".

Effectively, genetic engineering via *Agrobacterium tumefaciens* combined with tissue culture techniques allowed the regeneration of genetically modified tomatoes that were tolerant to *Tomato yellow leaf curl virus* (TYLCV). Despite these promising results that could resolve the economic incidence of this geminivirus in the region through the development of tolerant/resistant lines of tomato, the transformed tomato plantlets tolerant to TYLCV were incinerated under the laboratory conditions, after being tested vis-à-vis the virus. In fact, since no appropriate glasshouses are available for studying the behavior of GM plants, the latest should be destroyed at early stages.

Currently, another research study is currently conducted in the same laboratory on the genetic transformation of cucumber for tolerance to viruses, also through a collaborative program with Arab and American institutions. Data are not yet available.

Although there is evidence that work with GMOs is being conducted in at least one academic research institutions, there is so far, no GMOs produced in Lebanon.

3.2. Main Gaps affecting GMOs Research and Development and Recommendations

It is evident that Lebanon is undertaking efforts to adopt biotechnology and its products into the agricultural sector. These efforts, however, are not mainly directed towards GMO production, risks and concerns. The major gaps that are limiting the development of genetic engineering in Lebanon are:

- The absence of a national strategy addressing the use of biotechnology in the agricultural sector.

- The lack of cooperation between academia, research, industry and government.

- The absence of biosafety legislations.

- The absence of appropriate infrastructure (glasshouses and others) to pursue the studies on GM plants after the first laboratory tests vis-à-vis transgenes.

- The deficiency of human skills specialized in genetic engineering.

- The lack of funds.

Whether Lebanon will choose, or strategize, to become an active participant in the biotechnology industry and a producer of knowledge remains to be seen. At this time, the following recommendations can be made:

- 1. Identifying promising niches for future research and development investments.
- 2. Providing support for capacity building to enhance research in agricultural biotechnology addressing in particular GMOs production and their risks assessment.
- 3. Establishing the appropriate/needed infrastructure to support biotechnology research.
- 4. Undertaking reforms and establishing opportunities to attract biotechnology industry.

4. Biosafety Regulatory Status

Recognizing the threats of GMOs to biological diversity and natural resources, Lebanon has ratified the CBD in 1994 and developed its National Biodiversity Strategy and Action Plan (NBSAP) in 1998.

Later Lebanon participated in several meetings and negotiations of the Cartagena Protocol on Biosafety, although it is not as of October 2009 a signatory of the Protocol. Nevertheless, Lebanon will adopt the protocol provisions and will develop its National Biosafety Framework.

4.1. Existing National Legislation

Biosafety concerns have not surfaced as a priority national issue in Lebanon. Some existing national laws, decrees or regulations are indirectly related to biosafety issues and GMOs 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 related to GMOs and biosafety, the implementation of these laws could have beneficial repercussions on biosafety in Lebanon.

4.1.1. Laws Related to Agriculture and Animal Health

- Agriculture Quarantine Law dated 10/6/1948. This law establishes a department for agricultural quarantine at the Ministry of Agriculture which is entrusted with the task of preventing the entrance of the plants which could carry diseases or problems related to the safety of plants.

- Sanitary and Phytosanitary Measures Law 778-2006. This law intended to meet the requirements set by the WTO in an attempt to facilitate Lebanon's accessions. Article 14 in this law bans the importation of genetically modified plants that may introduce new diseases and toxins into the country. It cites: *"Taking into account the provisions (6), (8), and (9) of this law, plants, plant products and pests shall not be introduced into the State at any of the following circumstances, and shall be re-exported within a period.*

of time determined by the Ministry, or shall be destroyed under the auspices of Ministry's departments on the violator's expense... If genetically modified or whenever this modification might result in risks or damages to humans, animals or plants."

- Animal Quarantine Law implemented by decree No. 12301 dated 20/3/1963. This law subjects all animals and animals' products, which are imported into Lebanon to an animal health control to prevent the leaking of diseases into Lebanese territory.

- Ministerial Decision No. 166/1 dated 13/4/1996 as amended by Ministerial decision No. 228/1 dated 14/5/1996: Importation of Live Animals. This decision said that animals should be free from infectious animal diseases.

- Ministerial Decision No. 18/1 dated 31/1/997 Vaccination of Imported Live Animals.

4.1.2. Laws Related to Environment and Biodiversity

- Law 256-1994: Framework Convention on Climate Change prepared by the Ministry of the Environment, with the objective of promoting *in situ* conservation of crop wild relatives;

- Law 260-1995: Convention on Biological Diversity prepared by the Ministry of the Environment with the objective of developing monitoring and early warning systems for loss of diversity;

- Law 469-1995: Convention on Combating Desertification prepared by the Ministry of the Environment with the objective of promoting sustainable agriculture;

- Law 444-2002: Protection of the Environment prepared by Ministry of the Environment and aiming at the conservation and the sustainable use of biodiversity through the protection of its natural resources. This law is therefore relevant to the regulations of GMOs-handling activities that present risks to environment and biodiversity. Article 21 stresses the necessity of conducting environmental impact assessment studies prior to the execution of a new project that might have a negative impact on the environment of the natural balance. Article 38 subjects any activity that might have a negative impact on natural resources to primary licensing by the Ministry of Environment. Article 44 provides for the control of the import, production, extraction, handling and disposal of chemicals that might threaten health, safety and the general environment primary licensing and continuous monitoring notably in emergency cases. Section 3 Chapter 2 calls for public participation in environmental management. Chapter 8 calls for the protection of biodiversity, nature and genetic heritage from any influencing activity.

4.1.3. Laws Related to Health Protection

Decree no. 11710 -1998. This decree establishes a committee at the Ministry of Public Health to organize the importation of natural medicine products in all their forms. The duties of this committee comprise studying the applications submitted requesting an authorization to import plants and herbs which have medical effects, proposing conditions for the importation and marketing of food supplements and the products which might have effect on health; accepting/rejecting the advanced application for the import, products not allowed for import and products requiring further studies and test before decision.

4.1.4. Laws Related to Food Safety

- Decree No. 12/253-1969, which provides the conditions to be met by canned or preserved food, and describes the mandates of each ministry regarding food safety.

- Decree no. 71-1983, as amended by the law No. 63188-1988, which has provisions for food satety.

- Decree No. 1836-1999 which provides for the compulsory specifications for certain types of food.

- Decree No. 7177-2002, which sets Lebanese standards for certain types of food.

More recently, a food safety law draft has been prepared by many institutions involving Ministry of Public Health, Ministry of Agriculture and Ministry of Economy and Trade and is also awaiting endorsement by the parliament since 2006. This draft propose the establishment of the Lebanese Food Safety Agency comprising the Science and Technical Department that will take in charge GMO/GMF risk assessment for health. However, the coordination among all these ministries is limited, and they are suffering from understaffing.

4.1.5. Laws Related to Trade and Customs

The Ministry of Economy and Trade enforces various laws and plays a critical role in import and export regulation. Overall, this Ministry controls the import of goods for health, safety and environmental reasons.

The customs under the Ministry of Finance has the authority to decide on the entry of products into Lebanese territory and whether or not an imported good is for commercial or non-commercial purposes through import licenses and borders control measures including permits, advanced permits, approval and post approval. Moreover, an advanced visa is required which is a signature of customs document by a relevant ministry, indicating its approval that imported goods meet certain technical requirements and standards and may clear customs. In case the relevant ministry and customs suspect non compliance of imported goods with applicable requirements, testing is conducted and the visa is issued on the basis of test results.

4.1.6. World Trade Organization Agreement

Lebanon has been negotiating accession to the WTO since 1999. The country has acquired observer status in anticipation of gaining memberships. This will provide Lebanon with more opportunity of market access for its goods and services.

Under the WTO accession, Lebanon is working internally on updating the laws related to the Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) agreements, which are both relevant to GMOs, and the process is in progress.

In the context of these agreements, several sanitary and phytosanitary measures were taken in Lebanon, such as food safety measures, and the ban of certain animal and plant species on the basis of scientific evidence that they carry certain risks. Moreover,

Lebanon is already a member of the three organizations that provide standards, guidelines, and recommendations under the SPS agreement. These organizations include the FAO/WHO Codex Alimentarus Commission for Food Safety, the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC) for plant health. These may later provide a much needed momentum for Lebanon in developing its own guidelines and standards regarding GMOs.

One major step was recently taken towards the implementation of TBT agreement. In 2003, the Ministry of Economy and Trade signed with the EU the financing agreement for the Quality Program (QUALEB) to create the necessary infrastructure for the operation of a quality system that begin officially in October 2004. The program is working under the authority of the Presidency of the Council of Ministers and aiming to establish a working quality infrastructure in Lebanon to create a quality culture and to improve consumer protection. QUALEB has formulated a national quality policy for the Government and drafted new legislation to bring the quality infrastructure of Lebanon in line with internationally accepted practices. It is building up capacities in the Lebanese Standards Institution (LIBNOR), working on the development of a national accreditation body (COLIBAC Law 722-2004). Components of the project that could have impacts on biosafety include the support for the development of institutions which have an essential role in analyzing the quality of products. This program foresees the establishment of accredited national biotechnology laboratory at the AUST in Beirut and provides it with appropriate equipments for GMOs detection to achieve international recognition of its competencies through accreditation.

4.2. International Conventions and Protocols on Biotechnology and Biosafety

4.2.1. The Convention on Biological Diversity

Lebanon has ratified the CBD on 11/8/1994, Law 360-1994. The country developed its National Biodiversity Strategy and Action Plan (NBSAP) in 1998 following a public participation strategy involving key players, representatives from national institutions and other stakeholders.

The obligations of Lebanon vis-à-vis biosafety were addressed in the NBSAP in light of CBD obligations. Knowing that the CBD articles 8 and 19 provide for the establishment of a mechanism to address the issue of modern biotechnology and biosafety. The action plan comprised the strict and quarantine ban/control of the import of potentially invasive animal and plant species. This action plan comprised also the establishment of an expert committee on biotechnology and genetic engineering to advise on regulatory requirements for dealing with biotechnology and genetically engineered organisms and the development of biosafety policy, legislations and regulations dealing with the handling, release and disposal of exotic or genetically engineered organisms.

4.2.2. The Cartagena Protocol on Biosafety

Finally Lebanon has ratified the Cartagena Protocol of Biosafety (CPB): Law No 31 dated 16/10/ 2008.

The country has developed its National Biosafety Framework (NBF) under the provisions specified in the Cartagena Protocol since July 2005. To that end, the United Nations Development Program's management, the implementing agency Ministry of Environment (MoE), subcontracted the work to the Initiative on Biodiversity Studies in Arid Regions (IBSAR), an interdisciplinary program at the American University of Beirut (February 2004 – July 2005).

The NBF developed for Lebanon included procedures for the safe application of biotechnology in accordance with administrative, legislative, risk assessment and public participation systems. The main activities of NBF were:

- 1. Creation of a national database, through surveys and analyses, relevant to biotechnology and biosafety issues, including legislation.
- 2. Establishment of a National Coordinating Committee.
- 3. Creation of a directory listing national experts in fields related to biotechnology and biosafety, risk assessment and risk management of GMOs.
- 4. Initiation of public participation, for awareness purposes, and participation in decision making, by holding national workshops targeted to relevant stakeholders including public and private sectors and national legislators.
- 5. Production of public awareness materials and publishing of inventories and guides.

The NBF proposed the Ministry of Environment to be the National Competent Authority. A National Biosafety Commission (NBC) gathering experts and representatives from various sectors and research institutes will handle the review of information required to be handed to importing countries with the Advanced Informed Agreement. The Commission will assume full responsibility in reviewing the documents and giving the authorization for import, passage in transit and use of GMOs. Other mandate of the NBC is the classification of the GMOs crops and products in three levels of risk.

On the other hand, the Lebanese Biosafety Clearing House (LBCH) was established as an effective tool for providing information and protocols under the provisions of the Cartagena Protocol.

At the legislative level, The NBF includes guidelines for the interim measures to be adopted for the implementation of the Cartagena Protocol articles while a biosafety decree will be drafted and developed at a later stage.

Actually, within the framework of the same project, a draft decree to implement the provisions of the Cartagena Protocol in Lebanon was developed by the Ministry of Environment in 2005 with support of UNEP/GEF and UNDP and technical support of IBSAR/AUB. This draft decree provides the necessary procedures to regulate the transboundary movement, import, export, passage in transit, contained use, release into environment, direct use as food, feed, and processing, handling, transportation, use in research and testing, and placing on the market, of goods containing GMOs with the aim of protecting the environment and the humans from the potential negative effects of the GMOs. The draft decree has proposed the establishment of a National Biosafety

Committee which includes representatives from all concerned institutions. The committee will be established once the decree will be endorsed. However the decree is not endorsed yet. It is therefore imperative to have the necessary legislative, administrative and policy instruments in place to minimize risks to the environment and human health that might emerge from applications of modern biotechnology.

5. Capacities for GMOs detection

5.1. Areas of implementation

Although there is evidence that work with GMOs is being conducted at various academic and research institutions, and that is highly probable that Lebanese imports have GMOs components, to date no official legislation outlines the mandatory of GMOs detection in Lebanon. However, after the development of the National Biosafety Framework for Lebanon, many Lebanese institutions took the initiative to start working on GMOs detection in line with Cartagena Protocol requirements and with respect to food safety. Table 2 presents the different laboratories working on GMOs detection or having potential to conduct GMOs detection work.

5.2. Case studies on GMOs detection

We have to note here that, excepting the AUB and UOB case studies, all the other studies relevant to GMOs detection have just been started in different institutions and concrete results are not yet available.

To date, all the case studies that have been undertaken in Lebanon focus on corn seeds and products. Qualitative and quantitative tests have been commonly used based on both conventional PCR and RT-PCR (BIO-RAD), searching mostly for the presence of Cauliflower Mosaic Virus CaMV 35S promoter and NOS terminator. Certain studies are planning to identify the Cry genes that might be present in the GM crops and products.

- AUB Case Study

The first case study on GMOs detection has been reported in 2007 at the Department of Agricultural Sciences of AUB through a M.Sc. thesis entitled "Prevalence of genetically modified corn in Lebanon and implications on biosafety". This study assessed capabilities in Lebanon to test GM plants and investigated the presence of GM corn in varieties imported to Lebanon. Twenty seed samples from field and sweet corn varieties were collected from the Lebanese market and were tested by conventional PCR for the presence of the CaMV 35S promoter, a promoter used in most GM plants. The CaMV 35S was detected in eight out of twenty samples analyzed, suggesting the presence of unrecorded existence of GM corn in Lebanon. These preliminary results should be confirmed by further tests using event specific detection methods to make sure that they do not represent false positives.

- UOB Case Study

The Department of Biology at UOB started to work on GMOs detection in 2008 within a two years M.Sc. graduate project "General screening of Corn cans and seeds for GMOs in Lebanon". Qualitative testing via conventional PCR was done in a first place searching for the presence of CaMV 35S promoter. The preliminary results indicate evidence of at least two brands of cans on 20 brands tested with positive results. Quantitative data via RT-PCR are not yet available and the identification of Cry genes is not yet achieved.

- LARI Case Study

The Department of Plant Biotechnology at LARI has started to work on GMOs detection in March 2009 with the perspective of implementation of the Cartagena Protocol on Biosafety in national institutions (NARS). The study aimed to assess capabilities at LARI to test GM plants and to investigate the presence of GM corn in varieties imported to Lebanon focusing on seeds for food, feed and agriculture that have been collected from importers and the local market.

Qualitative GMOs testing by conventional PCR was used searching for the presence of CaMV 35S promoter for 33 corn entries. The DNA melting temperature was also determined by Real Time PCR. A sequencing of the amplicon was also achieved in order to validate the preliminary data in the absence of certified positive and negative controls. The results indicated the presence of only one positive sample on 33 entries tested. This positive case was found in one entry for feed coming from Argentina, while its import was not accompanied by a file or label indicating this fact.

- AUST Case Study

The Laboratory of Molecular Biology of AUST has been designated in 2007 by the Lebanese Ministry of Economy and Trade to be the accredited laboratory for GMOs testing; and, it is actually finalizing the ISO 17025 accreditation application.

The laboratory has launched in October 2008, a study aiming at the establishment of the basic platform for the implementation of the Cartagena Protocol on Biosafety. The study includes the development of the protocol's procedures for the detection and quantification of GMOs in all GM products, which fall under the Cartagena Protocol provisions. Furthermore, the study integrates a general assessment of all imported GM products as feed and food for processing and seeds for agriculture.

The first stage of the study established the GMOs testing strategy. The laboratory started to work on GMOs testing using the quantitative Real Time-PCR. The procedure consists of screening and quantifying the CaMV 35S promoter and NOS terminator as well as a species reference gene. Recently, the laboratory has standardized the testing methods using positive and negative controls and Certified Reference Material (CRM). The quantification of CRMs showed accurate results and therefore validated the laboratory's testing procedure.

The second stage of the study involves the assessment of GMOs food. The laboratory has screened a small sample from the Lebanese market, for the presence of CaMV35S promoter and NOS terminator using Real Time-PCR. The results indicated the absence of the GMO sequences in this sample.

Currently, the laboratory has initiated a survey of the Lebanese market involving GMOs. Moreover the laboratory is setting up the conditions to extend its studies regarding the testing strategies as well as the tested materials.

5.3 Detection fees

The average cost for GMOs detection was estimated by AUST in August 2009 according to the multiplex PCR as following:

- 100-150 \$ / sample for screening by Real Time PCR;

- 500-600 \$ / sample for certified quantification by Real-Time PCR. The price per sample will decrease with the increase of samples number.

5.4. Gaps, Needs and Recommendations

As indicated above, all the ongoing activities on GMOs detection are still limited to the technical adjustment and the standardization of the protocols.

The most important needs for GMOs detection in Lebanon are:

- The absence of biosafety regulations

- The lack of funds: limited internal funds are allowed to cover the consumables expenses.

Many recommendations could be proposed:

- Application of the interim regulatory measures developed within the development of NBF that will guide action vis-à-vis all GMOs activities, waiting for the endorsement of the draft decree by the Government.

- Capacity building in terms of sampling/collecting procedures and GMOs testing in all kind of agricultural products.

Table 2. The Lebanese laboratories working on GMOs detection or having potential to conduct GMOs detection work, case studies and recommendations.

Institution / Department / Laboratory / mail address of contact person	Area of implementation	Period	Case Study	Methodology	Preliminary Results	Constraints, Needs & Recommendations
American University of Beirut (AUB) abujawyf@aub.edu.lb	R & D Within the NBF project	2005-2007	Seeds and sweet corn varieties collected from market	Traditional PCR Testing for CaMV 35S	8 positive samples on 20 samples tested.	Funds availability for consumables.
University of Balamand (UOB) jihad.attieh@balamand.edu.lb	Applied Research within undergraduate M.Sc. thesis	2008-2009	General screening of Corn cans GMOs in Lebanon	Traditional and Real Time PCR Testing for CaMV 35S Testing for Cry genes	2 positive brands on 20 brands tested.	Funds availability for consumables.
American University for Science and Technology (AUST) Faculty of Health Sciences Laboratory of Molecular Biology mansour.issam@gmail.com gabousleymane@aust.edu.lb	R & D Upon designation by the Ministry of Economy and Trade to be the accredited laboratory for GMOs detection.	Ongoing work	 General assessment of all imported products as feed and food for processing and seeds for agriculture in order to prepare the technical platform for the implementation of Catagena Protocol. GM detection in corn seeds for feed, food and agriculture. GM detection in Sovbean. 	Quantitative Real Time PCR Testing for CaMV 35S And NOS terminator	Data not yet available.	Funds availability for consumables. Needs for trainings on seed sampling and GMOs detection in processed food (oil, jam, etc).
Lebanese Agricultural Research Institute (LARI) Department of Plant Biotechnology <u>lchalak@lari.gov.lb</u> lamischalak@hotmail.com	R & D Technology transfer	Ongoing work	Corn seeds for food, feed and agriculture belonging to 33 entries and collected from importers and local market.	Traditional PCR Testing for CaMV 35S Melting Temperature with Real Time PCR Sequencing	One positive sample on 33 entries tested.	Funds availability. Needs for the establishment of an appropriate infrastructure for Risk Assessment of GMOs on biodiversity and agriculture. Needs for trainings on seed sampling and risk assessment.
Lebanese Agricultural Research Institute (LARI) Department of Food Safety Accreditation for microbiological test methods (ISO 17025) in process	Monitoring Food Quality	Not yet	Not yet	Availability of molecular equipments such as Real Time PCR	-	Needs for trainings and capacity building on GMOs testing techniques in GMF.
fanarlab@lari.gov.lb						This laboratory has a potential for GMOs testing upon request within the Food Safety Draft Law.

6. Conclusions and Recommendations for Lebanon

Lebanon is given a great attention to strengthening human resources and developing the institutional and infrastructural capacities in biotechnology to be able to cope with new developments and applications of modern biotechnology as they arise, with emphasize to achieve biosafety issues.

This attention is, however, mainly directed on the technical adjustment of GMOs detection. Up to date, not a single program including a risk assessment and/or management component has been conducted. Knowing that risk assessment is vital element for determining, implementing and controlling biosafety conditions and is defined as a scientific method to assess the risks posed by any new technology that may have potential adverse effects on human, animal or environmental health. It serves as the basis for the decision making process for granting consents for GMOs release and marketing.

Considering high vulnerability of mountain biodiversity of the country, nature conditions, diversity of biological species, genetic resources, the most complex issue is a risk assessment with possibility of GMOs release into the environment. It is therefore imperative to have a risk management strategy including the implementation of a variety of measures in place to minimize risks to the environment that might emerge from applications of modern biotechnology.

Accordingly, the implementation of a national biosafety policy requires systematic capacity building at the national level:

- 1. Identifying and operationalizing the responsibilities of different public and private institutions in terms of GMOs research, risk and management. Knowing that some relevant research institutes such as LARI (NARS) should be responsible of developing guideline and studies on risk assessment and management.
- 2. Synergizing efforts and promoting cooperation between the involved ministries (more particularly Ministry of Environment, Ministry of Agriculture, Ministry of Economy and Trade) and research institutions in terms of GMOs risk assessment and management.
- 3. Developing capacities for risk assessment and management of GMOs technologies and methods, categorization criteria, analysis and listing through a central body that is qualified for this function as well as supporting infrastructure.
- 4. Attracting international experts for participation in risk assessment and preparation of a risk management plan.

At the regional level, three recommendations are strongly required:

- 1. Establishing a regional platform for sharing expertise and know-how to harmonise laboratory procedures, and standardized techniques of GMOs detection.
- 2. Initiating and maintaining networks with the regional countries of the project that would ensure continued public awareness, collaboration and strengthening capacities in the different issues relating to biotechnology and biosafety.
- 3. Inquiring the possibility of assigning a laboratory of Excellency among the six involved countries, that could provide further consultancy, capacity building and assistance as well in GMOs testing, confirmatory analysis and result interpretation.

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