



## BIOSAFETY

# LEGISLATIVE FRAMEWORK and INSTITUTIONAL ARRANGEMENT

## Republic of Macedonia

**MINISTRY OF ENVIRONMENT AND PHYSICAL PLANNING  
ADMINISTRATION FOR ENVIRONMENT  
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# 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...*



*results*

*..developed:*

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



DRAFT  
NATIONAL BIOSAFETY FRAMEWORK  
FOR REPUBLIC OF MACEDONIA



Skopje, February 2005

UNEP-GEF Biosafety Projects

...2007 - 2008...



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



## СЛУЖБЕН ВЕСНИК НА РЕПУБЛИКА МАКЕДОНИЈА

Број 35    Год. LXIV    Петок, 14 март 2008    Цена на овој број е 260 денари  
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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

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[Gmo](#)

### BIOSAFETY SYSTEM

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### LEGISLATION

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### BCH

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## Welcome to the Macedonian Biosafety Portal

**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.

# 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).

# main challenges

- 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.



## Thank you for your attention

