

UNEP-GEF Biosafety Projects



BIOSAFETY LEGISLATIVE FRAMEWORK and INSTITUTIONAL ARRANGEMENT Republic of Macedonia

MINISTRY OF ENVIRONMENT AND PHYSICAL PLANNING ADMINISTRATION FOR ENVIRONMENT Mrs. MARIJA DIRLEVSKA CALOSKA, Advisor for GMO

Competent Authorities



- Ministry of the Environment
 - Act on GMOs
 - Cartagena Protocol on Biosafety
 - Agency for Food and Veterinary
 - Ministry of Agriculture, Forestry and Water Economy





Advisory Bodies to Competent Authorities

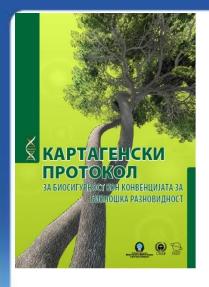


- Ministry of the Environment
- Commission on Management of GMO
- 15 members
- Scientific Committee on GMO
- 7 members





Biosafety in Republic of Macedonia



- Cartagena Protocol on Biosafety ratified in 2005
- UNEP/GEF Project Development of NBF (2003 - 2005)
- EU funded Project Strengthening of Environmental Management / Sector Approximation Strategy (CARDS 2005)
- UNEP/GEF Project Strengthening the capacities for effective participation to the BCH (2008 - 2010)
- UNEP/GEF Project Support the implementation of the NBF (2011 -2014)





UNEP/GEF Project Development of NBF (2003 - 2005)

... Established National Coordination Committee...













Skopje, February 200

results

..developed:

- » National Survey on Biosafety
- » Draft National Biosafety Framework
- » Draft Law on GMO 2005
- » Public pool opinion on Biosafety





...2007 - 2008...



Law on GMO (Official Gazette of RM 35/08)



CЛУЖБЕНВЕСНИК НА РЕПУБЛИКА МАКЕДОНИЈА Број 35 Год. LXIV Петок, 14 март 2008 Цена на овој број е 260 денари www.slvesnik.com.mk contact@slvesnik.com.mk



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549.	Закон за генетски модифицирани организми	67	552.	"Македонија" - Скопје во Акционерско друштво во државна сопственост Статут на Акционерско друштво за аеродромски услуги "Аеродроми на	113
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UNEP/GEF Project Strengthening the capacities for effective participation to the BCH (2008 - 2010)



MACEDONIAN BIOSAFETY CLEARING HOUSE









MK | EN

MAIN MENU

Introduction

Gmo

BIOSAFETY SYSTEM

Cartagena Protocol on Biosafety

EU Directives

LEGISLATION

Laws, regulations, agreements

National Competent

National Bodies

Laboratories

BCH

Central BCH

National BCH

News

Usefull Links



Macedonian Biosafety Portal is the website on biosafety created by UNEP/GEF Project on "Building Capacity for Effective Participation in the Biosafety Clearing - House (BCH)".

On this portal you may find information on the biosafety system such as information regarding to the biosafety legislation (national and international), competent authorities, competent bodies in Republic of Macedonia that ensures high level of protection of human health and of the environment in the management of genetically modified organisms.

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UNEP/GEF Project Support the implementation of the NBF (2011 - 2014) - project objectives

- Fully operational NBF???
 - harmonized legislation
 - in direction with the CPB
 - approximated international agreements
- National biosafety framework (regulatory, decision-making, monitoring, state control and enforcement) in Republic of Macedonia has not been fully completed and/or operational in all the necessary segments.





Project components:



- 1. Biosafety policy
- 2. Regulatory regime
- 3. Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)
- 4. Follow-up mechanism (monitoring of environmental effects and enforcement: control and inspections)
- 5. Public awareness and participation





Component 3 - Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)

 Training on risk assessment and risk management was held in Leunovo National Park Mavrovo, april 2014.





LEGISLATIVE FRAMEWORK

· GMO ACT

provides a horizontal type of legislation on the use of GMOs and their products, and intermediate other existing legislation in the areas of agriculture and health care.

- Act regulates:
- Contained use of GMOs;
- · Deliberate release of GMOs into the environment,
- Placing on the market
- Importing and exporting GMOs or products containing GMOs





LEGISLATIVE FRAMEWORK

GMO ACT - exclusions

GMO ACT that refer to placing products on the market and to the import/ export of GMOs and products will not apply to:

- Foodstuffs for use in human food which are regulated by the Ministry of Health
- Pharmaceuticals which are regulated by the Ministry of Health.





LEGISLATIVE FRAMEWORK

In accordance with the Law on Genetically Modified Organisms ("Official Gazette of the Republic of Macedonia" No. 35/2008) in 2012, it was adopted

Decree on the content, scope and methodology for environmental risk assessment, appropriate for the nature of the introduced genetically modified organism and environment (Official Gazette of the Republic of Macedonia No. 22/2012).







- Republic of Macedonia is still in the process of completing its legal and administrative biosafety framework.
- Institutional mechanisms and entities for administering biosafety have not been clearly defined, including competent national authorities and their responsibilities according to the scope of their competencies.
- In the area of risk assessment, Republic of Macedonia has a lot of priority needs: establishment of risk assessment review mechanisms, including scientific advisory committees fully operational), Risk assessment methodologies.







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Thank you for your attention

