RISK ASSESSMENT AND RISK MANAGEMENT IN ROMANIA AS A PART OF THE BLACK SEA SUB-REGION

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ROMANIA

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BLACK SEA SUB-REGION (BSR)

CARTAGENA PROTOCOL ON BIOSAFETY / RISK ASSESSMENT

- *Risk assessments undertaken pursuant to this Protocol shall be carried out in a **scientifically** sound manner, in accordance with Annex III* […]

- *The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment*.

- *The cost of risk assessment shall be borne by the notifier if the Party of import so requires.*

CARTAGENA PROTOCOL ON BIOSAFETY / RISK ASSESSMENT

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 ON BIOSAFETY / RISK ASSESSMENT

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

RISK ASSESSMENT

- 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

- Scientific evaluation is required for informed decision
- How it is used?
  - RO and BG: developed according to the EU regulatory framework
  - TK, Ukraine are using similar tools in different regimes

RISK ASSESSMENT

- **Transparency**
  - Publication of draft decisions accompanied by all public documentation
    - Up to this moment – RO – public consultation
    - TK, Ukraine, BG
  - External scientific expertise
    - RO no, not data available for BG, Ukraine, TK

New information regime

RO and BG according to the EU regulation

reevaluation of the dossier

APPROACHES …

- Policy options
  - Evidence-based scientific evaluation vs. consideration of socioeconomic factors
  - Consideration of risks and benefits vs. only risks
  - Definition of safety standard (s)

APPROACHES …

- Key questions
  - How are risk factors for a particular GMO determined?
  - How should international standards and agreements be incorporated?
  - Should the assessment process distinguish demonstrable vs. hypothetical risks?

APPROACHES …

- Key questions…
  - Who should be responsible for undertaking the necessary experimentation, testing and/or surveillance to satisfy risk assessment data requirements?
  - Other than risks, should the assessment include an examination of potential benefits or other issues?
  - Should broader social, ethical, or economic issues be factored into risk-assessment decisions?

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 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**.

PUBLIC ENGAGEMENT

- During authorization procedure
  - EU countries
- During time period of the decision taken
  - According to new information
  - RO, BG

FIRST CONCLUSION

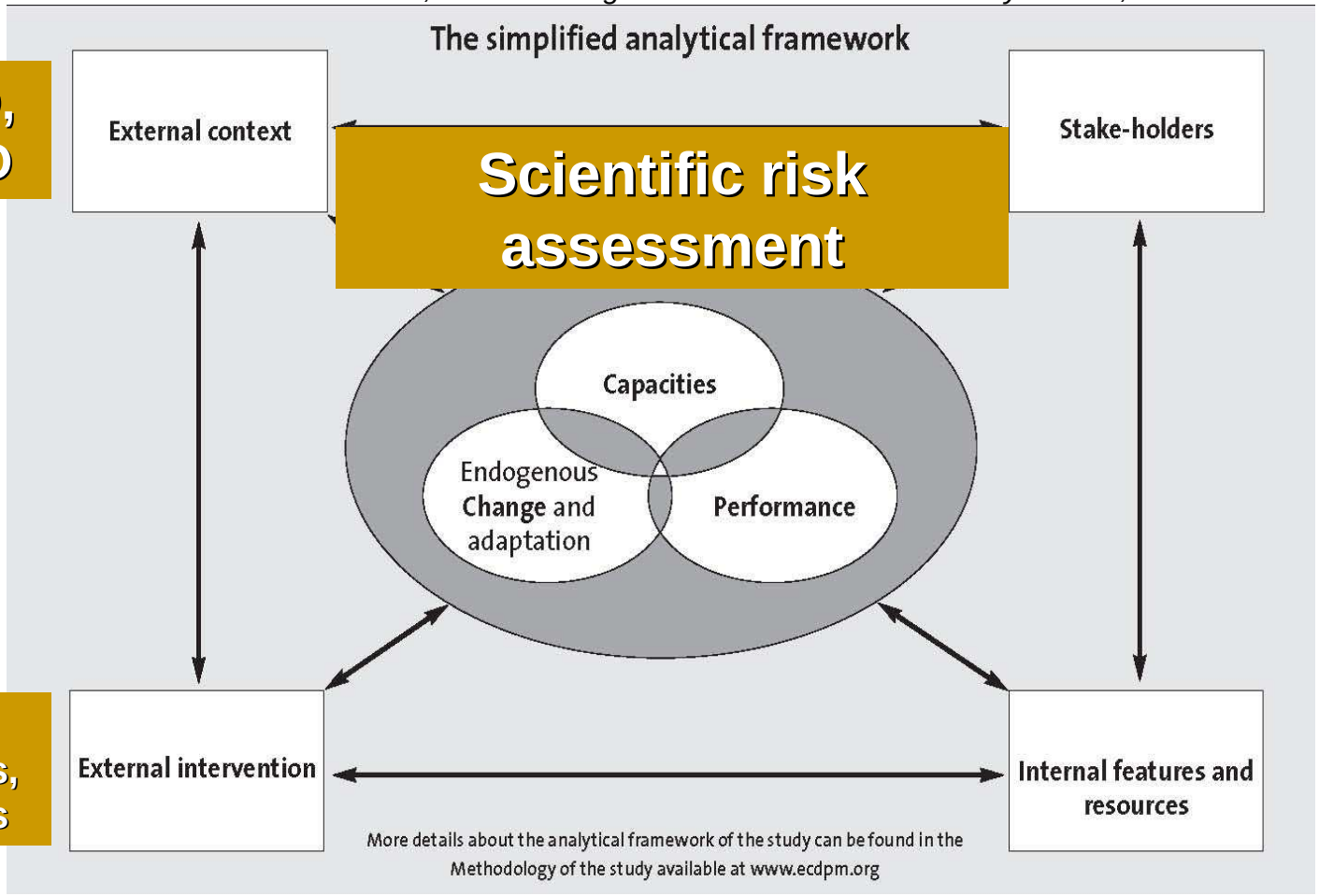
- Scientific risk assessment is the **cornerstone** of biosafety regulatory systems and public-policy decisions related to the safety and acceptability of LMOs.

RISK ASSESSMENT CAPACITY

Heather Baser, ECDPM Programme Coordinator and Study Leader, e-2003

CP, WTO, CA, WHO

Strategy & Action plans, Regulations



IMPLEMENTATION OF REGULATIONS

- **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)

IMPLEMENTATION OF REGULATIONS

- Romania case
  - Biosafety Commission 2002
    - Decision 2002
      - Establishment & functioning
      - Financial resources
      - Give scientific advice according to the GMO act from 2000 but **not properly according to the new regulation EO 43/2007**.

IMPLEMENTATION OF REGULATIONS

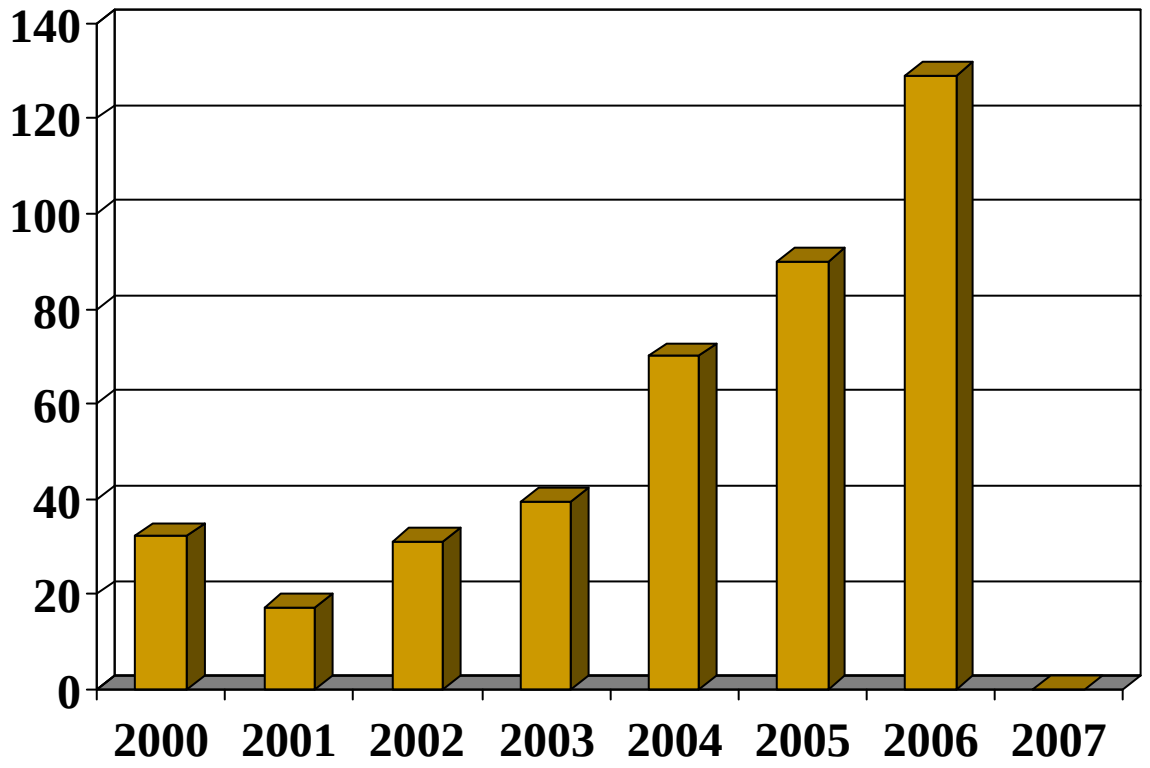
- Romania case…
  - BC Issues
    - Human resources (toxicology, alergology, etc.)
    - Transparency to the public
    - Meetings
  - Authority issues
    - Communication with BC commission
    - Payment of BC members
    - Decisions

IMPLEMENTATION OF REGULATIONS

- Romania case…
  - Decisions made during the implementation phase impact directly on the economic costs associated with assessing and mitigating risks and ensuring compliance.
    - BC was active and issued scientific advices at the ME request
    - Scientific advices were always positive and without any recommendations

SOYBEAN CASE

RR soybean (5-enolpyruvylshikimate-3-phosphate synthase: gene conferring tolerance to herbicide products containing glyphosate)



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.

- Maize (*Zea mays* L.) – *T-25* line, tolerant to ammonium glufosinat, gene: *pat,* Pioneer Hi-Bred Seeds Agro SRL; scope: testing in the field, 2000-2006.

- 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, 2004/2006-2006.

OTHER CROPS

- Sugar beet (*Beta vulgaris* L.) Roundup Ready – *GTSP 77* line, tolerant to glyfosate, gene *CP 4 EPSPS* from *Agrobacterium sp*., Monsanto, scope: testing in the field, 2000- 2003.

- Potato (*Solanum tuberosum* L.) *Bt* - Superior New Leaf variety, resistant to Colorado beetle (*Leptinotarsa decemlineata*), gene *Cry III A,* Monsanto, scope: deliberate release, 2000- 2003

2007 FIELD TESTING NOTIFICATIONS

Romania case…

Company	Species	Genes
Syngenta B/RO/07/01	maize	*crylAb*[1], *pat*[2]
Syngenta B/RO/07/02	maize	*epsps*[3]
MONSANTO B/RO/07/03	soya	*epsps*[3]
R&D Station BistritaB/RO/07/04	Plum tree	*PPV-CP*[4], *nptII*[5], *gus*[6]
Pioneer Hi-Bred B/RO/07/05	maize	*cry1F*[7], *pat*[2]
Pioneer Hi-Bred B/RO/07/06	maize	*cry34Ab1, cry35Ab1*[8],*pat*[2]
Pioneer Hi-Bred B/RO/07/07	maize	*cry34Ab1, cry35Ab1*[8], *cry1F*[7], *pat*[2], *epsps*[3]
Pioneer Hi-Bred B/RO/07/08	maize	*gat4621*[9], *zm-hra*[10]
Pioneer Hi-Bred B/RO/07/09	maize	*gat4621*[9] , *zm-hra*[10], *cry1F*[7], *pat*[2]
Pioneer Hi-Bred B/RO/07/10	maize	*gat4621*[9], *zm-hra*[10],*cry1F*[7], *cry34Ab1* & *cry35Ab1*[8], *pat*[2]
Syngenta B/RO/07/11	maize	*epsps*[3]
Pioneer Hi-Bred B/RO/07/12	maize	*cry1F*[7], *pat*[2], *epsps*[3]
Pioneer Hi-Bred B/RO/07/13	maize	*crylAb*[1], *epsps*[3]
Pioneer Hi-Bred B/RO/07/14	maize	*epsps*[3]

[1] Gene conferring tolerance to certain Lepidoptera species
[2] Gene conferring tolerance to glufosinate ammonium herbicides
[3] 5-enolpyruvylshikimate-3-phosphate synthase: gene conferring tolerance to herbicide products containing glyphosate
[4] Plum pox virus coat protein gene
[5] Neomycin phosphotransferase II: gene used as a selectable marker gene
[6] β-glucuronidase gene
[7] Gene conferring tolerance to certain Lepidoptera species
[8] Gene conferring tolerance to certain Coleopteran species
[9] Glyphosate-N-acetyltransferase: gene conferring tolerance to herbicides containing glyphosate
[10] A modified maize acetolactate synthase: gene conferring tolerance to a range of ALS-inhibiting herbicides such as sulfonylureas.

BSR NOTIFICATIONS - 2007

- Notifications
  - Field testing
    - RO 2.5 ha total,
  - Placing on the market
    - RO 325 ha MON810
    - BG no cultivation
    - TK no
    - Ukraine n.a.

HARMONIZING

- Political decision to follow EU regulation
  - since 1999 – RO, later for BG, TK, Ukraine
- Legislative framework
  - 2000 RO, 2007 TK (not for microorganisms),
  - 2006 Ukraine had no GMO act,
  - BG 2006 had the first full GMO act
- Regional cooperation
  - As part of EU, RO and BG are sharing the same problems related to GMOs
  - Involved in the examination of TK GMO regulation

HARMONIZING

- 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”

HARMONIZING

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

IMPLEMENTATION CAPACITY

- For small countries, where the national science community is small, the ability to capitalize on external expertise and information may be a crucial condition for implementing the Protocol.
  - RO, TK, BG and Uk have almost the same biosafety research capacity and because of the financial difficulties did not developed scientific expertise at the same level like the EU developed countries

HARMONIZING BIOSAFETY IN BSR

- The harmonization of risk analysis principles, information requirements, and standards of assessment can be instrumental to maximizing the use of institutional, financial, technical, and human resources within a region.

LAST CONCLUSIONS

- For BSR countries 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!