



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

**The current status,
experiences gained and lessons
learned in the implementation of
risk assessment and risk management
provisions of the Biosafety Protocol
in the West Balkans**

**Aleksej Tarasjev
Institute for Biological Research,
Belgrade University, Serbia**



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

DISCLAIMER

This presentation


**Does not represent views and positions of any
particular government or organization**

Is based on both official and unofficial sources

Does not include confidential information

Is open to corrections and additions

Biosafety Clearing-House

Convention on
Biological Diversity[Home](#) [The BCH](#) [The Protocol](#) [Finding Information](#) [Registering Information](#) [Resources](#) [Help](#)Country Profiles... 

Welcome to the BCH Central Portal

The Biosafety Clearing-House (BCH) is a mechanism set up by the [Cartagena Protocol on Biosafety](#) to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol. Global access to a variety of scientific, technical, environmental, legal and capacity building information is provided in all 6 of the UN languages. BCH account holders can create and manage records in the BCH through the [Management Centre](#).

Latest news

2007-11-01 [November 2007 Release of the BCH...](#)
2007-03-27 [March release of the Biosafety Clearing-House...](#)
2007-03-07 [Costa Rica - "Convención Interinstitucional para el Desarrollo de Capacidad Nacional" sobre el Centro de Intercambio de Información sobre Seguridad de la Biotecnología para Costa Rica...](#)

[More news...](#)

Latest Additions

2007-11-9 [Capacity Building Opportunity...](#)
2007-11-8 [New Zealand - Risk Assessment...](#)
2007-11-8 [Biosafety Course...](#)
2007-11-8 [Finland - Risk Assessment...](#)
2007-11-8 [Finland - Risk Assessment...](#)
2007-11-8 [Finland - Risk Assessment...](#)
2007-11-8 [Finland - Risk Assessment...](#)

[More additions...](#)



Convention on
Biological Diversity

CEE Regional Workshop on Capacity-Building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms Chisinau, Republic of Moldova, 26-28.11. 2007.

Razvitak okvira
nacionalne biološke
sigurnosti za
Republiku Hrvatsku



Hrvatski | English

Kontaktirajte nas | Mapa weba | Napredno pretraživanje

Search

- O projektu
- O nama
- Zakonska regulativa
- Vijesti
- Česta pitanja i pojmovi
- Linkovi

Okvir za razvoj nacionalne
strategije biološke sigurnosti

Publikacije

Discussion Papers on Liability
in the Context of Biosafety

Zakon o genetski
modificiranim
organizmima

A B C...
Pojmovnik

Razviti katalog web linkova

Naslovnica

Pogledajte osveženi katalog web linkova
o GMO problematiki

Dobro došli na stranice o GMO problematiki!

Ove web stranice su napravljene u okviru projekta "Razvitak okvira za nacionalnu biološku sigurnost za Republiku Hrvatsku".

Ovaj Projekt treba uspostaviti zakonodavni, administrativni i stručni sustav koji će omogućiti provođenje Protokola o biološkoj sigurnosti (Kartagenski protokol) u Hrvatskoj.

Kartagenski protokol prvi je međunarodno obavezujući dokument koji uređuje problematiku protogreničnog prijenosa, provoza, rukovanja i uporabe živih **genetski modificiranih organizama (GMO-a)** koji mogu imati štetan utjecaj na očuvanje i održivu uporabu biološke raznolikosti, uzimajući također u obzir i negativan utjecaj na ljudsko zdravlje.

Stranice su dizajnirane u svrhu pruženja informacije hrvatskoj i međunarodnoj javnosti o Projektu i problematiki genetski modificiranih organizama (GMO-a) općenito (zakonska regulativa), vijesti iz zemlje i svijeta, itd.). Budući da stranice imaju i edukativsku ulogu, ovdje možete pronaći i pojmovnik iz područja genetike i biotehnologije.

Stranice pružaju pregled zakonodavstva o biološkoj sigurnosti, rezultate nacionalnih anketa, prezentacije i izvješće svih organiziranih radionica, publikacije i korisne linkove na srodne web stranice drugih državnih i međunarodnih institucija.

Kako bi bili u mogućnosti u potpunosti ostvariti funkcionalnost stranica, molimo Vašu suradnju, zato svoje komentare i sugestije pošaljite pod kategoriju [Kontaktirajte nas](#).

Vijesti

[Hrvatsko ekološko društvo odlazi na godišnju skupštinu](#)

Hrvatsko ekološko društvo ove godine obilježava 35 godina rada.

[Pročitaj više...](#)

[Mrežnica bi uskoro mogla postati park prirode](#)

Sporezom su potpisali župan Nedjeljko Stanić i gradonačelnici Karlovača, Slunja, Duge Rese i Ogulina, te načelnici općine Barilović, Tounja i Reparske Stole.

Vlada Republike Srbije

[Naslovnica](#) | [kontakt](#)

Pretraži:



Dobrodošli na zvaničnu prezentaciju Ministarstva poljoprivrede, šumarstva i vodoprivrede Republike Srbije

[NASLOVNICA](#) | [BUDŽET](#) | [STIPS](#) | [REGISTRACIJA POLJOPRIVREDNIH GAZDINSTAVA](#) | [STRATEGIJA](#) | [INFO CENTAR](#) | [TEMA](#)

- ORGANIZACIJA I KONTAKTI
- BUDŽET
- DOKUMENTI, UREDBE
- NACRTI ZAKONA
- WEB LINKOVI
- PITANJA I ODGOVORI
- ARHIVA VESTI



GMO su postali stvarnost savremenog društva i neophodno je da svaka zemlja razvije odgovarajući okvir (regulatorni, administrativni) u cilju uspostavljanja određenih pravila i standarda koje treba ispoštovati u vezi sa GMO.

Poslednjih 30-tak godina, mogućnosti izmene oblika života su doživele pravu revoluciju primenom tehnika moderne biotehnologije. Naučnici su naučili kako mogu da izdvoje i prenesu deo deozoksinonukleinske kasetine (DNK) ili čitave gene iz jedne vrste u drugu. Na ovaj način dobijeni organizmi poznati su kao "živi modificirani organizmi (LMO)" ili "genetski modificirani organizmi (GMO)" ili "transgeni organizmi".

Najcititaniji tekst:
Aktivnosti
ministarstva:
[STRATEGIJA
POLJOPRIVREDE
SRBIJE](#)

Alternativne i linkovi

- Više o: Aktivnosti ministarstva
- Novosti od ministarstva

Reprizna emitovanja ponedeljkom u 8.45 - RTS2.



SCOPE

- **Based on Cartagena Protocol on biosafety articles 15 and 16 covering Risk assessment and Risk management**
- **Contained use not fully covered since it is exempted from AIA procedure of Cartagena Protocol and it is covered by various laboratory safety manuals and good laboratory practice**
- **With emphasis on deliberate release (including field trials) environmental impact assessments since they are more likely to be specific for a region**



TOPICS ADRESSED

- **The current status, including examples from countries in the sub-region;**
- **The experiences gained and lessons learned**
- **The difficulties/challenges encountered;**
- **Risk assessment capacity-building needs and priorities;**
- **Previous and ongoing risk assessment capacity-building efforts, including training activities;**
- **Recommendations for improving risk assessment and risk management in the sub-region region and for enhancing local capacities.**



Convention on
Biological Diversity

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

Balkan Peninsula













Convention on
Biological Diversity

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

REGULATORY REGIMES







<i>Country</i>	<i>CPB Parties</i>	<i>CNA / NFP</i>
	In force since 09.05. 2005	Ministry of Environment, Forestry and Water Administration Ministry of Agriculture and Food Ministry of Health
		Ministry of Foreign Trade and Economic Relations
	In force since 11.09.2003	Nature Protection Directorate, Ministry of Culture
	In force since 09.12.2005	Ministry of Environment and Physical Planning
	In force since 03. 06.2006	Ministry of Agriculture, Forestry and Water Management
	In force since 03. 06.2006	Ministry of Agriculture, Forestry and Water Management



Convention on
Biological Diversity

CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.

REGULATORY REGIMES







<i>Country</i>	Laws and Regulations	Pending changes in legislation
	Various laws and international treaties have relevance, including <i>Law on Environmental Impact Assessment</i>	Draft <i>Law on Biosafety</i>
	Only <i>Law on food</i> have some relevance	Government made decision to put draft <i>Law on GMO</i> in parliamentary procedure (Nov 07)
	<i>Law on GMO</i>	
	Various laws and international treaties have relevance	Draft <i>Law on GMO</i>
	<i>Law on GMO</i> on federal FRY level until 2002	Drafting national law
	<i>Law on GMO</i>	Amending <i>Law on GMO</i>



Convention on
Biological Diversity

CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.

ADMINISTRATIVE SYSTEMS







<i>Country</i>	Actual <u>Advisory</u> and Decision making bodies	Proposed <u>Advisory</u> and Decision making bodies
	Relevant ministries	<u>Biosafety Council</u> National Biosafety Committee
		<u>GMO Council</u> Directorate for plant health (federal) Ministry for environment (on level on entity), Direcorate for veterine (federal)
	<u>Council on GMO with Board on contained use and Board on environmetal release</u> Relevant ministries	
	Relevant ministries	<u>Comission on GMO management</u> <u>Scientific Committees</u> Relevant Ministries
	Ministry of Agriculture, Forestry and Water Management ?	<u>National Biosafety Committee</u> Ministry of Environment Protection
	<u>National Biosafety Committee</u> Ministry of Agriculture, Forestry and Water Management	<u>National Biosafety Committee</u> Ministry of Agriculture, Forestry and Water Management



Convention on
Biological Diversity

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

DECISIONS

<i>Country</i>	Decisions and risk assessments
	
	
	Field trials (Maize 1997-1999)
	
	
	Field trials (Maize 2001-2006, Arabidopsis 2007)



Convention on
Biological Diversity

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

FIELD TRIALS ON GM MAIZE

**Performed on well known GM events, that were
released to the environment in other countries
(Liberty Link, Roundup Ready, Bt , NK603)**



Convention on
Biological Diversity

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

FIELD TRIALS ON GM ARABIDOPSIS

**GM Arabidopsis designed for landmine detection
(Aresa, Copenhagen)**

**Application with new modification events and
constructs**

Result of biotechnology but not agrobiotechnology



Convention on
Biological Diversity

CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.

RISK MANAGEMENT AND ILLEGAL PLANTINGS : CASE OF GM SOYBEAN

**In Serbia illegal plantings in 2005 of RR
Soybean were detected on 425 ha. 7800 t were
collected from much larger area**

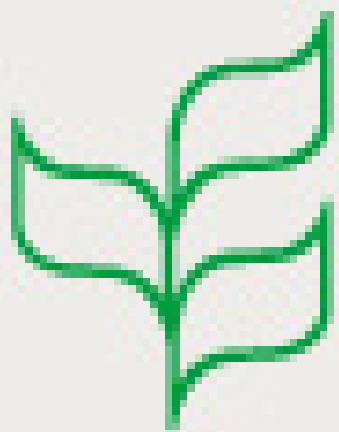
**In 2006 only 5% of those fields were positive
for GM**



Convention on
Biological Diversity

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

Previous and ongoing risk assessment capacity-building efforts, including training activities



Convention on Biological Diversity

CEE Regional Workshop on Capacity- Building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms







Chisinau, Republic of Moldova,

26-28.11. 2007.



Convention on
Biological Diversity

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

<i>Country</i>	UNEP GEF Development of NBF Project	UNEP GEF BCHProject	UNEP GEF Implementation Project
	Yes	Yes	
			
	Yes		
	Yes		
	Started as part of FRY/Not covered in final report		
	Yes		



OTHER PROJECTS AND OPPORTUNITIES IN RISK ASSESSMENT CAPACITY BUILDING

Other activities in West Balkan Region directly connected with risk assessment

USDA/FAS

● **MATRA**

●

Other activities connected with risk assessment with participants from West Balkan region

● **FAO/ Comenius**

● **ICGEB**

● **BSBA**

● **Genok**

● **EIGMO**

●



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

Experiences, lessons, difficulties and challenges



THE EXPERIENCES GAINED AND LESSONS LEARNED

- **All countries in the region oriented towards membership in EU / importance of EU approaches toward risk assessment and reporting of risk assessments;**
- **Countries in transition;**
- **Regulatory and administrative systems under development or reconstruction**
- **Evaluation of risk assessment presented by applicant;**
- **External experts in advisory bodies;**
-



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

THE DIFFICULTIES/CHALLENGES ENCAUNTERED

Unstable regulatory and administrative systems

Changes in agencies responsibilities

Changes in agencies structure

Problems in implementing existing systems;

Request handling

Monitoring

Enforcement

Lack of harmonization and synergism between regulatory systems in different countries

Open issues related to risk assessment and risk management

Crosses with conventional varieties, stacked genes...

Reporting risk assessments



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

THE DIFFICULTIES/CHALLENGES ENCAUNTERED

Lack of efficient information sharing

Information sharing and BCH

Information sharing among countries in the region

**Risk assessment and Biosafety issues mostly limited to
agrobiotechnology;**

Lack of regional approaches on capacity building in biosafety



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

Needs, Priorities and Recommendations



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

RISK ASSESSMENT CAPACITY BUILDING NEEDS AND PRIORITIES

Risk assessment and other scientific and technical expertise ;

Access to reference materials / databases on risk assessment

**National risk assessment frameworks, principles, procedures and
mechanisms**

Risk assessment methodologies;

Risk management :

**Detection, management and prevention of unintentional transfer of
LMO**

Emergency measures for unintentional LMO releases

Risk management frameworks, strategies and mechanisms

Tools for monitoring the handling and use of LMOs



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

RISK ASSESSMENT CAPACITY BUILDING NEEDS AND PRIORITIES

Mechanisms for follow-up, monitoring and assessment :

Training in Inspection procedures and control measures

**Scientific and technical cooperation in Long-term LMO monitoring and
surveillance**

**Training in Mechanisms for detecting unintentional or illegal LMO
movement ;**

Scientific and technical expertise :

**Scientific and technical cooperation in Scientific methods and protocols
relevant to risk assessment and management**

Training in Detection, testing and quantitative analysis of LMOs



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

RISK ASSESSMENT CAPACITY BUILDING NEEDS AND PRIORITIES

Legislative and regulatory framework :

- Development of legal frameworks**
- Implementation of legal frameworks**
- Regulatory training (legal, policy, enforcement, inspection etc.) ;**

Administrative framework :

- Decision-making system and administrative procedures**
- Inter-agency communication and coordination**

Technical, scientific and telecommunications infrastructures:

- Decision-making system and administrative procedures**
- Inter-agency communication and coordination**
- Establishment of mechanisms for regional and international cooperation
and sharing of experiences**



RECOMMENDATIONS FOR IMPROVING RISK ASSESSMENT AND RISK MANAGEMENT IN WEST BALKANS AND FOR ENHANCING LOCAL CAPACITIES

To serve as starting point for discussion

- Developing of projects and activities for *implementation* of existing or planned regulatory and administrative systems needed for risk assessment/ risk assessment evaluation and risk management
- Establishment of mechanisms for regional and international *cooperation and sharing of experiences* in risk assessment and risk management;
- Involvement of relevant specialists from *different fields of expertise* needed for successful environmental risk assessment
- Training in detection and sampling methods for different GMOs;



RECOMMENDATIONS FOR IMPROVING RISK ASSESSMENT AND RISK MANAGEMENT IN WEST BALKANS AND FOR ENHANCING LOCAL CAPACITIES

To serve as starting point for discussion

- Including biosafety, risk assessment and risk management topics in university curriculum of various profiles of needed specialists
- Training in biosafety, risk assessment and risk management topics for various profiles of needed specialists
- Solving funding issues;
-
-



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

Thank you!



**Convention on
Biological Diversity**

**CEE Regional Workshop on Capacity-Building and Exchange of Experiences
on Risk Assessment and Risk Management of Living Modified Organisms
Chisinau, Republic of Moldova, 26-28.11. 2007.**

**Questions, comments,
additions...**