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Environment**

MLDE-UNEP / GEF PROJECT

Development of a Biosafety National Framework in Algeria

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1. INTRODUCTION TO BIOSAFETY

The setting up of the Biosafety National Framework consists of a combination of an administrative system, regulations and technical instruments developed to ensure an appropriate level of protection for the safe transfer, handling and use of Living Modified Organisms (LMOs) which can affect the protection and the sustainable use of genetic diversity, in addition to the risks which they may represent for human health. Furthermore, such a framework will provide more transparency and a better visibility of the innovations of research organizations and industries.

This Biosafety National Framework includes 4 key elements, namely:

- A Biosafety administrative organization.
- A Biosafety regulatory system.
- A decision-making procedure and a follow up system of LMOs released into the environment
- A mechanism aimed at encouraging the participation, the sensitization and the training of the public.

In the area of biotechnologies, Algeria initiated training and research programs in the 1980s, geared mainly towards the development of classical biotechnologies in the fields of health, agriculture and the environment. As for modern biotechnologies, the development of molecular biotechnology or genetic engineering was restricted to theoretical courses and the use of molecular labeling techniques.

Thus, it is clear that issues related to Living Modified Organisms (LMOs) have not been really taken care of so far. As a result, due attention has not yet been granted to possible impacts and risks which the introduction of such organisms into the environment may have although Algeria is one of the countries which have adopted the precautionary principle by banning the import of LMO plants and seeds.

It is true that in the absence of a LMO production, the main risk may be derived from the fact that Algeria is an importer of raw foodstuffs (cereal grains, leguminous and oleaginous plants) or finished products (sugar, cattle feed, foodstuffs). With the opening up of its market and the large imports of raw materials which could include LMO derived products, Algeria is not prepared yet it to ensure an efficient management and follow up of the LMOs which may be introduced into the environment or food.

In addition to that, important programs have been carried out since the year 2000 to promote national production and thus allow the recovery and the revitalization of the national economy to attain global competitive standards. In the field of agriculture, a national strategy aimed at boosting the sector resulted in the elaboration of the National Agriculture Development Plan (NADP) aimed at subsidizing agricultural production projects.

Moreover, the Ministry of Land Development and Environment has developed a national environment strategy (NES) and a national plan of action for environment and sustainable development (NPAE-SD). This 10 year strategy is aimed at achieving three main objectives:

- Integrate environmental viability into social and economic development programs.
- Induce sustainable growth and alleviate poverty
- Draw up efficient public policies aimed at regulating the environmental externalities of an economy based growth.

This overall development strategy must be part of the larger context which currently governs the World through free economic exchange on the one hand and the need to protect the environment and more particularly biological diversity as well as the risks which may result from the use of modern biotechnologies on the other hand.

Algeria cannot certainly conduct high-level research in all the fields of biotechnologies. The setting up of a Biosafety National Framework will enable the country to have access to the necessary measures for the control of LMOs, evaluate and manage risks associated with them. These measures should include appropriate regulations, an efficient supervisory/decision making system as well as skilled human resources.

2. THE GENERAL BIOSAFETY NATIONAL POLICY

Despite the absence of a specific biodiversity strategy, Algeria has been involved in various activities involving biotechnology, biodiversity and Biosafety.

First , Algeria signed and ratified the Convention on Biological Diversity (presidential decree n° 95-163 dated 7 Moharrem 1416 corresponding to 6 June 1995 relative to the ratification of the Convention on Biological Diversity signed in Rio de Janeiro on 5 June 1992) and the Convention to Combat Desertification (presidential decree n° 96-52 dated 22 January 1996 relative to Algeria's affiliation to the UN Convention to Combat Desertification in countries seriously affected by drought and/or desertification , particularly in Africa, adopted in Paris on 17 June 1994.

Besides, Algeria signed in May 2000 and ratified on 8 June 2004 the Cartagena Protocol on Biosafety (presidential decree 04-170). Algeria was represented through its official representative at the Convention on Biological Diversity in the Inter-government Committee of the Cartagena Protocol (ICCP) and at the Protocol meetings as part of the Conference of the Parties COP-MOP 1 (February 2003, Kuala Lumpur) and COP-MOP 2 Parties (May 2005, Montreal).

Focal points representing Algeria in the Convention on Biological Diversity are:

- The Ministry of Foreign Affairs, The General Directorate for Multilateral Relations: official delegate at the COP-MOP meetings
- The Ministry of Land Development and Environment, Directorate for Biological Diversity, Natural Habitat, the Protection of Sites and Landscapes: The National Agency for the Execution of the UNEP/GEF development Project on Development of National Biosafety Frameworks.

It is important to note that the Algerian Biosafety Framework is guided by measures aimed at preventing potential negative impacts on the environment, particularly on the protection of biological diversity, taking into account human health. The precautionary principle was adopted since 2000 by issuing a ministerial order forbidding the introduction and the use of genetically modified plant materials to protect local genetic resources and agricultural development systems oriented towards biological agriculture. However, the implementation of this law faces difficulties due to the absence of control, responsibility and compensation systems.

The present project involved various ministries in considering the type of framework to be set up: Land Development and Environment, Agriculture and Rural Development, Fisheries and halieutic Resources, Foreign Affairs, Higher Education and Scientific Research, Public Health, Trade, Finance and Small and Medium Enterprises.

As for the development of biotechnologies, a national biotechnology committee was set up in 1997 to offer training and research programs in biotechnologies in the sectors of health, agriculture and the environment. This committee is still in force but its missions have been delayed due to the absence of a functioning mechanism.

In the field of training, some sixty higher education organizations, including 10 universities and 5 academic organizations are involved in various biotechnology disciplines, namely biomedical sciences, veterinary sciences, agronomy, natural and marine sciences and environmental sciences. These organizations are located in Algiers (Houari Boumediene University of Sciences and Technology, National Veterinary School, National Agronomic Institute), Annaba (Badji Mokhtar University), Blida, Constantine (Mentouri University), Mostaganem, Oran (Es-Senia University of Sciences and Techniques), Sétif (Ferhat Abbas University), Tizi-Ouzou (Mammeri University), Béjaïa and Tlemcen. The reform of the programs allowed the introduction of new courses and subjects at all levels (graduation and post-graduation). However, in the fields related to modern biotechnologies, courses are too often theoretical due to the lack of human, material and financial resources. The latest ongoing reform consists in a transition to a Bachelor-Master-Doctorate system and the mobility of this reform will allow for the teaching of courses recognized in biotechnologies through national and international co-operation and exchange and thereby reinforce the training system.

An ongoing project will lead to the opening of the Doctoral School of Biotechnologies in September 2006 which will host the different academic organizations from the Central, Eastern and Western parts of the country. This school shall be coordinated by the National Centre of Biotechnology based in Constantine.

As far as research is concerned, the first national program on biotechnologies was set up in 1991 and updated in 1995. This program is integrated into the National Research Programs adopted since 1997 and funded through the National Research Support Fund. The main fields targeted by the program are agriculture, the food industry, health and environment through the use of classical biotechnologies. The management of this program is carried out by 3 institutions:

- The National Agency for the Development of Academic Research
- The National Agency for the Development of Research in Health.
- The National Institute of Agronomic Research in Algeria

Moreover, the Ministry of Land Development and Environment drew up in 2003 a National Environment Research Program which enabled the funding of 100 research projects, including a considerable number of projects on biodiversity and an invitation to bid was launched in 2005 on biotechnologies.

The establishment of National Research Laboratories, endorsed by an executive decree in 1998, allowed the opening of 600 laboratories in 2000, including some twenty laboratories with a particular attention to the development of biotechnologies. These laboratories are run by the Ministry of Higher Education and Scientific Research and work on various aspects such as food technologies, microbial, animal and plant biotechnologies, and genetic resources in basic and applied sciences.

Other laboratories, under the aegis of different ministries, are involved in biotechnology research projects.

In the field of agriculture, the National Institute of Agronomic Research in Algeria and the National Institute for Forestry Research house laboratories involved in research activities on biotechnologies. The Centre for Scientific and Technical Research on arid zones has established a biotechnology unit divided into two divisions; one on the plant aspect and the other one on the animal aspect. The Algiers Centre of Nuclear Research has developed projects on the variety-related creation and symbiotic fixation. Besides, development institutes are in charge of testing the production and the introduction of new species, landraces and varieties, such as the Technical Institute of Fruit and Vine Arboriculture, the Technical Institute for Extensive Crops, the Technical Institute of Market and Industrial Gardening and the Livestock Farming Technical Institute.

In the field of environment, the Centre for the Development of Renewable Energies is focusing on research in the production of biogas which has now reached the production phase and the phase of pilot project for use.

In the field of health, Algeria's Pasteur Institute, with its various laboratories, is considered as a reference at the international level by many organizations. Its field of action is varied (microbiology – virology, mycology, bacteriology-,

immunology, cellular and molecular biology). It is undoubtedly the only institution which can conduct rigorous impact studies, control and follow up through considerable material resources backed with facilities in the supply of chemical, biological and genetic products as well as in consumables.

New infrastructure which will become operational shortly have been set up and will greatly support research and training in biotechnology namely the National Centre of Biotechnologies in Constantine under the aegis of the Ministry of Higher Education, the National Centre for the Development of Biological Resources in Algiers, under the aegis of the Ministry of Land Development and Environment and the Agricultural Biotechnologies Station in Algiers, under the aegis of the Ministry of Agriculture and Rural Development. Laws establishing the first two institutes have been already promulgated and their activities have started.

The creation of the National Centre for the Development of Biological Resources (NCDBR) is a result of the implementation of the national strategy for the protection and sustainable use of biological diversity, elaborated by the Ministry of Land Development and Environment. Its mission consists in carrying out a systematic inventory of spontaneous and domestic fauna and flora, to periodically evaluate genetic erosion and put in place an *Ex situ* and *In situ* conservation system of biological resources. The main activities of this centre are:

- The creation of a databank within a national network
- Collaboration with research and development institutions to exchange views on research methods in the field of genetic resources.
- The creation of a valuation and research network in biotechnology for economic and social development.
- The establishment of a gene bank, a project under execution.

The main mission of the National Centre for Research on Biotechnology (NCRB) are:

- To conduct research on biotechnologies applied to agriculture, health, food industry and the environment.
- To participate in the elaboration, the setting up and implementation of national research programs on biotechnologies
- To set up joint or associated laboratories in the field of biotechnologies
- To assist in the establishment of companies in the field of bioindustries and in the provision of services and expertise in the field of biotechnologies

Finally, biotechnological production started in the 1970s through the development of antibiotic production units, *in vitro* cultivation stations and

micro propagation, the construction of water treatment stations, the construction of a unit for the production of proteins of cellular organisms out of methanol, still at the stage of a project. In October 2003, the National Group SAIDAL, the main drug producer in Algeria, signed an agreement with AVENTIS for the production of insulin. Other production companies which could also resort to biotechnologies as pharmaceutical or food production processes or substances include:

- Inter-professional Milk Group (GIPLAIT)
- The National Center for Artificial Insemination and Genetic Improvement
- Algeria Pasteur Institute
- Food processing Public or private companies , oil mills, flour mills, dairy products and drinks
- National Office of Cattle Feed

At the international level, Algeria has taken part in a large number of initiatives, among which are the Biosafety coordination committee meeting in Africa attended by 35 countries in Addis Ababa under the auspices of the African Union in 2001. The objectives of the meeting were to finalize a model law on Biosafety in accordance with the provisions of the Cartagena Protocol to provide a larger protection to developing countries and draw up a common framework for national legislations. The Council of Ministers of the African Union recommended in July 2003 to follow this law in drafting national regulations. This initiative was preceded by another African consultation organized by the African Union concerning a standard law on access to biological resources, local communities' rights and profit sharing in accordance with article 8 of the Convention on Biological Diversity. Algeria, through its Ministry of Trade, organized in June 2000 the final experts' meeting on the harmonization of the English and French versions.

In addition, Algeria, through its Ministry of Land Development and Environment, is preparing its Biosafety National Framework through the UNEP/GEF project for the Development of Biosafety National Frameworks. This framework includes a regulatory system, an administrative system, a decision-making system, risk assessment and management procedures as well as mechanisms to secure the participation and information of the public.

In addition, Algeria hosts the headquarters of the African Agency for Biotechnology (AAB) which started its activities in 1997. It aims at promoting a strategy for the development of new and traditional biotechnologies in order to efficiently resolve problems of development, environment protection and living conditions in Africa. The objectives of this agency also involve biosafety and the protection of biological resources. AAB has currently put in place a

multinational study project to elaborate an African program for the development of commercial biotechnology, financed by the African Development Bank, AAB and member countries.

3. REGULATORY SYSTEM

3.1 CURRENT STATUS OF THE REGULATORY SYSTEM

Algeria has a large number of laws, orders, decrees and regulations related to the protection of the environment in general and biological diversity in particular. Laws regarding international agreements and conventions are:

Presidential decree 95-163 dated 06 June 1995 regarding the Ratification of the Biological Diversity Convention, signed on 05 June 1992 in Rio de Janeiro.

Presidential decree n° 04-170 dated 08 June 2004 regarding the Ratification of the Cartagena Protocol on Biosafety related to the Convention on Biological Diversity, adopted on 29 January 2004 in Montreal.

As far as national laws are concerned, a single legislation has been promulgated in the form of an order by the Ministry of Agriculture and Rural Development, it concerns Genetically Modified Organisms. This order is meant as a preventive measure to avoid any risk of genetic erosion of the phytogenetic heritage related to the effects of the genetic flow associated with the use of a transgenic plant materials and to meet the necessary technical conditions for a natural agricultural production (organic agriculture). This order stipulates:

Ministerial order n° 910 dated 24 December 2000 forbids the import, production, distribution, marketing and use of genetically modified plant material. It stipulates that “the import, distribution, marketing and use of plant material which was subject to an artificial transfer of genes from another organism belonging to a different species, eg: from a bacterial gene is forbidden”. With reference to article 13 of law 87-17 dated °1 August 1987, plant material means “living plants or living parts of plants including buds, grafts, scions, tubers, rhizomes, cuttings, shoots and seeds for multiplication or reproduction purposes”. Scientific institutions and some research bodies could, for analysis and research purposes and upon request, be authorized by the phytosanitary authority represented by the Ministry of Agriculture and Rural Development’s Directorate for Plant Protection and Technical Control “to introduce, hold, carry and use, under previously defined conditions, genetically modified plant material”. Applications for import authorizations must include “the surname and first name of the applicant, the company name, the nature of the plant material to be introduced, the purpose, the place, the conditions and the duration of the operation or use”.

Other national laws were adopted without a large consultation or expert advice to comply with international trade agreements knowing that Algeria is in the

phase of negotiation to join the World Trade Organization. These laws are designed particularly to meet the requirements set by agreements on Trade Related Rights to Intellectual Property (TRIPS) in article 27-3b that compels States to adopt a system to protect biological resources either through patents or by a *suis generis* system.

Law 05-03 dated 06 February 2005 related to seeds, plantations and the protection of plant. This law, which is being implemented under the aegis of the Ministry of Agriculture and Rural Development, determines conditions for approval, production, multiplication and marketing of seeds and plantations used in plant production and for the protection of plantations obtained. There are shortcomings in the protection of genetic resources of interest to the agricultural and food industry.

Order nr. 2003-07 dated 19 July 2003 related to patents. It bans all patents on plant varieties, animal breeds and processes particularly those of a biological nature as well as inventions that could cause harm to human and animal health or to the environment.

Furthermore, international agreements and conventions, which Algeria has become a party to, were translated into regulations and were published in the Official Gazette:

- Presidential Decree 96-04 dated 10 June 1996 relative to the Ratification of the United Nations Convention to Combat Desertification.
- Presidential Decree 85-111 dated 07 May 1985 relative to the affiliation of Algeria to the International Organization for Biological and Integrated Control of Noxious Animals and Plants.
- Presidential Decree 85-112 dated 07 May 1985 relative to the affiliation of Algeria to the International Plant Protection Convention, this convention has recently integrated GMO into phytosanitary concerns.
- Decree 82-439 dated 11 December 1982 relative to the affiliation of Algeria to the Convention on wetlands of international importance, particularly waterfowl habitats, signed in Ramsar, Iran on 02 February 1971.
- Decree 82-498 dated 25 December 1982 relative to the affiliation of Algeria to the Convention on international trade of endangered wild species, fauna and flora, signed in Washington on 3 March 1973.
- Decree 82-440 dated 11 December 1982 relative to the ratification of the African Convention on the protection of wildlife and natural resources, signed in Algiers on 15 September 1968.
- Presidential Decree 98-125 dated 18 April 1998 relative to the affiliation of Algeria to the Convention on the creation of the European

and Mediterranean organization for the protection of plants, amended on 21 September 1988.

Moreover, Algeria is involved in many projects, agreements and treaties, including:

- Draft code of conduct on biotechnologies, especially genetic resources of use for the food industry and agriculture, initiated by the FAO in 1995.
- The *Codex Alimentarius* Commission on the standardization of foods from modern biotechnologies foods and their safety.
- World Trade Organization to which Algeria is being affiliated and which entails the integration of relevant agreements to the WTO rules.
- International Union for the Protection of New Varieties of Plants (UPOV) in which Algeria has the status of observer.
- African model laws on safety in biotechnology and on the protection of the rights of local communities, farmers and obtainers and for whom the rules of access to biological resources, constitute reference legislation to elaborate a national legislation.

3.2 PROSPECTS AND NEEDS

The elaboration of national laws on genetically modified organisms and on biological resources proves to be a difficult task in the absence of consensus among the sectors involved and of reliable expertise to draw up a coherent and clear regulation. Capacity building is necessary for the implementation of the Biosafety Protocol and it has become urgent to encourage the setting up of a multi-sectoral commission. Such a commission will be entrusted with elaborating the regulatory frameworks related to LMOs, by-products and their different use, harmonizing the national legislations and clearly and transparently defining the tasks and prerogatives of each sector.

Moreover, it has become more than necessary to invest in training national legal professionals in international law and to specialize in issues related to the environment in general and biological diversity and Biosafety in particular.

COMPLIANCE WITH THE OBLIGATIONS OF THE PROTOCOL

Concerning the Cartagena Protocol, its ratification by Algeria implies taking into account national laws. For this purpose, laws must be established by setting up:

An administrative system

- Appointing a national focal point and competent national authorities

Each party shall appoint a national focal point in charge of liaison with the Secretariat and one or more competent national authorities in charge of administrative functions. In case of many authorities, their respective fields of responsibility must be defined (Article 19 of the CPB)

- Information management and correspondence with the Biosafety Clearing House

The Biosafety Clearing House is created to facilitate the dissemination of scientific, technical, ecological and legal information and help implement the Protocol (article 20). The information is about laws, regulations and agreements (articles 11, 14, 20), simplified procedures (article 13), contact details of authorized people (article 17), risk assessment and final decisions (article 20), cases of illegal cross-border movements (article 25) and compliance with obligations (article 33).

The organization and functioning, the composition and the mission of the competent national authority, the national focal point, of the Biosafety National Committee and experts' commissions shall be defined through the regulations.

Obligations and commitments of the Cartagena Protocol on Biosafety

- Using LMOs without any risk

Legal measures must be drawn up in order to avoid causing any harm to human health and bio-diversity during the development, the handling and the use of LMOs (article 2). For LMOs that are not taken care of by the Protocol, measures in line with international rules must be taken for the use, transportation, packaging and identification of these LMOs through the provision of information about products used as foodstuffs, their use in confinement and their introduction (article 18).

Conditions, modalities and measures of protection relative to voluntary dissemination and experiment, confined use and research, production, marketing, import, export and transit must be governed by regulations.

- Legal Liability

Legal liability measures must be taken by an exporting Party, on the accuracy of the information sent during an export notification (article 8) and the specific information requested for the introduction or use of LMOs for food or processing purposes (article 11). As far as importing parties are concerned, the review of relevant legal procedures and obligations will be submitted in the obligations for the required procedures.

- Advance Informed Agreement procedure

The Advance Informed Agreement procedure in line with the Protocol (article 7) and with the article on risk assessment (article 15) is an obligation to be introduced in national laws. The evaluation is carried out according to proven scientific methods in accordance with procedures and relevant regulatory mechanisms, particularly for cross-border movements and the life cycle observation periods for locally-produced LMOs (article 16).

- Confidential information

Measures shall be taken by the importing party to authorize the indication of confidential information, apart from those that are compulsory and to work on the protection of information and their non use for commercial purposes (article 21).

- LMO Movement

In case of a non deliberate LMO movement, appropriate measures must be taken to inform the countries affected, the Biosafety Clearing House and other international bodies (article 17). As far as illegal LMOs are concerned, measures must be taken for the prevention, law enforcement and costs associated with their elimination (article 25).

Decision-making, risk assessment and management procedures

- Introduction into the environment

Receipt of a notification, in line with the indications requested, shall be acknowledged by the importing Party in a period of 90 days (article 9). The decision making process is established in accordance with the risk assessment procedure (article 15) and sent in writing to the notifying party within a period of 270 days (article 10). A review of the decisions can take place after the introduction. The importing Party must inform the notifying party in a period of 30 days. An exporting Party may request to reconsider the decisions of an importing party that sends a reply in a period of 90 days (article 12).

- Use in foodstuffs or processing

The Parties must inform the other Parties, via the Biosafety Clearing House, of the use or marketing decision of LMOs as food/feedstuff or for processing , in a period of 15 days. The information considered must be in line with the Protocol. The Parties may request additional information and carry out a risk assessment. The final decision-making should not exceed a period of 270 days (article 11).

Public participation mechanisms

Legal measures and mechanisms must be set up to facilitate and encourage the participation of the public through access to information on LMOs and access to the Biosafety Clearing House and its consideration during the decision-making process (article 23).

These measures can translate into modalities of management, publication and dissemination among the public of information related to LMOs, the conditions to be taking into account, opinions and comments in the decision-making and the investigation organization terms and public consultation.

SPECIFIC AND PARTICULAR MEASURES

The Protocol on Biosafety provides a minimum framework regulating the import, export, transit, storage and use of LMOs in order to protect biodiversity, the environment and human health. However, risk assessment and management, as defined by the Protocol, could not constitute the whole regulatory system concerning the control and management of the LMOs. In fact, considering States' sovereignty and acknowledging the insufficiency of the current knowledge, it allows countries to adopt the approach of the precautionary principle and to take particular measures for lack of scientific certainties.

In addition, regulations will be drawn up, particularly those which have not been dealt with or not dealt with in depth by the Protocol such as labeling, traceability, liability and redress mechanisms.

Particular measures

- Taking into account all the LMOs and products derived from LMOs: LMOs disseminated into the environment, LMOs used in confinement, LMOs processed for food, products derived from LMOs.
- The preservation of the centers of origin and diversity, particularly plants cultivated to prevent harmful consequences of genetic contaminations by the transfer of genes.
- Economic considerations, particularly the impact on agrarian development systems, co-existence with conventional, biological, agri-ecological and farming land systems.
- Social, cultural and ethical considerations
- The participation of the public through public consultations in the dissemination of decisions, hearings before decision making, putting information at the disposal of the public, the requirement of

transparency and full information on marketed LMOs or those under assessment.

Labeling and Traceability

Labeling is the instrument for a detailed and full tracking system that provides access to information and operates as a risk management mechanism. Provisions and control, monitoring and follow up procedures must be envisaged. Labeling and traceability will:

- Confirm a certain transparency of the information concerning marketed LMOs
- Control unauthorized or illegal imports or disseminations
- Regulate contamination levels for seeds, taking into account segregation of systems.

Liability and Redress

Provisions related to issues of liability for damage caused by LMOs to biodiversity, the environment and health must be provided for and should aim at implementing an international liability regime.

As a conclusion, the elaboration of a law related to the control and management of LMOs should abide by the Cartagena Protocol on Biosafety and the two African model laws. Indeed, this law must reinforce the adoption of the precautionary principle as a decision-making mechanism it should also aim at incorporating risk assessment and management procedures, public participation mechanisms in the process of Biosafety, compensation and liability mechanisms.

4. ADMINISTRATIVE SYSTEM

4.1 CURRENT STATUS OF THE ADMINISTRATIVE SYSTEM

COMPETENT MINISTRIES

Many ministries are directly or indirectly involved in activities related to the use of LMOs in agriculture, food and research. The Ministry of Land Development and Environment, through its Directorate of Biological Diversity, Natural Habitat, Sites and Landscapes Protection, as well as the Ministry of Agriculture and Rural Development through its Directorate of Plant Protection and Technical Controls, are involved since they are responsible for biological resources management.

In addition, the Directorate for Pharmaceutical Products Management at the Ministry of Health and the Directorate for Quality and Consumption at the Trade Ministry must get involved in elaborating coherent national legislations that would comply with the obligations set forth by the different international agreements and conventions.

Currently, only the Ministry of Agriculture and Rural Development regulates the LMOs. It is therefore the competent authority for genetically modified seeds and plants through its Directorate of Plant Protection and Technical Controls. It is therefore involved in voluntary dissemination.

As far as international negotiations are concerned, Algeria is represented at the Conferences of Parties serving as Protocol Meetings (COP-MOP) by the General Directorate for Multilateral Relations of the Ministry of Foreign Affairs.

BIOSAFETY COMMISSIONS

Algeria is yet set up a Biosafety National Committee that would be the decision-making body for the Competent Authority(ies). However, many committees, commissions and meetings of resource persons have allowed a better acquaintance with the challenges associated with modern biotechnologies and with the setting up of a Biosafety framework aimed at reducing the potential risks of introducing LMOs. In addition, scientific and technical committees have been established to consider the development of modern biotechnologies and suggest plans and projects.

Those different committees include:

- The Biotechnology National Committee
- The UNEP/GEF Project National Coordination Committee.

EXPERT LABORATORIES

Independent expert laboratories will be selected and will be entrusted with reinforcing the expertise of control laboratories and conducting research in the fields of Biosafety. Many research bodies have laboratories that could fulfil these tasks subject to possibilities for capacity building.

The constitution of a network of these laboratories could represent the reference and the final expert body for decision-making by the deliberating body of the competent authority(ies).

In the field of agriculture

- Academic bodies
 - National Agronomical Institute (INA)
 - National Veterinary School (ENV)
 - University faculties of Agronomy and biology

- Research bodies
 - Algeria's National Institute of Agronomical Research (INRAA)
 - National Institute of Forest Research (INRF)
 - National Centre of Artificial Insemination and Genetic Improvement (CNIAAG)
 - National Institute of Veterinary Medicine (INMV)
 - National Centre of Biotechnology, Constantine
 - National Centre of Atomic Energy (COMENA)

In the field of health

- Academic bodies
 - University faculties of Medicine and Biology
 - Teaching hospital departments
 - Higher Teachers' School preparing teachers for higher education (ENS)
 - Research bodies
 - Algeria's Pasteur Institute (IPA)
 - National Institute of Public Health (INSP)
 - National Agency of Health Development (ANDS)

- National Centre of Biotechnology, Constantine
- National Centre of Atomic Energy (COMENA)

In the field of industry

- Academic bodies
 - The National Polytechnic School (ENP) (Higher School of Science and Technology)
 - University faculties of biology and technology
- Research bodies
 - National Centre of Biotechnology, Constantine
 - National Centre of Atomic Energy (COMENA)

In the field of trade

- Algerian Centre of Quality Control and Packaging (CACQUE) and departmental inspectorates

In the field of environment

- Academic bodies
 - The National Polytechnic School (ENP) (The Higher School of Science and Technology)
 - Institute of Maritime Sciences and Coastal Development (ISMAL)
 - University faculties of environmental sciences
- Research bodies
 - National Centre of Biological Resources Development
 - National Centre of Biotechnology, Constantine
 - National Centre of Atomic Energy (COMENA)

4.2 PROSPECTS AND NEEDS

MULTISECTORAL AD HOC COMMISSION

Putting in place an *ad hoc* commission representing all the sectors involved has become indispensable to validate the options which will be selected for the organization of an administrative system, the elaboration of a Biosafety policy in Algeria and formalization of the National Framework mechanisms.

This commission would include the following sectors:

- Diplomatic representation: The General Directorate for Multilateral Relations (Ministry of Foreign Affairs)
- Environment: The Directorate of Biological Diversity, Natural Habitat, Sites and Landscapes Protection (Ministry of Land Development and Environment) and the National Centre for the Development of Biological Resources.

- Agriculture: Directorate of Plant Protection and Technical Controls (Ministry of Agriculture and Rural Development)
- Health: Directorate of Quality Control and Regulations (Ministry of Public Health)
- Trade: Directorate of Foreign Trade and Directorate of Quality and Consumption (Ministry of Trade)
- Scientific Research: Directorate of Research Programs (Ministry of Higher Education and Scientific Research)
- Industry: Algerian National Institute of Industrial Property (Ministry of Industry)
- Legislation (Head of the Government)

This commission should also include the Directorate of Customs and particularly the Department of Law enforcement against Fraud (Home Office) and the Parliamentary Commission in charge of Agriculture and Environment (People's National Assembly)

In addition, this commission will also be entrusted with reflecting on the Algerian representation at the international level, particularly during COP-MOP meetings. It is evident that the different sectors involved will have to be integrated to form a delegation of many members which is a pre-requisite for the follow up of the whole process and influence negotiations.

COMPETENT NATIONAL AUTHORITY (IES)

Two scenarios have been considered during the consultations and debates of the different workshops organized:

The choice of a competent national authority

- Designation of a Central Directorate which will be established and placed within one of the above mentioned ministries. This authority must be provided with the necessary infrastructure, human and financial resources in order to fulfil its missions.

- Creation of a Biosafety Agency under the authority of several of the above mentioned ministries or under the authority of the Head of the Government to underline the cross-cutting character of the area.

The choice of many competent national authorities

In this case, each of the sectors must define the Genetically Modified Organisms of which it is in charge and implement the appropriate Biosafety framework.

In any case, whatever competent authority is selected, administrative procedures for the management and control of LMOs which are being marketed or are likely to be disseminated in the environment or introduced in foodstuffs must be defined.

The Competent Authority shall also endeavor to work together with the competent authorities of neighboring countries and persevere in order to harmonize LMO regulatory mechanisms. Moreover, assistance, supervision and cooperation are necessary to face up all the challenges related to LMOs and thus build up a coherent national framework.

For this purpose, channels such as the African Biotechnology Agency or the Arab Maghreb Union (Food Security Committee chaired by the five Agriculture Ministers) could play a role in this process. In other respects, projects will be conducted with international organizations such as the WHO, the UNDP, the UNEP, OILB, OIE, FAO, GEF, CIHAM, IAEA and the GTZ.

NATIONAL FOCAL POINT

The National focal point is a legal person. It is designated to keep contacts with the Secretariat of the Protocol and with the Biosafety Clearing House. The proposals of the different workshops consisted in granting the competent authority the prerogative of designating this focal point at the level of:

- A Ministerial department. Generally, the focal point of the Protocol is hosted by the ministry(ies) involved in the Convention on Biological Diversity. For Algeria, it is, as mentioned above, the Ministry of Foreign Affairs and the Ministry of Land Development and Environment.
- A scientific or research institution. It would be interesting, for more efficiency, to consider this possibility by assessing the level of expertise of some scientific bodies on Biosafety as well as technical and material facilities are often less cumbersome than those of Ministerial departments.

BIOSAFETY COMMISSION

The different workshops have shown the necessity of setting up a Biosafety National Committee that would be the decision making body of the Competent National Authority and would be mandated to ban, issue or reject authorizations.

This committee would consist of a maximum of forty members and would include:

- Representatives of Ministries (12): Land Development and Environment, Agriculture and Rural Development, Public Health, Fisheries and Halieutic Resources, Trade, Higher Education and Scientific Research, Foreign Affairs, Home Office, Justice, Industry, Finance, Religious Affairs.
- Ex officio experts (14): Agriculture, health, environment, food, economics, law, sociology
- Parties concerned (14): associations, professional organizations, public companies, consumer associations, private companies, pharmaceutical companies.

Different recommendations have been formulated so that this committee can really control the Biosafety process and ensure the continuation of its actions. These recommendations include:

- The designation of alternates to the representatives of Ministries to carry out the working program and ensure the continuity and the follow up of assigned missions.
- Ensure that all the committee members are involved in the field of biotechnologies and Biosafety through a rigorous selection to favor high quality work
- Adopt as much as possible gender parity since observations indicate a higher involvement of women in biological diversity and Biosafety.

The primary missions of this committee will consist in:

- Developing as a priority, a traceability and labeling system, control and expert commissions to lay down risk assessment, management and decision-making procedures.
- Formulating the administrative tasks for the implementation of the Protocol by elaborating administrative management manuals, together with a file recording and data storage system at each step of the procedure, popularized manuals of the procedures, forms used for all the procedures requested, information protection system and mechanisms for public participation.

- Supporting laws in force banning voluntary dissemination in agriculture by developing an administrative system, risk management and decision-making procedures within this sector.

EXPERT SCIENTIFIC COMMISSIONS

These commissions will be placed downstream of the Biosafety National Committee and upstream of the risk assessment and management control system. They will consist of scientists from the different sectors mentioned above. Their number will vary according to the strategy which will be selected. One of the suggestions would be to designate multisectoral commissions each one in charge of a particular use of LMOs (voluntary dissemination and experiments, confined use and research, production and marketing, import, exports and transit), their role will be to:

- Undertake risk assessments, approve the control measures and give their opinion on the authorization of applications to the Biosafety Committee/Competent Authority and Focal Point.
- Ensure the follow up of LMOs introduced or being introduced and the monitoring of unauthorized LMOs.
- Encourage the establishment of laboratory networks for the development and the standardization of control and risk assessment methods.
- Draw up a creative and non adaptive research strategy in biotechnology and establish directives and orientations related to the expected results and impact studies.

At this stage, capacity building must be envisaged and does not represent a difficult operation. It is essentially about training human resource and familiarizing them with the challenges, international agreements and treaties and developing control and risk assessment and management systems.

An interesting training course is supported by UNEP and consists of a 12-day training session at the Norwegian Ecological Institute (Genok Institute, Tromso University, Norway). The same type of training, in French, would be of considerable support for training experts.

(BIOSAFETY CLEARING HOUSE)

It would be appropriate to make a project request to the UNEP-GEF on capacity building to implement the Biosafety Clearing House (BCH). This BCH would represent, downstream of the international BCH, the exchange centre for the prevention of biotechnological risks. Its objectives would consist of:

- Human capacity building to facilitate access to the Central Portal of the BCH

- Technical capacity building to purchase and install the necessary equipment.
- An awareness-raising and information program for the public.

5. DECISION-MAKING, RISK ASSESSMENT AND MANAGEMENT SYSTEM

5.1 CURRENT SITUATION

All sectors have their own control infrastructure and organizational systems. The infrastructure could be the control and risk assessment bodies in the future.

IN THE FIELD OF AGRICULTURE

In 2000, the Directorate of Plant Protection and Technical Controls of the Ministry of Agriculture and Rural Development was appointed as the National Phytosanitary Authority. It is in charge of controlling seeds at the borders and within the country and examining all plant import applications.

LMOs control system

Currently, only plants and seeds are subject to regulations. It is worth mentioning that the regulations ban the import, distribution, marketing and use of genetically modified plant materials (plants, seeds, buds, crowns, grafts, rhizomes, cuttings and shoots).

As far as imports are concerned, importers of plant materials must submit a GMO free certificate for imported plants and seeds. This certificate must be signed by the National Institute of Plant Protection.

A dispensation is given to scientific institutions and research bodies for analysis and research purposes and upon their request, introduce, keep, carry and use – in previously set conditions – genetically modified plant material.

The application for authorization must include:

- The surname, first name and company name of the applicant
- The nature of plant material to be introduced
- The purpose, place, conditions and duration of the operation or use.

Plant and seed control system

The import of plants and seeds as well as their local production are subject to different controls. The phytosanitary control aims at:

- Preventing the introduction and propagation of regulated harmful organisms
- Ensuring the regular phytosanitary monitoring within the national territory
- Meeting the needs of countries importing local agricultural products.

An organizational system is represented in the 48 counties and a decentralized control system allows the coverage of the needs of all the country's agricultural areas. The main bodies involved are:

- The National Institute of Plant Protection (INPV) that has more than ten stations and laboratories of analysis.
- The National Centre for Plants and Seeds Control and Certification (CNCC) in charge of controlling the national production. It has regional branches.
- The County Directorate of Agriculture (DSA): 48 Directorates assisted by phytosanitary inspectorates.
- Control Laboratories at the Borders (LCF): at 5 airports and 10 ports.
- Pilot areas: farmers and seeds and plots of land for the multiplication of seeds and plants.

IN THE FIELD OF HEALTH

This sector is also endowed with a regulatory system and infrastructure to control human and animal diseases, the quality of pharmaceutical products and substances for medical purposes. The main bodies are:

- National Toxicology Centre (CNT)
- National Laboratory for the Control of Pharmaceutical Products (LNCPP)
- National Blood Agency (ANS)
- Health Control at the Borders, multisectoral (CSF)
- SAIDAL Group's Research and Development Centre (CDR – SAIDAL)

It is worth underlining that the first two bodies, CNT and LNCPP, are part of a multisectoral commission supervised by the Ministry of Trade, represented by the Algerian Centre for Quality and Packaging Control (CACQE).

IN THE FIELD OF TRADE

Currently, the Algerian Centre for Quality and Packaging Control (CACQE) and the County Inspectorates are in charge of controlling the quality of food products. However, it is restricted to specific missions and could not meet

emerging tasks on its own, particularly health measures required by accession to the WTO.

It has therefore been decided at the end of 2004, to establish the Algerian Agency for the Prevention of Consumption-related Risks (ALPREC) that will be based at the CACQE and its mandate was extended to all consumer goods (food, health, industrial). The mission of this agency, under the aegis of the Directorate of Quality and Consumption of the Ministry of Trade are as follows:

- Identify and prevent risks related to consumption
- Assess the conformity of products and services offered for consumption
- Develop analytical and test instruments
- Propose appropriate measures to fight against risks related to the consumption of industrial products, food products and services for the health and safety of the consumer as well as for the environment.
- Put in place an organized and coordinated framework of an intersectoral alert.

To carry out these different missions, the ALPREC should rely on the CACQE's existing bodies and should set up:

- A central testing laboratory for industrial products and for calibration
- A central analysis laboratory, specialized in the control of conformity of food and hygiene products
- The recruitment of 1,500 additional employees, trained in quality process

In addition, the national committee of *Codex Alimentarius* is being elaborated and should be operational during the year 2005.

IN THE FIELD OF ENVIRONEMENT

The environment sector has many control systems, particularly on the various pollutions and degradation of land and water ecosystems. For this purpose, there are regional control laboratories as well as Directorates of the environment in each of the 48 counties.

However, new obligations related to the prevention of biotechnological risks to the environment and biological diversity are not yet taken care of. The National Centre for the Development of Biological Resources could be a control body and develop risk assessment and management strategies.

5.2 PROSPECTS AND NEEDS

CONTROL CAPACITY BUILDING

It is urgent for each sector to set up its control system by relying on human and material resources available. It is even more urgent for plant and seed control system as plant material is forbidden. A control laboratory should be quickly put in place and could rely on the expertise of the National Institute of Agronomical Research or the National Agronomical Institute.

The creation of specific units for the control of LMOs should not be a difficult task. Capacity building in this field must be envisaged on control techniques and standardizations. This type of training is envisaged in the future in certain academic bodies such as the National Agronomical Institute where the Laboratory of Phytopathology and Molecular Biology is preparing a convention with the Laboratory of LMOs detection of the INRA, Versailles, which is in charge of the coordination of associated European laboratories for GMO detection and tracking. In addition, it will be necessary to acquire instruments for analysis (ELISA reader, real time PCR) necessary for risk assessment and management.

These perspectives would be considered by formulating a project for the forthcoming phase of the UNEP-GEF project as soon as the administrative and organizational decisions are taken.

These control systems would be appointed as reference and mandated by the competent authority via the National Biosafety Committee and the scientific expertise commissions. The findings of their control would be sent to the expertise commissions which would provide an additional opinion.

THE SETTING UP OF PROCEDURES

This part is absolutely urgent as it determines the entry into force of a new law on LMOs. No law could be applied if it is not preceded by the existence of the whole system of control and analysis and the commissions which will be entitled to provide the necessary expertise.

The procedures which will be implemented are set out in the Biosafety Protocol with obligations and deadlines to comply with. Other more strict procedures may exist if the environment and the biological diversity are threatened or if the scientific findings are not conclusive or if impact studies are disputable. You will find hereunder orientations for the future regulation that would enable

putting quickly in place risk assessment, management and decision making procedures.

The basic principles of the procedures

Procedures should be based on four main principles:

- The principle of caution: States are sovereign in the adoption of the principle of caution for different reasons. This principle can be materialized through a decision to adopt a moratorium or a ban for the following reasons:
 - Absence of studies on the harmlessness of a given LMO on human health, biological diversity and the environment.
 - The protection of the centers of origin and diversity, an obligation of States under the Convention on Biological Diversity and the International Treaty of on the Protection of Plant Genetic Resources for food and agricultural purposes.
 - The disputable interest from the economic, social, cultural and ethical points of view
 - The noxious impacts on existing land, conventional, agricultural, ecological and farming development systems.
- The prior informed principle in full knowledge of the facts under which any agreement is made based on all the necessary information required for a decision to grant approval. This is the information provided by the Biosafety Protocol and additional information related to the degree of protection States provide on a given LMO.
- The risk assessment and management principle, prior to taking any decision which, in addition to the information provided, would require additional consultations and expertise based on sound scientific risk assessment principles
- The principle of transparency, which expresses the capacity to track the product along the production and distribution line, it is the reason why it is important to set up upstream all the control system to implement the regulation.

General framework of procedures

Any use of a living modified organism should be subject to an authorization by the National Competent Authority.

Any application for deliberate release, experiment, import, export and transit, research and use in a confined space or marketing and production is subject to the elaboration of a risk assessment study on human health, biological diversity

and the environment. The elaboration of intervention plans must also be envisaged in case of genetic pollution or biological incidents.

- Deliberate release and experiment: means any deliberate introduction of a GMO into the environment, including experiments for specific purposes that are to be defined. An option would be to proceed step by step and to initiate the pre-agreement procedures for experiment in green houses, aquaculture basins and buildings designed for fish and animals. Safety protocols should be envisaged.
- Import, export and transit: subject to a prior approval after submission of a file containing the requested information and a risk assessment through additional studies.
- Research and use in confined space: Information to the national authority should be a precondition for any research related to LMOs, conducted on the national territory as well those conducted abroad, which Algerian research institutions are associated with. Measures shall be taken according to the scientific measures adopted. Confined use consists in any operation of LMO cultivation, storage, use, transportation, destruction or elimination. Procedures, protocols and regulations are to be implemented as well as the marking of sites, areas, surfaces and laboratories for a confined use.
- Marketing and production: Marketing means the provision to third parties or the provision of LMOs by third parties. Prior approval procedures and protection measures must be envisaged. GMO production can take place under a production authorization and is subject to a rigorous control and risk assessment and management before marketing.

OPTIONAL FRAMEWORK FOR DECISION-MAKING PROCEDURES

The proposals and the recommendations of the various consultations and workshops led to the elaboration of a general outline of a Biosafety National Framework which may constitute a structure for its implementation.

Applications for permits will be dealt with on a case by case basis and the provision of complete data will be required -subject to rejection-. As soon as the notification is received, the Competent Authority sends it simultaneously to the National Biosafety Committee, to the Focal Point and the public information mechanism. The national authority has a deadline of 90 days to acknowledge receipt.

Depending on the use of the considered GMO, the NBC sends the application to the scientific commission of experts for review. The latter sends the file to the different control systems together with a risk assessment request in accordance

with clearly set out directives. The opinion of the control commissions is then sent to the scientific expertise commission involved. The latter will carry out an assessment and give its opinion to the BNC.

In other words, once the file is received, the focal point shall inform the Biosafety Clearing House and the public information mechanism activities committees from municipal assemblies that are in charge of information and consultation with the public. Results of this consultation are made public and sent to the BNC.

Once the comment of the different parties is received by the BNC, the latter shall proceed to a final study of the file and submits to the national competent authority the conclusions leading to the rejection or the approval. The final decision is to be taken by the national authority and the deadline may not exceed 270 days. Of course, this deadline may be extended if additional information is needed.

Moreover, a revision of the decision and an additional assessment can take place and shall be carried out by the scientific expertise commissions in charge of follow up and surveillance.

6. PUBLIC PARTICIPATION AND INFORMATION

6.1 CURRENT STATUS OF PUBLIC PARTICIPATION AND INFORMATION

PUBLIC OPINION

The Algerian people remain insufficiently informed on the issues relating to Biosafety, biodiversity and biotechnology. One must say that there is no use, production or research on LMO. Besides, it is true that, on the food level, the concerns are more related to access to foodstuffs and to sale prices than to the quality and content of the products.

The current debate on LMOs is not intense and involves only administrations, research and a small section of the public. Resource people are not directly trained in these fields and the debate is focused often on general issues or on highly specialized but theoretical scientific aspects.

In this respect, capacity building is urgent through the implementation of a program which includes resources for laboratories, skilled people, operating mechanisms for the commissions and information dissemination mechanisms.

Besides, institutional projects have been elaborated to contribute to the Biosafety process, both its establishment as well as the participation of all actors involved. The Ministry of Land Development and Environment is running the project for the development of a Biosafety National Framework, partly supported by the UNEP-GEF project. A National Coordination Committee representing different institutions, departments and associations supervises the activities of the project.

It is also worth noting that it is possible to collect information from the African Biotechnology Agency which issues a news bulletin, *Abiotech*, and has a web site: www.aab.org.dz

FARMERS' ORGANISATIONS

Like all the population, farmers are not particularly involved in the debate on LMOs. The advent of hybrid seeds, a few years ago, is a technology which has aroused a great interest. This lack of interest among farmers for biotechnologies is due to a lack of sensitization and their low representation as organized groups.

Most farmers do not hold degrees in agronomic sciences and therefore lack basic knowledge although the tendency is now changing. The training provided by technical institutes and vocational training centers is not focused on biotechnologies but rather on cultivation techniques and productivity improvement through natural methods.

In addition, the different agrarian reforms and the recent changes which have been introduced into the development strategies have led to the total restructuring of the agricultural sector. Furthermore, due to the particular status of land, farmers have become very independent and as a result are poorly represented.

However, there are organizations which may constitute important channels for raising awareness, training and information considering the central position of farmers in the debate:

- The National Union of Algerian Farmers, the only central trade union organization which has the advantage of representing the majority of farmers.
- Chamber of Agriculture, represented in the 48 counties, is involved in training and popularization.
- Associations made up of categories of producers considered as a new farmer organization (apiarists, viticulturalists, wine producers).

ASSOCIATIONS' INITIATIVES

Initiatives by associations are gradually developing leading to increased awareness on the issue of bio-diversity and the LMOs. Associations such as AREA-AD (Association for Refection, Exchange and Action on Environment and Development) or APEB (Association for the Protection of Environment and Development, Béni-Isguen) have been running training and information sharing projects for many years.

AREA-AD association has been involved in Biosafety and the LMOs since 1999 and is currently coordinating a project on public participation to the Biosafety process in Algeria, funded by the German Cooperation Agency GTZ.

Biannual information bulletins are published in French and Arabic (Bio-sécurité-DZ) and also through the web site www.areaed.asso.dz). The published information covers international, regional and national legislation, the scientific aspects of biotechnologies and Biosafety, impact studies on the environment, health and land systems, relationships with intellectual property rights and the ownership of living organisms and economic and social challenges.

Many international workshops have been organized on tracking and information (Algiers, December 2003), the impact of LMOs on farming (Ghardaïa, September 2004), legal frameworks for the control of LMOs and the protection of biological resources (Tipaza, April 2005). International experts had the opportunity of sharing their experiences with a public representing various associations, professional organizations, research departments, academic bodies and parliamentary institutions.

A workshop will be held in November 2005 and will focus on draft regulatory frameworks and harmonization at the regional level. In addition, a draft project on GMO training and Biosafety for the benefit of Francophone Africa is being elaborated in co-operation with the Phytopathology and Molecular Biology Laboratory of the Agronomic National Institute.

6.2 PROSPECTS AND NEEDS

CAPACITY BUILDING FOR PUBLIC PARTICIPATION

Capacity building for public participation should constitute an important orientation during the implementation phase of the National Framework. To this end, effective participation must be envisaged through:

- Involvement in the whole process of public engagement of associations, professional organizations, consumer social organizations, companies and industries.
- The setting up of a public consultation mechanism that would be managed by municipal assembly committees. The setting up of a LMO public register in which all applications for holding and/or using LMOs will be recommended based on the necessary documentation.

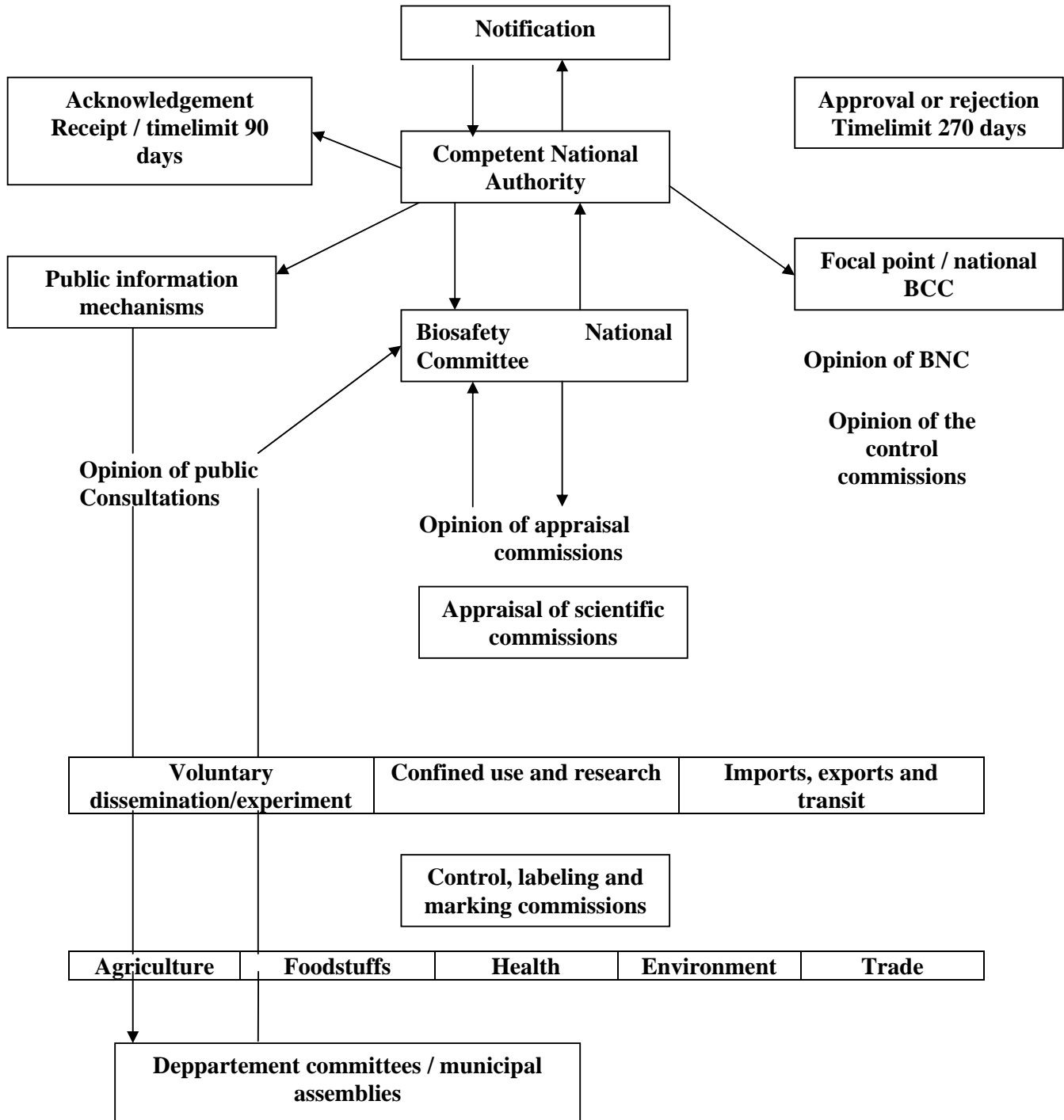
LEVELS OF PARTICIPATION

- First of all, it is necessary to focus on raising awareness at all levels, schools, universities, agriculture, health and environment professional organizations. For this purpose, the provision of educational and pedagogical instruments is indispensable together with a considerable translation work.
- Then, it is important to inform the public at all levels about the LMOs which are introduced into the country. For this purpose, a mechanism managed by the BNC should establish connections with all the country's departments through municipal councils made up of department assemblies that shall be in charge of informing, at the local level, the

associations and parties interested in :MO-related issues. In addition , all information channels must be developed: Audiovisual means, media – television, radio, newspapers, discussion and exchange forums.

- Finally, It will consist of public participation in the decision making process. For this purpose, scientific committees in charge of risk assessment and management must involve the public concerned through a mechanism which will be set up under the authority of the municipality where the introduction takes place in order to have a concerted decision.

THE BIOSAFETY NATIONAL FRAMEWORK



Discussion with the public involved

Observations:

The obligation to abide by the 270-day deadline has raised some concerns during some workshops although it was noted that in Article 10-d of the Cartagena Protocol, there is a possibility to extend this deadline for a determined time.

Public information must be carried out in the best conditions and deadlines so that its participation in the process is effective.

7. UNEP-GEF PROJECT ON THE BIOSAFETY NATIONAL FRAMEWORK IN ALGERIA

The first version of the Biosafety National Framework for Algeria was prepared during the UNEP-GEF project on the development of a Biosafety Framework in Algeria, conducted by the Ministry of Land Development and Environment as part of the UNEP-GEF project. The latter aims at assisting countries in implementing the Cartagena Protocol on Biosafety through the development and implementation of their respective national frameworks on Biosafety.

National Executing Agency: Ministry of Land Development and Environment. Directorate of Biological Diversity, Natural Habitat, Site and Landscape Protection, les Quatre Canons, 16000 Algiers, Algeria.

Project number: GF/2716-01-4319

Project duration: 2 years (started in September 2002, ends in September 2004)

National project cost:

- Cost from UNEP-GEF funds: 166,900 USD
- Government contribution: 77,700 USD
- Total cost: 244,600 USD

General description of the project phases

Phase 0. Administrative management of the project

The project was hosted by the Directorate of Biological Diversity, Natural Habitat, Sites and Landscapes Protection that is the National Implementation Agency. A project main consultant was designated as well as a National Coordination Committee in charge of supervising the project activities.

Phase 1. Studies and investigation

The purpose of this phase was to establish a detailed overview of the situation of biotechnologies, biodiversity and Biosafety in Algeria and to identify the parties involved. The studies conducted according to previously established terms of reference were:

- Institutional Capacity in the research and development of biotechnology
- Importance and impact of LMOs and commercial products
- National bodies for the implementation of the Biosafety Protocol

- Mechanisms to harmonize decision making, risk assessment and management.
- Existing legislation that could have an impact on the use of modern biotechnologies

Phase 2. Analysis and consultation

During this phase, a series of workshops were organized to propose conclusions to the studies and investigations, to identify the gaps and the requirements to enable the implementation of a National Biosafety Framework in Algeria.

A training workshop on the assessment and the management of risks and the decision making process as well as a workshop on the participation of the public have been held.

Phase 3. Preparation of the first version of the National Biosecurity Framework

This document is the result of this phase. This first version takes into account all the debates and discussions during the workshops that were held as well as all the reviews conducted during the studies.

7.1 ACTORS INVOLVED IN THE BNC

The identification of actors involved in Biosafety issues was carried out during the first phase of the project, which led to the determination of the composition of the National Coordination Committee of the Project. This committee is made up of about thirty members representing different sectors involved in issues related to LMOs and Biosafety as described hereunder:

- Ministries: Foreign Affairs, Industry, Land Development and Environment (Algeria GEF Focal Point), water resources, Fisheries and fishing resources, higher education and scientific research, Health, Population and Hospital Reform, Agriculture and Rural Development (Directorate of Plant Protection and Technical Control), Trade
- Scientific and technical institutions: National Agency for Wildlife Protection, Pasteur Institute, National Institute of Plant Protection, National Centre for Artificial Insemination and Genetic Improvement, Algerian Centre for Quality Control and Packaging, National Institute of Agronomical Research (focal point of the African Biotechnology Agency), Centre of Renewable Energies Development, National Institute of Forestry Research.
- Universities: National Agronomical Institute, Houari Boumediene University of Sciences and Technology, Blida University.

- Associations: Boumerdes Ecological Association, AREAED association, Algerian Ecological Movement.
- Industry: SAIDAL

Along the project and during the analysis and consultations phase, other institutions have joined the think tank. Among them we can mention:

- Members of the National Biotechnology Committee
- Members of the commission in charge of drawing up the law on LMOs and biological resources.
- People representing the civil society: civil society organizations, national education teachers, journalists from different media (TV, radio, newspapers).

7.2 INVENTORIES

The inventories have been set up in the form of lists and are being processed to develop a data base which could be accessed on the future web site of the national Biosafety Clearing Centre. These inventories can be summed up as follows:

- Resource persons inventory: 372 people were recorded and listed with their surnames, first names, positions, organizations, contact details, businesses and fields of interest.
- Inventory of the regulations in force: A list was drawn up concerning the laws, rulings, decrees and other laws related to the protection of the environment, biodiversity and Biosafety. A total of 86 laws were listed with their titles, numbers (in the Official Gazette), dates of entry into force and keywords.
- Inventory of Laboratories: a national inventory was established of laboratories involved in biotechnologies, biodiversity, agriculture, and environment, human and animal health. For the Ministry of Education and Scientific Research, 124 laboratories were listed with the name of the laboratory, the organization and the head of the laboratory. The same work will be carried out for laboratories of the ministries concerned.
- Listing of research projects: Projects related to the environment, agriculture, biotechnologies and health were recorded with their title, project code, person in charge, organization, contact details and field of interest.

7.3 WORKSHOPS HELD

A workshop on the **identification and analysis of the options to implement the terms of the protocol and the conclusions of the studies and investigation** was held in Algiers on 23 and 24 February 2004. About fifty participants attended and represented ex officio people, members of the National Coordination Committee, the National Biotechnology Committee, the multisectoral commission in charge of drawing up the national law on LMOs, the Scientific Council of the National Agency for Academic Research Development and the Scientific Council of Research in Health, as well as other resource persons. The documents available are:

- Workshop program
- Collection of the papers and PPT files used.
- List of participants

A training workshop on **risk assessment and management measures** was held in Algiers on 15 and 16 June 2004. About thirty people from various regulatory and follow up institutions involved in the Biosafety process took part in this workshop. The following documents are available:

- Workshop program
- A collection of the papers and PPT files used.
- List of participants

A workshop on **public involvement mechanisms in the biosafety process** was organized in Algiers on 29 June 2004 for about thirty participants. Presentations focused on the knowledge of LMOs, the regulatory, administrative and GMO management systems, the presentation of the National Biosafety framework implementation budget and public involvement mechanisms in the Biosafety Protocol. The following documents are available:

- Workshop program
- Collection of the papers and PPT files used.
- List of participants

7.4 DOCUMENTS PRODUCED DURING THE PROJECT

Final versions of the documents related to the studies were collected and are available in French. These documents will be translated and referenced according to the requirements of the project and the national implementation agency. The titles of the five reports:

1. Importance and impact of the dissemination of Genetically Modified Organisms, F. Chehat

2. National, bilateral and multilateral cooperation programs on the reinforcement of structures, research and development and the application of biotechnologies. M. Laouer & A. Abdelguerfi.
3. Situation of Biosafety in north African countries: institutional and regulatory aspects and conditions to implement the Cartagena Protocol on Biosafety. Z. Bouznad
4. Review of existing mechanisms for the harmonization of the risk assessment and risk management data and approval. K. Korichi-Hamana.
5. Review and assessment of the existing legislation that could have an impact on the use of modern biotechnologies. S. Chouaki

In addition, a synthesis document of the workshop on the identification and analysis of options to implement the terms of the protocol and the conclusions of the studies and investigation is currently being reviewed and edited and shall be published for a wider circulation and use as a working document.

7.5 INTERNATIONAL AND NATIONAL MEETINGS

- Workshop for French-speaking Africa on the *assessment and management of risks and the participation of the public in the Biosafety process*, organized by UNEP-GEF, Dakar, Senegal, April 2003.
- National Workshop on *the participation of the public in the Biosafety process: Information and tracking*, organized by the Algiers National Agronomical Institute and AREA-ED association, Algiers, Algeria, December 2003.
- Workshop for French-speaking Africa on *setting up administrative and regulatory systems of the Biosafety National Framework*, organized by UNEP-GEF, Ouagadougou, Burkina Faso, April 2005.

Other activities achieved

Database:

The design of the biotechnology/Biosafety database is finalized. This database comes in four (04) index cards (projects/activities, list of experts, legislation, research institutions). It is being enriched and will be operational from the BCH(Biosafety Clearing House) and the site of the Ministry of Land Development and Environment www.mate-dz.org and particularly the web site of the project : biosécurité-dz.org

8. CONCLUSIONS

The text of the Cartagena Protocol on Biosafety was adopted in January 2000. It is, at the international level, the normative framework from which the Parties shall enact national legislations to transfer, store and use the LMOs, particularly to regulate the cross-border movements and the imports of such organisms. Parties to the Protocol, including Algeria, acknowledge as signatories the fact that, besides their plant material, genetically modified plants are fundamentally different from plants obtained through conventional selections. In fact, plants from modern biotechnology bear new risks, which make it compulsory to put in place a particular legislative framework. Countries still have a sovereign right to regulate the LMOs and their by-products at the national level and the Protocol established the regulation and enacting framework of standards at the international level.

The principle of caution was reaffirmed and integrated in the decision-making procedures of the Protocol. This means that, failing scientific certainties, the Parties must exercise caution and are authorized to forbid or limit the import of LMOs due to their potential harmful effects. The Parties that have signed the Protocol must regulate the LMOs at the national level, this implies that countries shall implement Biosafety laws and regulations with the capacity of controlling all the LMOs that will cross the national borders, to track and assess the safety of the imported and produced LMOs.

In Algeria, although an order from the Ministry of Agriculture bans the import, distribution, marketing and use of genetically modified plant material, there is no control over this plant material. It is true that for the time being, the crops at issue are not priorities in Algeria, but we must bear in mind that transgenic wheat is ready and was due to be marketed in 2004 if the European populations (particularly Italian) had not organized a large campaign against its introduction.

Furthermore, and as far as other GMO-derived products are concerned, there is fear that a large number of them is being introduced with no information and that Algeria is passively importing LMOs for consumption. The risk would mainly come from cattle feed that is totally imported (concentrated maize and soya oil cakes), from cultivations as grains for processing (maize for flour, soya, colza and maize for oils) and imported finished products (canned maize, chocolate and biscuits that contain soya lecithin).

The Biosafety National Framework should include all the key elements for the reinforcement of the protection of the environment and biological diversity, human health and the protection and valuation of agrarian systems and traditional knowledge towards potential risks resulting from the introduction and

dissemination of LMOs. It should follow the example of the Convention on Biological Diversity, the Cartagena Protocol on Biodiversity, the two African standard laws and the International Treaty on the Protection of Plant Genetic hytogenetic Resources for agricultural and food purposes.

The immediate action to take in Algeria are:

- Call for the setting up of an ad hoc commission to approve the strategy for the implementation of the national biosafety framework.
- Speed up the setting up of the Biosafety National Committee whose primary missions will be the consolidation of BNC and examining the criteria and parameters of setting up administrative systems, regulatory systems, decision-making, risk assessment and management systems as well as public participation mechanisms.
- Reflect on regulations to implement, taking into account the existing national legislations and the international treaties and agreements. A large legal vacuum was noted not only regarding the control and management of LMOs but also regarding the management and protection of biological resources. The review of these laws or their reinforcement through other regulations, particularly the one concerning LMOs and that destined for biological resources will enable the reinforcement of the legislative system and a better visibility of the prerogatives and missions of all the sectors concerned.
- Finalize the discussion on Biosafety National Framework and choose an option to commence the implementation work of all the key elements of the Framework (notification procedures, prior agreement procedures, risk assessment and management procedures and guidelines, public register setting procedures).
- Inform, heighten the awareness of the public and encourage its participation. Training programs must be elaborated at all education levels (from national education to higher education). In other words, the scientific and regulatory expertise capacities are to be reinforced through short training sessions. Moreover, it is about putting everything in place so that public participation is effective in the decision-making process and the risk assessment and management mechanisms.