

National biosafety system risk assessment and risk management in Romania

**South Eastern European Meeting on GMO Analysis in
Sofia, Bulgaria:
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Legal Framework

- Contained use – (lab, greenhouse)
 - Containment level authorization
 - Import, export, transit
- Deliberately release of GMO
 - Authorization for testing
 - Import, export, transit
 - Placing on the market
 - Cultivation/ deliberately release - authorization
 - Import, export, transit
 - Procedures regarding the chain from the producer to the consumer

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Contained Use

- EGO 44/2007 approved with changes by the Law 8/2008 – applies procedures for authorizing contained use facilities,
 - Risk assessment/ risk management/ monitoring/ emergency measures/ enforcement/
 - import, export and transit
- MO – regarding the format of the national register for genetically modified microorganism

Deliberately Release

- EGO 43/2007 regarding deliberately release of the genetically modified organisms
 - Sets up procedures for testing and placing on the market respectively:
 - Authorization
 - Risk assessment/risk management/ monitoring/ enforcement /public consultation/ Community level consultation
 - Import/export/transit

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EU Legislation

- Regulation 1829/2003 (food, feed authorization)
- Regulation 1830/2003 (traceability and labeling)
- Regulation 65/2004 (unique identifier)
- Regulation 1946/2003 – (export and transit)
- Directive 2001/18/EC – communitarian level communication system
- Directive 90/219/EEC – communitarian level communication system

Subsequent Legislation

- MO 923/2005 on the approval of Summary Information Format Relating to the placing on the market of GMOs, as or in products
- MO 1295/2005 on the approval of the Summary Notification Information Format for the notification concerning the deliberate release into the environment of GMOs, for purposes other than placing on the market

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International Instruments

- Convention on Biological Diversity
 - Law 58/1994 which in art. 8 g and 19 states the need for a protocol on biosafety development
- Cartagena Protocol on Biosafety
 - Law 59/2003
- WTO agreements starting to 1995

Projects

- EU Project “Supporting the Accession Process of the Candidate Countries, Overview of Transposition Progress Monitoring” Conducted by COWI, Denmark, and local experts
- UNEP GEF Project “Development of the National Biosafety Framework for Romania”

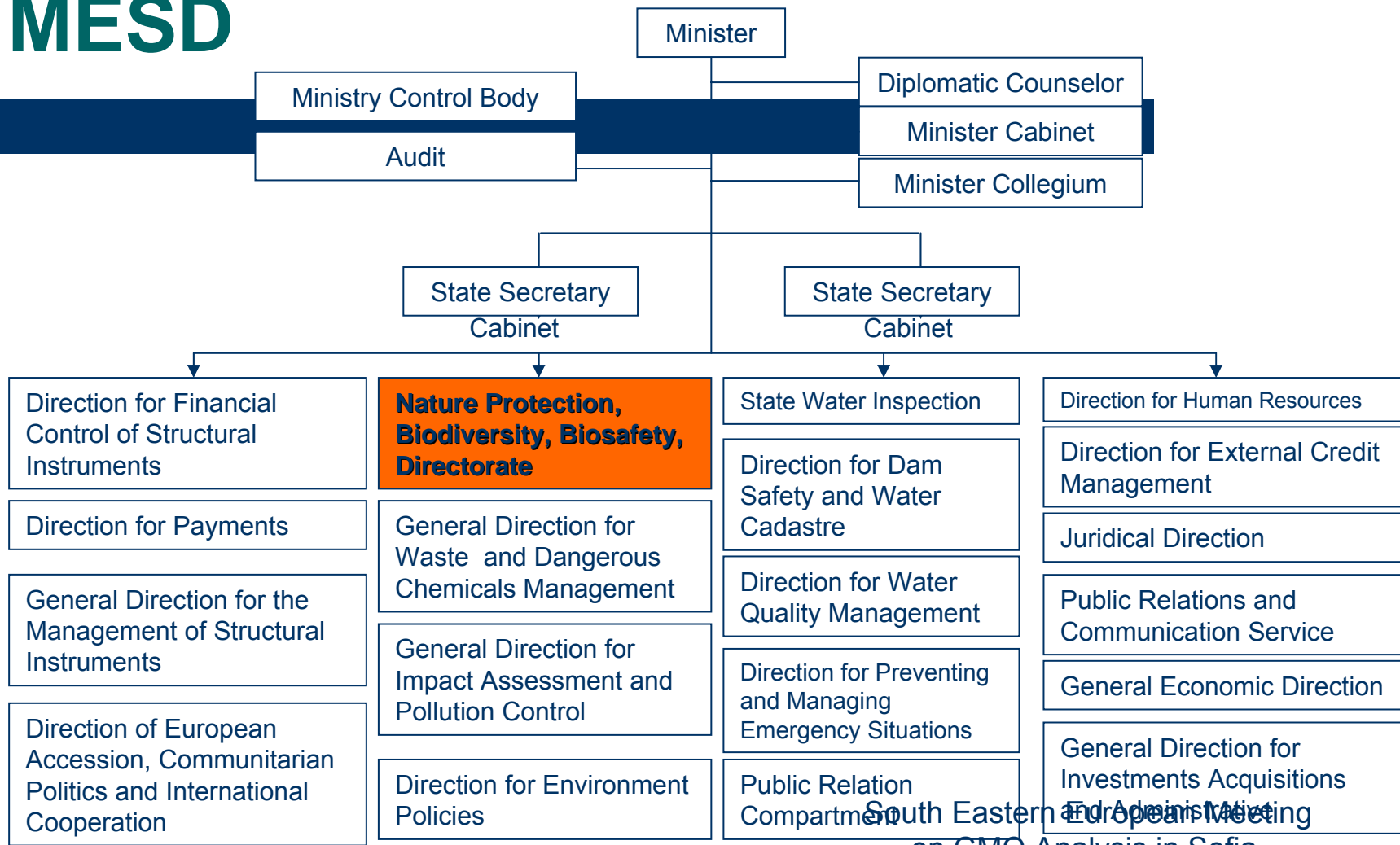
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Administrative Framework

- MESD – the public authority for biosafety policy development – environment risk assessment
- NEPA – the competent authority for issuing authorizations – environment risk assessment
- BC – the scientific body for risk assessment
- NEG – the authority for enforcing the environment legislation
- Other authorities: MARD – RA agriculture, MH – RA human health, MRE – RA research , NSVFSA – RA food feed, NCPA – RA consumer protection

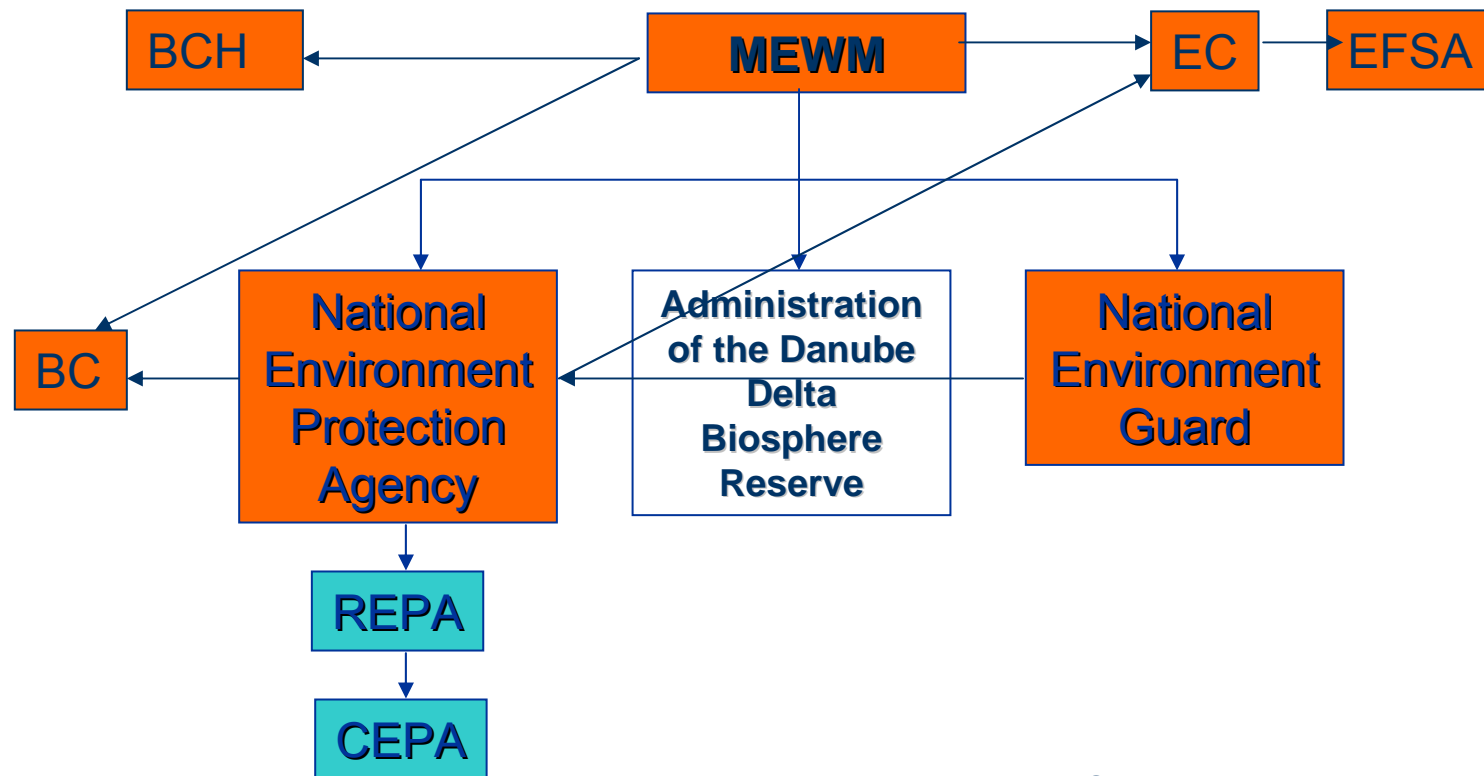
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MESD



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Biosafety Framework

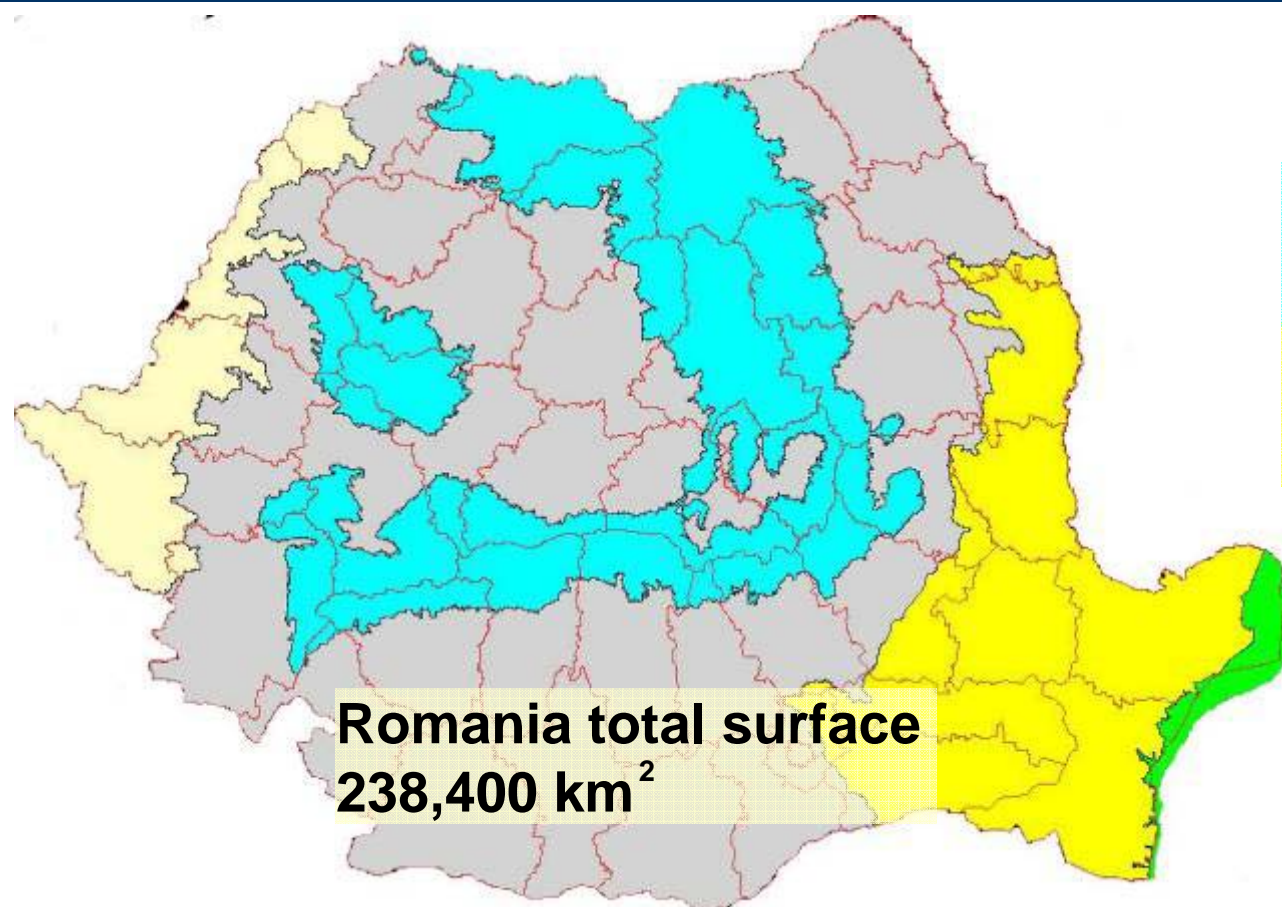


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Enforcement

- Institutional Protocol 3357/July 2006
 - NEG – for environment, MAFRD – for agriculture, NASVFS – food / feed chain, NACP – for consumer protection at the retailers level
 - Action plan for 2006 – for registering GM soybean (127.945 ha, 1153 farmers registered, 151 farmers – penalties for 4000 ha)
 - Action plan for 2007 – for controlling the removing of the GM soybean and registering GM maize MON810
 - Action plan for developing and continuing of the 2007 action plan

Biodiversity in Romania



Romania total surface
238,400 km²

Continental-53.63%
127,810.84 km²

Alpine-22.75%
54,213.68 km²

Steppic-16.85%
40,147.65 km²

Pannonic - 6.02%
14,345.84 Km²

Pontic- 0.75%
1,798.58 km²

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Risk Assessment

- According to Cartagena Protocol on Biosafety for authorizing the deliberately release of th GMOs into the environment
 - It is the central milestone for dossier analysis based on science

Cartagena Protocol

ANNEX III

- *Objective*
 - [...] to **identify** and **evaluate** the **potential adverse effects** of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.
- *Use of risk assessment*
 - [...] to **make informed decisions** [....]

Cartagena Protocol...

ANNEX III

- *General principles*
 - should be carried out in a scientifically sound and transparent manner [...]
 - lack of scientific knowledge [...] should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
 - Risks [...] should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
 - should be carried out on a case-by-case basis

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Cartagena Protocol...

- Risk assessment principles lead to the consideration of the following variables
 - the effect of the new gene (s) on the fitness of the GMO in the ecosystem
 - the ability of the GMO to escape
 - the stability of the existing community

Risk Assessment

- EU: EFSA guidance documents for risk assessment: 2004/2005/2006
 - Hazard identification → characterization → exposure assessment → risk characterisation → qualified presumption of safety
 - Comparative approach: concepts of “familiarity” and “body knowledge”, concept of substantial equivalence, intended and unintended effects
 - General info, characterisation of recipient, donor, products, description of genetic modification...

Risk Assessment...

- Scientific risk assessment is the cornerstone of biosafety regulatory systems and public-policy decisions related to the safety and acceptability of LMOs.

Risk Management

- Adequate scientific capacity provides improved assessment of potential risks and/or benefits, and can improve the quality of risk-management decisions and the capability for inspection and monitoring.

Requirements

- **Establishment** and proper **functioning** of appropriate mechanisms for
 - risk assessment
 - risk management
 - risk communication
 - appropriate management practice (financial, technical, and human resource constraints, Cohen 2001)

Practice for Testing

- BC issues scientific advices
 - Human resources (toxicology, alergology, etc.)
 - Transparency to the public
 - Meetings
- Authorities issues consents for their competency
- Public communication publishing on DG JRC and on the Romanian web site.
- NEPA issues the final authorization after consulting MESD

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Practice for Placing on the Market

[A] Directive 2001/18 part C

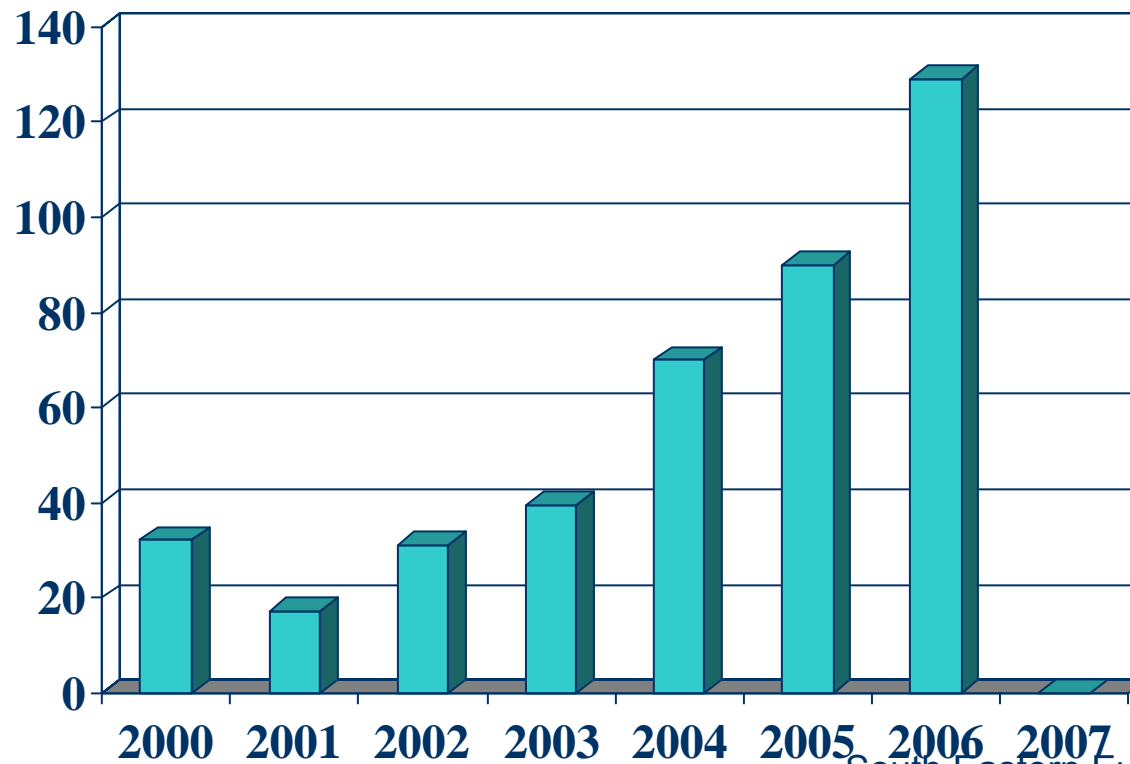
- BC issues scientific advices
 - Human resources (toxicology, alergology, etc.)
 - Transparency to the public
 - Meetings
- Authorities issues consents for their competency
- Public communication publishing on DG ENV and on the Romanian web site
- NEPA issue the evaluation report sent with the notification to EC and EC consultation
- NEPA issue the authorization

Practice for Placing on the Market

[B] Regulation 1829/2003 food feed

- NSVFSA receive the notification and after checking the completeness send it to EFSA
- EFSA evaluates the risks and ensure the publication on the website
- EC level evaluation
- Public consultation for competent authorities for Directive 2001/18/EC
- Authorization at EU level

Soybean RR



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Maize

Maize (*Zea mays* L.) – Mon 810 line, resistant to *Ostrinia nubilalis*; gene *Cry III A (b)*, Pioneer Hi-Bred Seeds Agro SRL, scope: testing in the field, 2000- 2006. Starting with 2007 is placed on the market (325 ha in 2007)

Maize (*Zea mays* L.) – T-25 line, tolerant to ammonium glufosinat, gene: *pat*, Pioneer Hi-Bred Seeds Agro SRL; scope: testing in the field, 2000-2008.

Maize (*Zea mays* L.) – NK 603 line, tolerant to glyphosate, gene *CP 4 EPSPS*, Pioneer Hi-Bred Seeds Agro SRL, Syngenta, scope: testing in the field, 2004/2006-2008.

Harmonizing Legislation

- Regional cooperation...
 - Still pending the bilateral cooperation with MD, TK, UK
 - Even BG and RO are EU countries there is no bilateral cooperation
 - The same between RO and HU or RO and Serbia as a third country for the EU
- History in regional cooperation
 - Through UNEP GEF project “Development of the national biosafety framework”

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Harmonizing Legislation...

- EU level
 - RO accepted after 2007 all products previously approved in EU by harmonizing the entire GMO regulation
 - RO set a distinction between the equivalency of environmental and human food safety risk assessments according to EU legislation

Conclusions

- For Romania it will be essential in the future to develop collaboration, exchange of information and expertise, training courses.
- Bilateral collaboration on biosafety would be a start

- Thank you for your attention!