

National Biosafety Framework in Bulgaria

Katya Trichkova

Legal expert

European integration Department

Ministry of Environment and Water

POLICY

No specific policy paper on biosafety is elaborated

REGULATORY REGIME

- 1996 - Regulation for release of GM higher plants, created by recombinant DNA
- MAIN PRINCIPLES:
- Permit regime for release of GMHP for research or commercial purposes
- Notification to the Council for Safe Use of GMHP

REGULATORY REGIME

- COMPETENT AUTHORITY
- Council for safe use of GMHP
- Chairman – Minister of Agriculture and Forestry
- Scientific Secretary – distinguished scientist
- 5 Permanent Members – Ministry of Environment and Waters, Ministry of Agriculture and forestry, Ministry of Health, Scientific organisations.
- External experts may be drawn in the Council's activities

REGULATORY REGIME

- **COMPETENCES:**
- Allows or reject the release of GMHP in the territory of Bulgaria
- Evaluates the risk assessment and safety measures, proposed by the applicant
- Keeps records
- Controls the relises approved

REGULATORY REGIME

- **CONTROL:**
- Field trials conducted from the applicant f
- 4 expert groups supports the Council and carried on monitoring and laboratory analyses on herbology, entomology and food safety.
- After 3 to 5 years of trials and assessments the Council may approve the application or denials permission for release of GMHP

APPLICATIONS SUBMITTED AND APPROVED (1998-2004)

- Permits for field trials only were issued on:
- MAIZE
- POTATO
- SUNFLOWER
- TOBACCO

LARGE-SCALE FIELD TRIALS

1999 – 13 000 ha

2000 – 19 000 ha

2001 – 6 400 ha

2002 – 2 200 ha

2003 – 2 119,5 ha

2004 – 0,5 ha

SPECIAL CONDITIONS

- Contracts between the company and the farmers that will undertake the large the large-scale field experiments must be signed.
- GM crop to be kept at a distance of 50 m minimum;
- Large-scale field trials to be carried out under the supervision of the representative of the applicant.
- All of the remaining seed quantities other than planting should be returned to the applicant;
- The farmers must not use the seeds for other purposes;

SPECIAL CONDITIONS

- Farmers are obliged to harvest separately the GM plants from non- GM and to store them also separately in special storehouses with respective designation;
- The production should be bought by a company, which is going to export it out of Bulgaria and EU member's countries; In case that the production is not bought out it must be destroyed and plant residues should be buried during the autumn soil tillage;
- Farmers who are supposed to test the hybrids should receive full explanations by the representatives of the company: how the hybrids were developed, practical instructions how to carry on the technology trials, etc.

NEXT STEPS

- **New Draft Law on GMOs** – in accordance with:
- EU Directives 90/219/EEC and 2001/18/EC
- Requirements of Cartagena Protocol
- Aarhus Convention

NEXT STEPS

- **SCOPE:**
- Contained use
- Deliberate release
- Placing on the market
- Transboundary movements

NEXT STEPS

- **COMPETENT AUTHORITIES:**
- Minister of Environment and Water
 - contained use
 - deliberate release
- Minister of Agriculture and Forestry
 - placing on the market

Consultative Scientific Committee on GMO

NEXT STEPS

- **MAIN PRINCIPLES**

- Permit regime for all activities
- Advanced Informed Agreement for transboundary movements
- Environmental risk assessment
- Public hearings (for deliberate releases and placing on the market)
- Post-release/post-marketing monitoring
- Labeling and traceability requirements