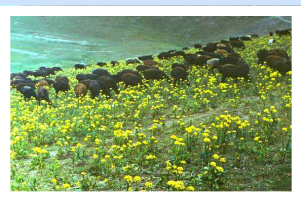
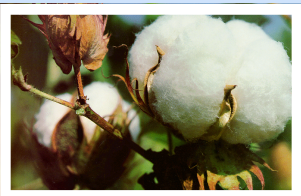
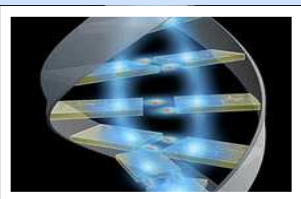


CEE Regional Workshop on Capacity-Building and Exchange of Experiences of Risk Assessment and Risk Management of LMOs



Implementation of risk assessment and risk management provisions of the Cartagena Protocol on Biosafety in the Caucasus and Central Asian countries

Anastasia Idrisova

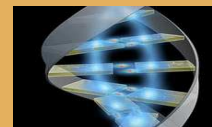
National Biodiversity and Biosafety Center

Republic of Tajikistan

*26-28 November, 2007
Chisinau, Moldova*

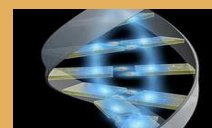
CONTENTS:

- Introduction
- Current status
- Difficulties and challenges
- Capacity building needs and priorities



Central Asia and Caucasus

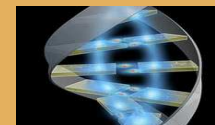
Country Name	Ratification of the Protocol	NBF Development	Law on Biosafety
Azerbaijan	2005	Draft	Draft
Armenia	2004	2004	Draft
Georgia	-	2005	Draft
Kyrgyzstan	2005	2005	Adopted
Kazakhstan	-	2005	Draft
Tajikistan	2004	2004	Adopted
Turkmenistan	-	-	-
Uzbekistan	-	-	-



Current situation

Regulatory framework:

- Prior to development of the NBFs and the Law on Biosafety the **countries lack a system/structure** for *GMO* risk assessment;
 - In the course of implementation the UNEP-GEF projects on development of the National Biosafety Frameworks the **fundamental principles and the structure for risk assessment and management were developed**;
 - As a regulatory component of NBFs the countries have elaborated the national **Law on Biosafety**.
-
- ❑ Prepared documents are insufficient as mostly they present the mere description of a key mechanism and a number of principles;
 - ❑ Complimentary policies, legislation, regulations and guidelines need to be developed for their replication on practice.



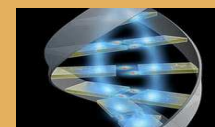
Current situation

Scientific capacity

- Countries have institutions and laboratories, which conduct relevant survey and scientific research;
- Countries have institutions and laboratories, which conduct relevant survey and scientific research;
- Laboratories are under-equipped, mainly to implement the *GMO* detection;
- Countries in most cases are constrained by traditional biotechnology, and there are no intentions for *GMO* development;

Meanwhile:

- ☐ Lack of experts with relevant knowledge and skills;
- ☐ Lack of the risk assessment experience;
- ☐ Lack of the relevant equipment and chemical agents;
- ☐ Lack of or shortage of guidelines for risk assessment;



ARMENIA

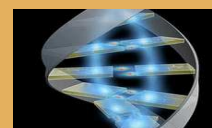


Party of the Cartagena Protocol since 2004.

There are 2 institutions, which deal with *GMO* production:

- Research Institute on Biotechnology under the Ministry of Trade and Economic Development
- Biological Department of the Yerevan State University

Procedures for Risk Assessment were developed and presented in the NBF document and draft Law on Biosafety; they comply with the requirements of the Cartagena Protocol



ARMENIA

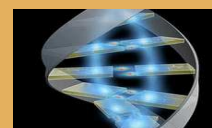
According to the NBF **Risk Assessment** should be conducted by **Expert Committee** which is responsible for:

- Accuracy of biosafety expertise and risk assessment results;
- Timeliness of implementation of biosafety principles, regulations, norms and deadlines;
- Maintaining documents and materials.

Expert Committee includes representatives of the following organizations:

- ⇒ RA Ministry of Nature Protection
- ⇒ Armenian Agricultural Academy
- ⇒ National Academy of Science
- ⇒ Scientific Research Institute of Biotechnologies
- ⇒ Yerevan State University

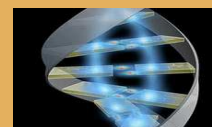
Expert Committee has **30 days** to conduct Risk Assessment and present its conclusions (Report). This Report is considered by Ecological Expertise and Ministry for Nature Protection and taken into account during decision-making.



ARMENIA

The following regulations should be developed to ensure conducting of adequate Risk Assessment:

- Regulation aimed at clarification of elements and the extent of the risk assessment when placing a product on the market;
- Regulation to identify contents of the notification for placing a product on the market;
- Regulation on contents and extent of monitoring program;
- Regulation on the packaging or declaration of the product;
- Approximation of the EU Regulation on transboundary movements of Genetically Modified Organisms.



KYRGYZSTAN

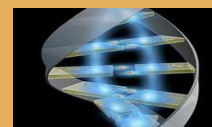


Party of the Protocol since 2005.

The country has conducted biotechnology research but mainly in the field of cell and tissue culture.

According to the NBF, **Risk Assessment** is carrying out by the Expert Groups or the **Expert Commissions** established for the period of the assessment from the registered list of specialists taking into account their qualifications.

Registers of experts are maintained by Special Competent Administrative Bodies depending on the area of expertise: Ministry of Healthcare, Ministry of Ecology and Emergencies, Ministry of Agriculture, etc.



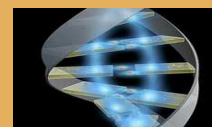
KYRGYZSTAN

The following documents have been developed:

- ✓ methodical criteria for risk assessment and authorized bodies;
- ✓ instructions on the principles of risk assessment;
- ✓ qualifications for experts and the procedure of formation the expert commissions;
- ✓ responsible authorities identified, etc

PROCEDURES

- ⇒ in case of LMO/GMO deliberate **release into environment** Risk Assessment should be conducted based on the field trials **by the Complex Experts Commissions** with the attraction of experts with different expertise.
- ⇒ for the LMOs intended for **contained use** or for **FFP** the assessment is carried out basically as a result of the analysis of materials on risk assessments which have been conducted by others. In doubtful cases additional examination is carried out.

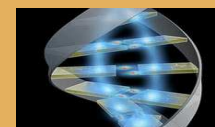


KYRGYZSTAN

At the moment, there is a **lack of qualified specialists**. That is why before the expert system will be established the materials of the examinations conducted by foreign experts and materials of the international information system will be used and taken into account.

Further steps:

- ⇒ Creation of experts' potential and preparation of methodical manuals on tests and risks assessment taking into account international requirements and technologies.
- ⇒ Training of experts and creation of a technical basis for the Database creation on global experience of experts' risks assessment and standard techniques for applications examination.
- ⇒ Preparation of the project or possible threats of *GMO's* penetration and character of possible ecological impact



TAJIKISTAN



Party of the Protocol since 2005.

- All the existing **state control institutions** have a sufficient experience in certain areas but the risk assessment provided by them does not include the *GMO* risk assessment, and thus such organizations **have neither experience, nor the relevant potential**.
- However, the **available research institutions** working on scientific development and investigations in the area of food product quality and safety, agricultural plants and forage, **are a potential** for further development of the scientifically confirmed assessment of risks of *GMO* use.

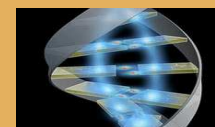
TAJIKISTAN

Risk Assessment system is presented in the NBF and in adopted Law on Biosafety. According to the NBF risk assessment has to be **carried out** by the **Expert Board**.

Expert Board will consist of experts from:

- Research institutions of Academy of Science RT,
- Tajik Academy of Agricultural Science RT
- Ministry for Healthcare
- and NGO representative.

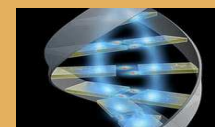
Upon the results of the risk assessment the Expert Board prepares a **scientific summary and recommend actions for minimising risks** to be considered by the National Biosafety Commission in the process of decision making.



TAJIKISTAN

Priority needs:

- ⇒ Development of guidelines for risk assessment and management related to the *GMOs*;
- ⇒ Preparation of directory with technical guiding principles of the risk assessment;
- ⇒ Development of the mechanism of reviewing the outcomes of the risk assessment by the National Biosafety Commission, including: * domestic regulations of the National Biosafety Commission procedures, * Guidelines on risk assessment for NBC;
- ⇒ Training of experts/specialists
- ⇒ Procurement of technical equipment for the laboratories.



Non-Parties - KAZAKHSTAN

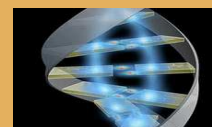


Kazakhstan **didn't ratify** the Cartagena Protocol yet, but has developed a number of related documents including National Biosafety Framework.

In the country there is a number of scientific institutions where research on *GMO* is conducting, such as Institute of Molecular Biology and Biochemistry.

There are also different scientific laboratories in the country able to identify *GMO* and conduct risk assessment.

At the moment there are no cases of carrying out risk assessments.



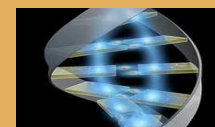
KAZAKHSTAN

According to the NBF and draft Law on Biosafety any activity connected with GMO should be carried out when there is a corresponding sanction from the Authorized Body on Biosafety based on the decision of **Commission on Biosafety**.

The National Commission on Biosafety:

- Decides, which competent bodies or scientific institutes conduct risk assessment;
- Obligated to make sure, that risk assessment on the basis of which the decision should be taken is carried out;
- Has responsibility for Risk assessment of genetically modified organisms in the contained use;

Risk assessment should be carried out within 270 days.

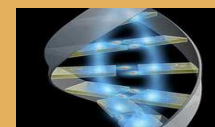


KAZAKHSTAN

Procedures:

- ⇒ In the case of **contained use of GMO** the risk assessment should be conducted in order to define the level of required protection measures. It is **carried out by the National Commission on Biosafety**.
- ⇒ **In case of GMO deliberate release into the environment** the risk assessment should be conducted in order to identify negative **GMO** impact on human health and environment. The National Commission on Biosafety will decide, which competent bodies or scientific institutes will conduct risk assessment.

The issues of **GM** product delivery to the market are regulated by the existing law «on Food Product Quality and Safety» but risk assessment issues are not defined there. It is necessary to amend the Law in a more extended way.



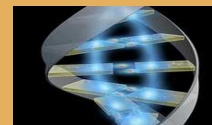
Non-Parties

GEORGIA

- ⇒ The comprehensive risk assessment of *GMO* was not conducted. Only in 1996-97 the impact assessment of *GM*-potatoes was conducted.
- ⇒ There are a number of specialists and a guide for risk assessment.
- ⇒ There is a need for financial support to improve the technical base and the experts qualifications.

UZBEKISTAN

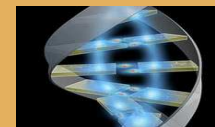
- ⇒ Development of legal documents is at the initial stage of development and requires a reorganization of the administrative and institutional mechanisms.



Non-Parties

TURKMENISTAN

- ⇒ Turkmenistan has not worked in the field of genetic engineering and biotechnology.
- ⇒ So far, no legal and administrative instruments dealing with the issues of the environmental security and human health using the products of modern biotechnology are developed.
- ⇒ Currently, several governmental institutions are authorized to assess and manage risks associated with *GMOs*: Customs committee, Inspectorate on plants quarantine, "Caspian control."
- ⇒ There is a shortage of administrative and scientific capacity to conduct risk assessment, monitoring and control.



SUMMARY

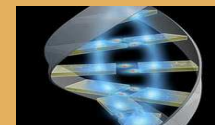
Risk assessment presently hasn't carried out in the sub-region.

CAPACITY:

- ✓ In most countries a priority steps are undertaken to develop procedures for risk assessment and risk management. This includes the development of the NBFs and the Law on Biosafety.
- ✓ There are institutions and scientists working in the field of biotechnology;
- ✓ Priorities are identified for capacity building and risk assessment;

DIFFICULTIES:

- Developed/adopted laws are not sufficient for effective risk assessment and there is a need in supplementary regulations;
- Lack of accessible guidelines and virtually no relevant experts to conduct risk assessment;
- Poor equipment facilities in institutions/laboratories;
- Scarce financial resources (support is needed).



CAPACITY BUILDING NEEDS

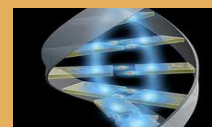
Implementation of NBFs to create the up-to-date biosafety system, including the system of risk assessment is needed.

The priority needs are the following:

- Development of regulations and by-laws on risk assessment;
- Development of the guidelines on risk assessment;
- Training of specialists;
- Procurement of laboratory equipment and chemical agents;

An important aspect is also the sub-regional cooperation to ensure the exchange of experience, available capacity and development of joint documents and decisions.

Currently, almost all activities are suspended, because countries are not capable to reach the planned by its own, and there is a need in outward support. At the same time, the GEF has suspended consideration of Biosafety projects, which affected the implementation of the Cartagena Protocol in countries and creation of the necessary capacity.





THANK YOU FOR ATTENTION!

