

National legislation in the field of genetically modified organisms

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Legislation:

- ✓ GMO Act (in force since 01.06.05)
- ✓ Regulation on the contained use of GMOs (in force since October 2005)
- ✓ Regulation on the deliberate release into the environment and placing on the market of GMOs (in force since October 2005)

GMO Act – Scope

- ✓ Contained use
- ✓ Release into the environment
- ✓ Placing on the market
- ✓ Transboundary movements

GMO Act - Exceptions

- Placing on the market of:
 - ✓ GM food
 - ✓ Food ingredients
 - ✓ human medicinal drugs and medicinal products for veterinary use which consist of or contain a GMO or a combination of GMOs

GMO Act – Competent authorities

- Ministry of Environment and Water
 - ✓ Contained use
 - ✓ Release into the environment
- Ministry of Agriculture and Forestry
 - ✓ Placing on the market

GMO Act - Consultative Commission on GMOs

- Gives opinions to the Minister of environment and water and the Minister of agriculture and forestry during the decision-making process
- Consists of:
 - ✓ 15 academic degree-holding scientists in the relevant spheres
 - ✓ government representatives (non-voting capacity)
 - ✓ NGO representatives (non-voting capacity)

GMO Act - main principles

- ✓ Permit regime for all activities, involving GMOs
- ✓ Advance informed agreement before the first transboundary movement of GMOs, intended for release into the environment
- ✓ Risk assessment for the human health and the environment

GMO Act - main principles contd.

- ✓ Public hearings (for the release into the environment and placing on the market of GMOs)
- ✓ Monitoring after the release into the environment and placing on the market
- ✓ Requirements for labeling and traceability

GMO Act -prohibitions

- ✓ The deliberate release into the environment and the placing on the market of the following GMOs is hereby prohibited: tobacco, vine, cotton, damask rose, wheat, and all vegetable and orchard crops [Art. 79 (1)].
- ✓ The deliberate release of any GMOs into the areas included in the National Ecological Network [Art. 80]
- ✓ The deliberate release into the environment and the placing on the market of any GMOs containing antibiotic resistance marker genes [Art. 81]

GMO Act -prohibitions contd

- ✓ Any genetic modifications of damask rose, vine and tobacco within Bulgarian territory [§ 4. (1)]
- ✓ The release into the environment and the placing on the market of genetically modified animals. [§ 4. (2)]

THANK YOU FOR YOUR ATTENTION

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FROM THE MEETING**