



Republic of Moldova

**Biosafety Implementation:
good practices & challenges**

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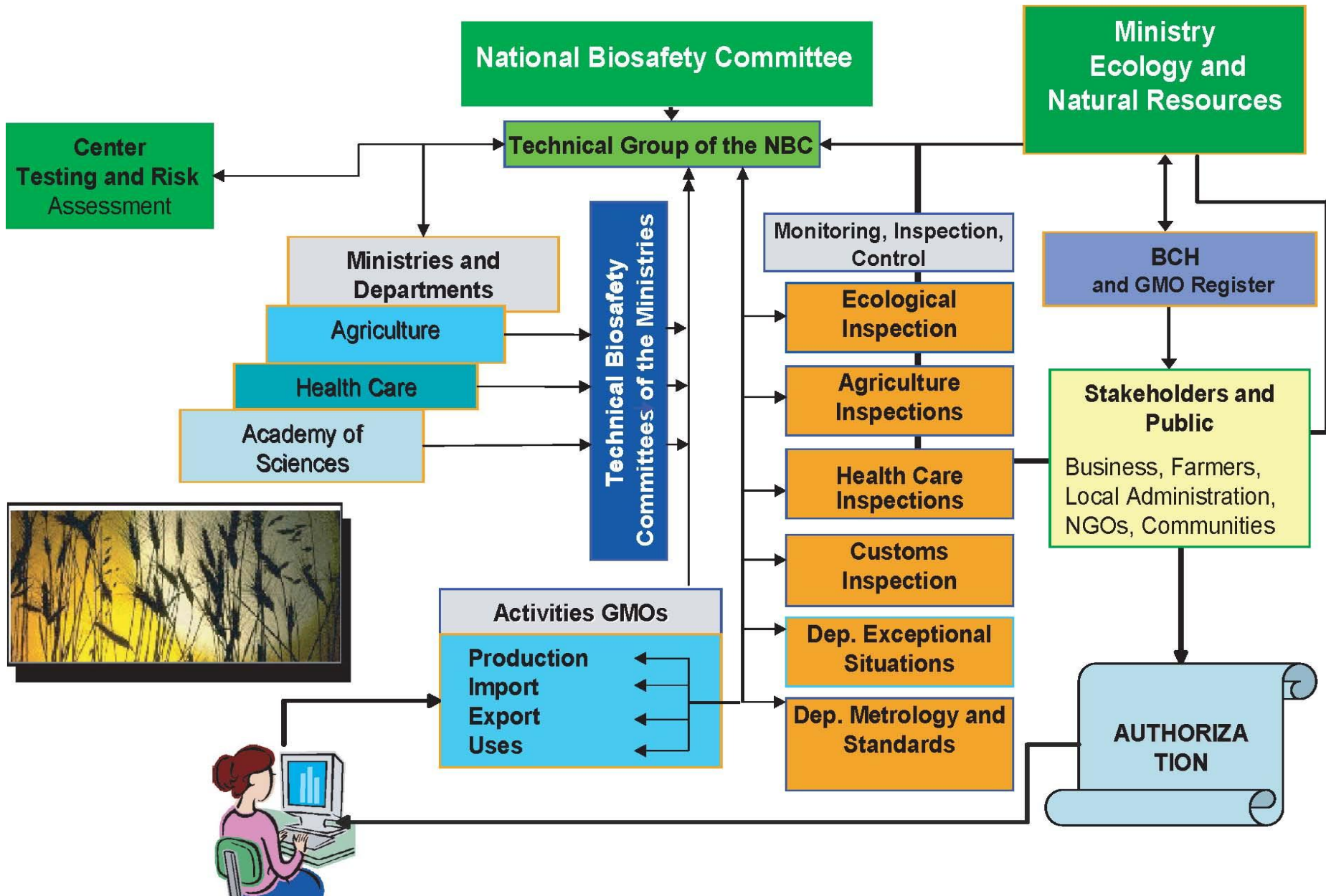
Country framework for the NBF implementation project

- ✚ Ratification of the Convention on Biological Diversity by the Resolution of the Moldovan Parliament no. 112-XV of 27 April 2001
- ✚ Ratification of the Cartagena Protocol on Biosafety by the Resolution of the Moldovan Parliament no. 1381-XV of 11 October 2002
- ✚ National Strategy and Action Plan on Biological Diversity, 2000
- ✚ Ministry of Ecology - National Biosafety Authority & FP, 2002
- ✚ National Law on Biosafety, 2001

National Regulations on Biosafety

- ***Law ratifying the Cartagena Protocol on Biosafety to the Convention of Biological Diversity (N° 1381-XV dated October 11 2002).***
- ***Law on biological safety (No 755 dated February 21, 2003).***
- ***Law concerning the entry, modification and addition into the Law on licensing different types of activity No 451- XV dated July 30, 2001 (No 214-XV dated June 24, 2004).***
- ***Government Resolution concerning the National Commission on biological safety (No 603 dated May 20, 2003).***
- ***Government Resolution No 1153, dated September 25, 2003, on Regulations concerning the issuance of permissions for various types of activities related to the testing, manufacture, utilization and creation of genetically modified organisms.***
- ***Government Resolution on appointment of the national authority responsible for liaison with the Secretariat of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity no. 197 of 25.02.2003***
- ***Governmental Resolution on labeling of food products and the standards on labeling of housekeeping chemical products, nr. 996 of 20.08.2003***
- ***Order on Regulations on Information and Public Consultations on Genetically Modified Organisms, No 19 of 10.02.2004***
- ***Joint Order of the Minister of Ecology and Natural Resources and Minister of Education on establishing of the National Biosafety Center, No 28/61 of February 18, 2004***

NATIONAL BIOSAFETY FRAMEWORK



Biosafety priorities identified for Moldova

- Enforce comprehensive National Biosafety Policy as the basis for the development of the adequate national regulations and institutional framework
- Establish responsive and fully functional national regulation framework in line with CP and national needs
- Enabling national system for handling request and decision-making as well as performing risk assessment and management associated to LMOs
- Encourage national system for "follow-up" activities, namely monitoring of environmental effects and legislation enforcement
- Enhance public awareness, education and participation to ensure access to information

FOCUSED ACTIONS to meet CPB obligations: GEF/UNEP Implementation Project (2006-2010)

- The main objective is to have, by 2010, a functional National Biosafety Framework (NBF) fully operational through:
 - biosafety policy
 - regulatory regime
 - system for handle requests (administrative, risk assessment & management, decision making)
 - follow-up activities (enforcement, monitoring for environmental effects)
 - public awareness and participation

Barriers and challenges

- Lack of experienced or authorized experts
- Inappropriate data and/or lack of databases
- Insufficient methodologies for assessment and evaluation
- Low level of cross-sectorial cooperation
- Insufficient scientific data and arguments regarding adverse risks of *OMGs*
- Experts express their concern regarding the approval process of drafts
- Insufficient level of awareness of public and decision-makers
- Corporative and group interest observed

CURRENT ACTIONS/expected outcomes

Policy development

- Action Plan elaborated
- Domestic Biosafety law improved
- Sectorial regulations strengthened with Biosafety requirements
- Secondary regulation and guides prepared

Capacity building for decision making

- Roles and responsibilities for handling of requests established
- Procedures for Notifications in place
- Risk assessment/management available

Enforcement & monitoring

- Procedures for monitoring and inspection in place
- GMO testing strengthened and available
- Emergency reply working
- Transportation, packaging & labeling respected

Public Participation

- Mechanism for public participation to decision making approved
- Trainings, workshops held
- Public awareness and education raised

Good practices in policy/regulatory framework

- ***Action Plan on Strengthening Biosafety Policies in the Republic of Moldova for 2008-2010.***
- ***Law on Modification and Completion of some Legislative Acts on Sectoral Legislation.***
- ***Law on Modification and Completion of Biosafety Law***
- ***Regulation on Public Information and Consultation in the Matter of Genetically Modified Organisms.***
- ***National Register on Genetically Modified Organisms***
- ***Summary of Notification for Genetically Modified Organisms or products Placing on the Market***
- ***“Monitoring Plan” to Decision of Government concerning the Approval of Regulation on Authorization of Obtaining, Testing, Use and Commercialization of Genetically Modified Organisms Nr. 1153 from 25.09.2003.***
- ***Regulation on Transboundary Movements of Genetically Modified Organisms.***
- ***Regulation on Packaging, Labeling, Storing and Transit of Genetically Modified Organisms.***
- ***Regulation on Monitoring, Inspection and Control of Deliberate Release of GMOs into the Environment and on the Market.***
- ***Regulation on Risk Assessment from Genetically Modified Organisms.***
- ***Regulation on Customs Procedures at the Import and Export of Genetically Modified Organisms.***

Concordance analysis: *Country response to engagements assumed under the CBD / CP*

CBD/CP
requirements
(by Art.)

Decisions
(COP/MOP)

Response of the R.M.
(Strategies, Programs,
Action Plans, Laws, GD,
Regulations, Standards,
Orders)

Measures to be
undertaken
(activities planned),
(references
to the legislative
document)

Terms of realization
of measures and
institutions
responsible for
implementation

Financial resources
for realization
(Financial framework)

Grade of execution
of planned activities
(full implemented,
partial,
non-implemented)

Barriers for
implementation of planned
activities
(ref. activities
implemented partial
or non implemented)

Measures to contribute
for overcome of the barriers
(impediments)
(ref. activities partial
implemented
or non-implemented)

New measures as response
of the RM to the engagements to CBD and CP

Steps to find assessment methods

**1) Data Stocktaking
(strategies, programs,
methods, toolkits, best
experience)**

- Guidelines recommendations
- International experience
- Internet offered data
- Desk study - legislation, policies and strategies; reviewing Reports and Studies performed previously
- Problem tree (key barriers analysis)
- Meetings and round tables
- Stakeholders consultations

2) Data analysis

- Concordance analysis
- SWOT analysis
- Input data & expected outputs

**3) Selection/Generalization
(available & appropriate)**

- Task oriented assessment
- Cross-sectoral integration
- Drafting policy/regulation
- Financial accessibility

Strategy for public awareness and PP

- **Objective for Component E:** Enhance national capacities for public awareness and participation into decision making process:
 - **Ratification and implementation of new Art. 6' and Amendment I' to the Aarhus Convention;**
 - **Establishing of mechanism for public access to decision making process,** provided by legislation (new Governmental Regulation);
 - **Drafting and adoption of a strategy for public awareness** via mass media, seminars, books, brochures, etc.;
 - **Creation and regularly updated Web page** with the open information for public;
 - **Establishing and updating of the Register on interesting public;**
 - **Establishing** of permanent contacts and **collaboration with the relevant NGOs and other stakeholders** with the purpose of involving them into the decision making process and into the process of adequate public information;
 - **Development of capacities for implementation of traceability and transparency;**
 - **Organizing of opinion polls** on the biosafety related issues.

Methods of implementation of a PP strategy

- ✦ Strong involvement of Parliament, Government, local authorities to information and discussion via seminars and workshops
- ✦ General public will be informed via mass-media (articles in newspapers, TV, radio broadcasts)
- ✦ Farmers aware via mass-media, publication of brochures, distribution via farmers associations
- ✦ Business (importers and food and feed producers) and consumers' associations - via special round tables with a special attention to testing and labeling
- ✦ Teachers - via special seminars using Center on Biosafety capacities with two aims - awareness and inclusion of biosafety issue to curricula

PP - What is already done? (national legislation study):

National law on Biosafety (2001):

Article 6. Ensures membership of one qualified **NGO** representative in National Biosafety Commission

Article 24 Labeling

Article 39. Public Information and Consultation

- (1) Permitting procedure of deliberate release to the environment and placing of LMOs to the market **is transparent**. Transparency of activity related to contained use of GMOs is ensured by the National Biosafety Commission (NBC).
- (2) In 10 days after receiving of notification the NBS has to inform public with the specification of the way to obtain information.
- (3) Comments of public are accepted during 30 days from the day of announcement and should be taken into consideration during making of decision on notified activity. In dependence of comments the **public hearings** could be organized to discuss different aspects of a problem.
- (4) NBC ensures **public participation** in decision making taking into consideration national legislation and multilateral treaties where RM is a Party.

PP - What is already done?

Improving the governmental regulations # 1153 of 25.09.2003, para 28 and 30

When notification submitted to the NBC, NBC:

- a) in 10 days informs public and consult the notification content;
- c) provides citizens with the information;
- d) places notification documents to WEB-page of the MENR;
- e) takes comments into consideration during 30 days from the date of information; organizes public hearings in case of necessity.

NBC has 90 days for decision making plus time necessary for consultation with public

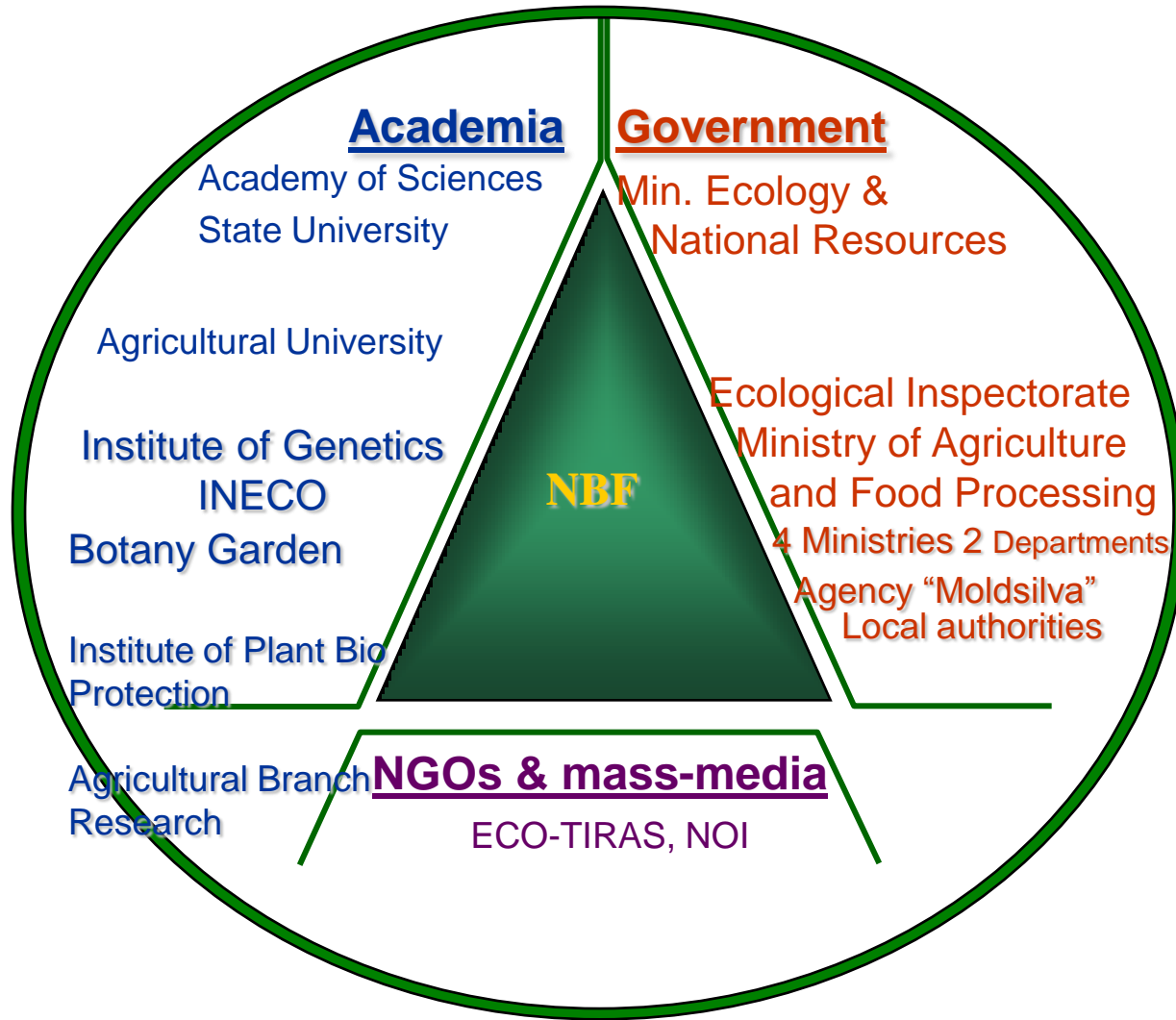
PP – Good practices of the implementation project

- Ratification and implementation of amendments to Art. 6 of the Aarhus Convention and Art. 23 of Cartagena Protocol;
- Awareness of the importance of procedures for public consultations and information exchange with parliament and government officials, scientists, media and general public is improved;
- The national Biosafety Web Site with feedback mechanism is developed, registered with the main search engines in the worldwide web, fully operational and updated on regular basis;
- Register of Interesting Public;
- Group of NGOs are working on biosafety issues and participate in international networks on biosafety;
- Various outreach materials produced and disseminated;
- Guidelines on public consultation are drafted out, became familiar to decision makers & public;
- Public is involved to decision making process;
- National economic policy is harmonized with Biosafety necessities. Political consensus on biosafety issue in RM;
- Biosafety issues are included to university curricula.

Good practices performed during implementation of NBF

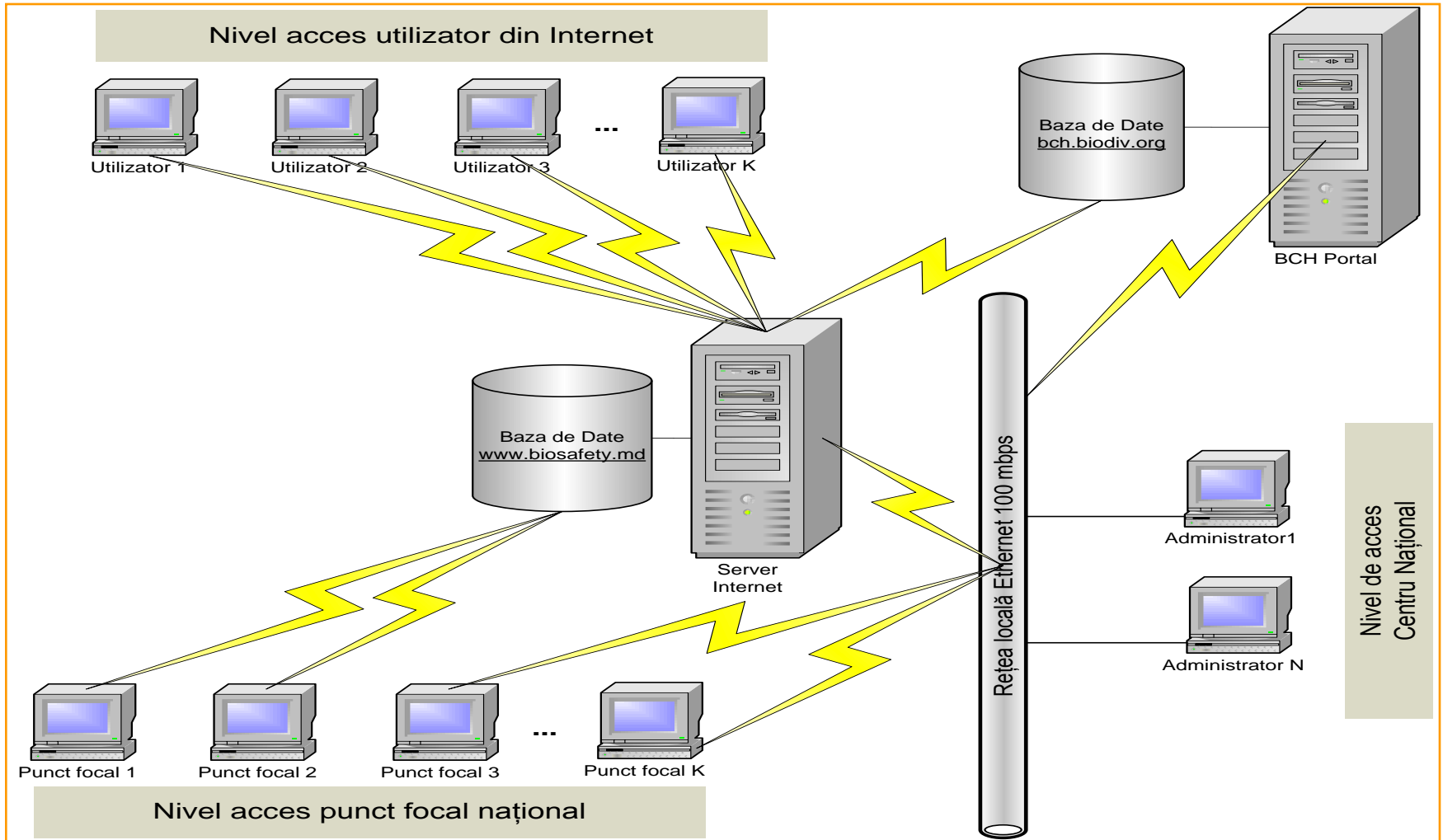
- overcome methodology insufficiency for policy formulation
- train local consultants and arise their capacity for policy/regulatory formulation
- meet public awareness and participation to decision making
- overcome divergence of opinion between public, government and research communities
- cross-sectoral approachment and involvement for overcome intergovernmental poor collaboration
- awareness, consultation, meeting consensus for draft policy and regulations through meetings, workshops, trainings and media
- awareness of public officials & policy-makers
- establish a network of sectorial Focal points /cross-sectorial collaboration
- Network of Biosafety relevant bodies and research and Roster of experts
- BCH - capacity building and exchange of information

Stakeholders' partnership



Architecture of the BCH system in Moldova

General scheme



MOLDOVA: BIOSAFETY CLEARING-HOUSE



Ministry of Ecology and Natural Resources



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- ◆ BIOSAFETY
- ◆ INFORMATION MANAGEMENT
- ◆ INSTITUTIONAL FRAMEWORK

- [National Authority](#)
- [Partner Institutions](#)
- [National committee](#)
- [Focal point](#)
- [Biosafety office](#)
- [International partners](#)

- ◆ LEGISLATIVE FRAMEWORK

- ◆ NORMATIVE FRAMEWORK

- ◆ NOTIFICATION GMO

- ◆ NATIONAL REGISTER OF GMOS

- ◆ USEFUL INFORMATION

- ◆ F.A.Q.

- ◆ FEEDBACK



[Convention on Biological Diversity](#)



[Global Environment Facility](#)



[United Nations Environment Programme](#)



[Ministry of Ecology and Natural Resources](#)

Events

12.03.2008 // [Information regarding the process of implementation of UNEP-GEF Project "Support for the Implementation of the draft National Biosafety Framework for the Republic of Moldova"](#)

22.02.2008 // [FAO-BiotechNews](#)

The News items included in the e-mail newsletter FAO-BiotechNews, which was launched by FAO in 2002 and later expanded to include the French and Spanish editions (FAO-BiotechNews-Fr and FAO-BiotechNews-Esp respectively) in 2003 and the Russian edition (FAO-BiotechNews-Ru) in 2005. The e-mail list provides Updates of news and event items that are relevant to applications of biotechnology in food and agriculture in developing countries. The items' main focus is on the activities of FAO, or other United Nations agencies/bodies and of the 15 research centres supported by the Consultative Group on International Agricultural Research. To subscribe to FAO-BiotechNews, send an e-mail message to mailex@mailex.fao.org leaving the subject blank and entering the one-line text message as follows: subscribe FAO-BiotechNews-L.

16.02.2008 // [REGISTER OF PLANT VARIETIES OF THE REPUBLIC OF MOLDOVA FOR YEAR 2007](#)

The Register of Plant Variety represents a database that refers to the plant varieties admitted to use in the Republic of Moldova. According to the Law of Republic of Moldova nr.915-XIII of July 11, 1996 for Plant Variety Protection the plant varieties can be used in production process only after the official tests and registration of the variety in the Register of Plant Variety of Republic of Moldova were made. Decisions for registration and with draw of the plant varieties from Register of Plant Variety is approved by the National Council for Plant Variety at the proposal of State Commission for Crops Variety and Registration. The Register of Plant Varieties for 2007 year included 1370 varieties. The varieties are classified by species and directions of utilization, varieties included in the Plant Variety Register contain the following information: Registration number (column 1); Variety name (column 2); Originator's number (column 3); Maintainer's number (column 4); Year of registration (column 5); Year of second time registration (column 6); Some morphological (7-13), and commercial characteristics (annex 1). The plant varieties which have Variety Brevet are indicated with the symbol "B". In annex 2 are indicated the addresses of originators' and maintainers' of the varieties included in the Register. This publication is an official document. The information included could be used only with the reference to the State Commission for Crops Variety Testing and Registration.

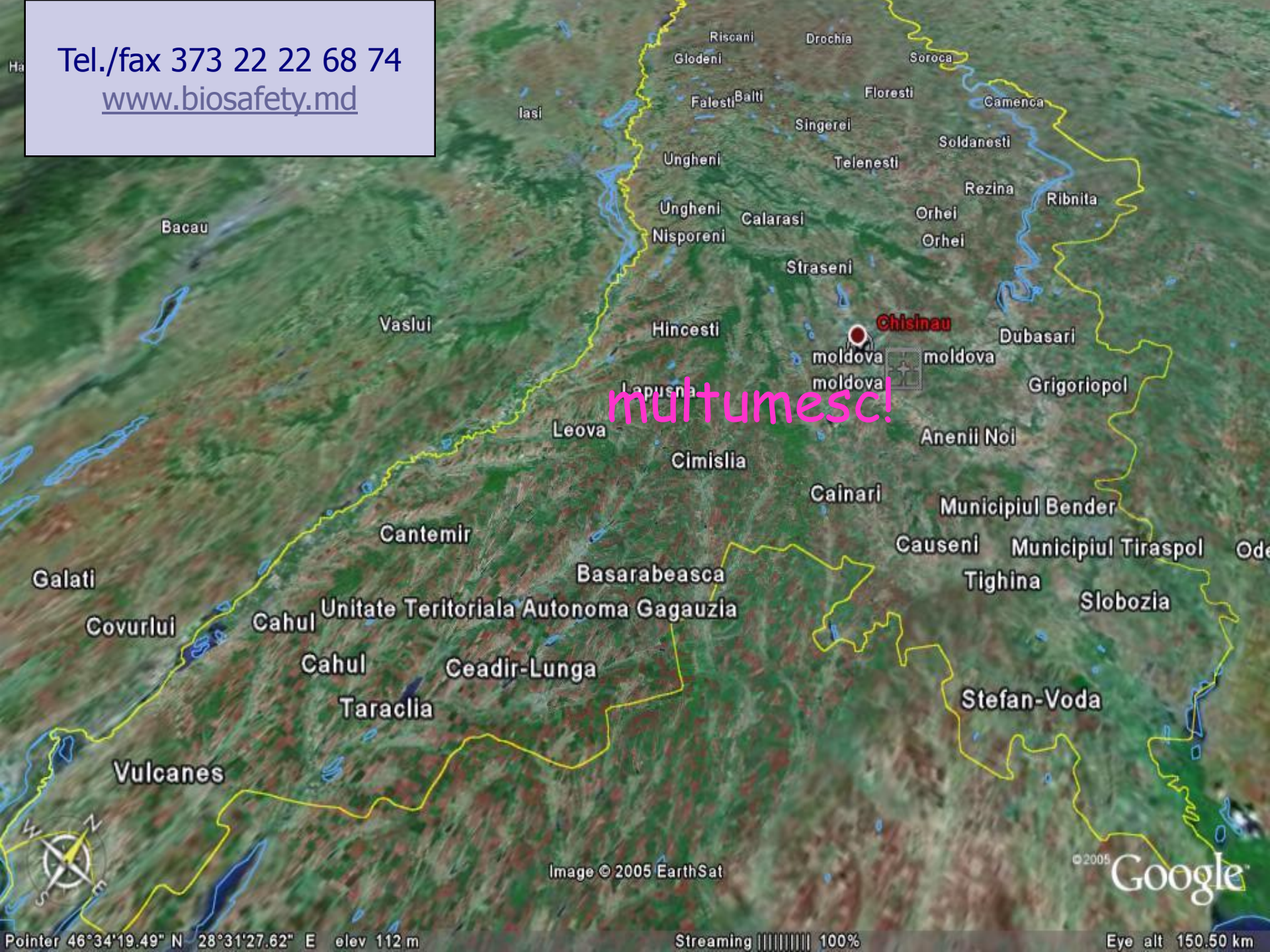
06.02.2008 // [Report on implementation of GMO's national electronic register](#)

The GMO's national electronic register is a register in which are administered all GMOs registered in the Republic of Moldova. As in any other software, the development process of this register was divided in 5 phases: (1) the analysis phase: the analysis of the existing GMO's electronic registers and working out of the technical task for national GMO's electronic register; (2) the design phase: defining the structure of data, the system components and their interaction, the security aspects and the interface of register with BCH portal; (3) the development and implementation phase: writing of program code, elaboration of database structure and integration of modules; (4) the testing phase: the register testing, introduction and editing of test GMO, registering of users and dictionaries; (5) documentation and users' training – training of experts that use the system.

29.01.2008 // [Instrucțiune privind aplicarea anexei nr. 5/2 "Planul de monitoring" la Hotărârea Guvernului despre aprobarea Regulamentului privind autorizarea activităților legate de obținerea, testarea, utilizarea și comercializarea organismelor modificate genetic nr. 1153 din 25.09.2003](#)



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