Risk assessment of LMO in Bulgaria

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Legislative framework

International agreements

- Cartagena Protocol on Biosafety
- Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

European Union Legislation

- Directive 2001/18/EC on the Deliberate Release into the Environment of GMOs
- Directive 2009/41/EC on the Contained Use of GM Microorganisms
- Directive 2004/35/EC on Environmental Liability with regard to the Prevention and Remedying of Environmental Damage

Legislative framework

National Legislation

- Law on Genetically Modified Organisms (GMO Law)
- Law on the Liability for Preventing and Remedying of Ecological Damages (Liability Law)
- Ordinance on Contained Use of GMO
- Ordinance on Release of GMO into the environment and on the market

Principles of Environmental Risk Assessment of GMO (ERA)

- **Contained in Annex II of Directive 2001/18/EC and Annex III of Directive 2009/41/EC**

- **Transposed in Annex 1 of Bulgarian GMO Law and in the two ordinances**

Principles of Environmental Risk Assessment of GMO (ERA)

- **Objective: to identify and evaluate on a case by case basis, potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment**

Principles of Environmental Risk Assessment of GMO (ERA)

General Principles:

- identify characteristics of the GMO and its use which have the potential to cause adverse effects compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations
- should be carried out in a scientifically sound and transparent manner based on available scientific and technical data;
- should be carried out on a case by case basis
- if relevant new information on the GMO and its effects becomes available, the ERA may need to be readdressed

Principles of Environmental Risk Assessment of GMO (ERA)

Methodology:

- 1. Problem formulation including hazard identification
- 2. Hazard characterisation
- 3. Exposure characterisation
- 4. Risk characterisation
- 5. Risk management strategies
- 6. Overall risk evaluation and conclusions

Bulgarian Experience
Contained use

- Bulgarian GMO Law covers the contained use of GM Microorganisms (four classes of contained use 1-4) and other GMO (two classes A and B)
- Registration of facilities for contained use is required
- Permission for individual projects is required for contained use of GMM class 2 or higher and for contained use of GMO class B
- So far five facilities for GMM class 1 have been registered and three of them are also registered for GM plants class A. All five are in academic institutions

Bulgarian Experience
Release into the Environment

- Permit is always required
- ERA should be carried out
- Positive opinion of the Consultative Committee on GMO is necessary
- Public consultation should be carried out
- Positive decision of the Council of the Ministers is required
- Currently the release of GMO is prohibited in and around Protected Areas and Natura 2000 sites. This covers the whole territory of Bulgaria and for this reason no permits have been issued

Bulgarian Experience
Release on the Market

- Permit is always required
- ERA should be carried out
- Positive opinion of the Consultative Committee on GMO is necessary
- Public consultation should be carried out
- European Commission and EU Member States should be consulted
- Positive decision of the Council of the Ministers is required
- Currently no such applications has been submitted to Bulgaria

Bulgarian Experience
Clinical Trials

- Positive opinion by the Minister of Environment and Water is required
- ERA should be carried out using the principles for Release into the Environment
- Positive opinion of the Consultative Committee on GMO is necessary
- Final Authorisation is issued by the Bulgarian Drug Authority
- Currently three positive opinions for Gene Therapy Trials have been issued, but we expect the number to increase

Thank you