



Ministry of Agriculture and Food  
**Food Quality and Safety Directorate**

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# **Legislative and Control Framework of GMO in Bulgaria.**

**Ministry of Agriculture and Food activities for GMOs.**

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**Competent Bulgarian Authorities applying legislation for GMO:**

**Ministry of Environment and Waters (MEW)**

Contained use of genetically modified organisms;

Deliberate release into the environment of genetically modified organisms;

**GMO**

**Ministry of Health (MH)**

**Ministry of Agriculture and Food (MAF)**

**Commercial cultivation of GMO**

Placing on market GMOs for food and feed use, food and feed containing or consisting of GMOs or produced from or containing ingredients produced from GMOs.



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**The main acts determining legislative framework of GMO  
in Bulgaria are:**

General law

- Law for Genetically Modified Organisms; (leading authority *MEW*)

Special laws

- Law for the Foodstuffs (leading authority *MH*);
- Law for the Feedstuffs (leading authority *MAF*);
- Law for Veterinary Activity (leading authority *MAF*);



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## Responsibility of Authorities according general GMO LAW in Bulgaria

**MEW** and the **MAF** implement the state policy concerning **GMOs** and coordinate the activity of the authorities responsible for complying with the requirements of law (*Art. 3, Law for Genetically Modified Organisms*).

**MEW grants**, alters and revokes authorization for **contained use of GMOs**, registration of premises for contained use of GMOs and deliberate release into the environment of GMOs (*Art. 4, Law for Genetically Modified Organisms* ).

**Placing on market GMOs** for non food use or produced from or containing ingredients produced from **GMOs which are not human food** in accordance with the Law for the Foodstuffs is proceeded only after **a permission granted by the MAF** (*Art. 59, 1, Law for Genetically Modified Organisms* ).

MEW ——— MAF ——— MH

**MH and MAF implement the state policy in the area of food safety** (*Art. 2a, Law for the Foodstuffs*).



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## **Responsibility of MH according specific law**

In order to obtain authorization any person before placing on market GMOs for food use, food containing or consisting GMOs or produced from or containing ingredients produced from GMOs **must submit an application to the MH** (Art. 23c, 3, Law for the Foodstuffs ).

MH is assisted by **Commission for Novel and Genetically Modified Food which gives statements about safety of GMOs for food use, food containing or consisting GMOs or produced from or containing ingredients produced from GMOs as well as opinion for applications to the EC, EFSA and other European Authorities for placing on market GMOs for food use, food containing or consisting GMOs or produced from or containing ingredients produced from GMOs** (Art. 23a, 1, 2, b, Law for the Foodstuffs).

**When GMOs** for food use, food containing or consisting GMOs or produced from or containing ingredients produced from GMOs **can be used both as food and feed only one application is submitted to the Ministry of Health** (Art. 23f, 4, Law for the Foodstuffs).



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## Responsibility of MAF according specific laws

**MAF and food implements the state policy in the area of feeds (Art. 4, Law for the Feedstuffs).**

**Placing on market of GMOs for feed use**, feed containing or consisting of GMOs and feed produced from GMOs is proceeded only after a permission granted by the European Commission in accordance with Regulation (EU) № 1829/2003 (*Art. 23a, 1, Law for the Feedstuffs* ).**Competent Authority according to Art. 17, § 2, Regulation (EU) № 1829/2003 is MAF** (*Art. 23a, 2, Law for the Feedstuffs* ).



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## **Responsibility of MAF according general GMO law**

**The MAF supervise and execute all legislative acts for GMO,**  
bringing them into force through *(Art. 109, Law for GMO):*

- Executive Agency Plant Variety Testing, Approbation and Seed Control;
- National Service for Plant Protection;
- National Veterinary Medical Service;
- National Service for Grain and Feedstuffs;
- Executive Agency of Vine and Wine;
- National Agency of Fishery and Aquacultures;
- State Forestry Agency;
- Executive Agency of Animal Selection and Reproduction.



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Control Framework of GMO in Bulgaria

MEW

Environment release, large  
scale field trials



MAF

Commercial cultivation  
and feed and animal  
origin food marketing

MH

Marketing of plant origin  
food



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**Control Responsibility of MAF according national legislative framework of GMO**

**GMO control:**

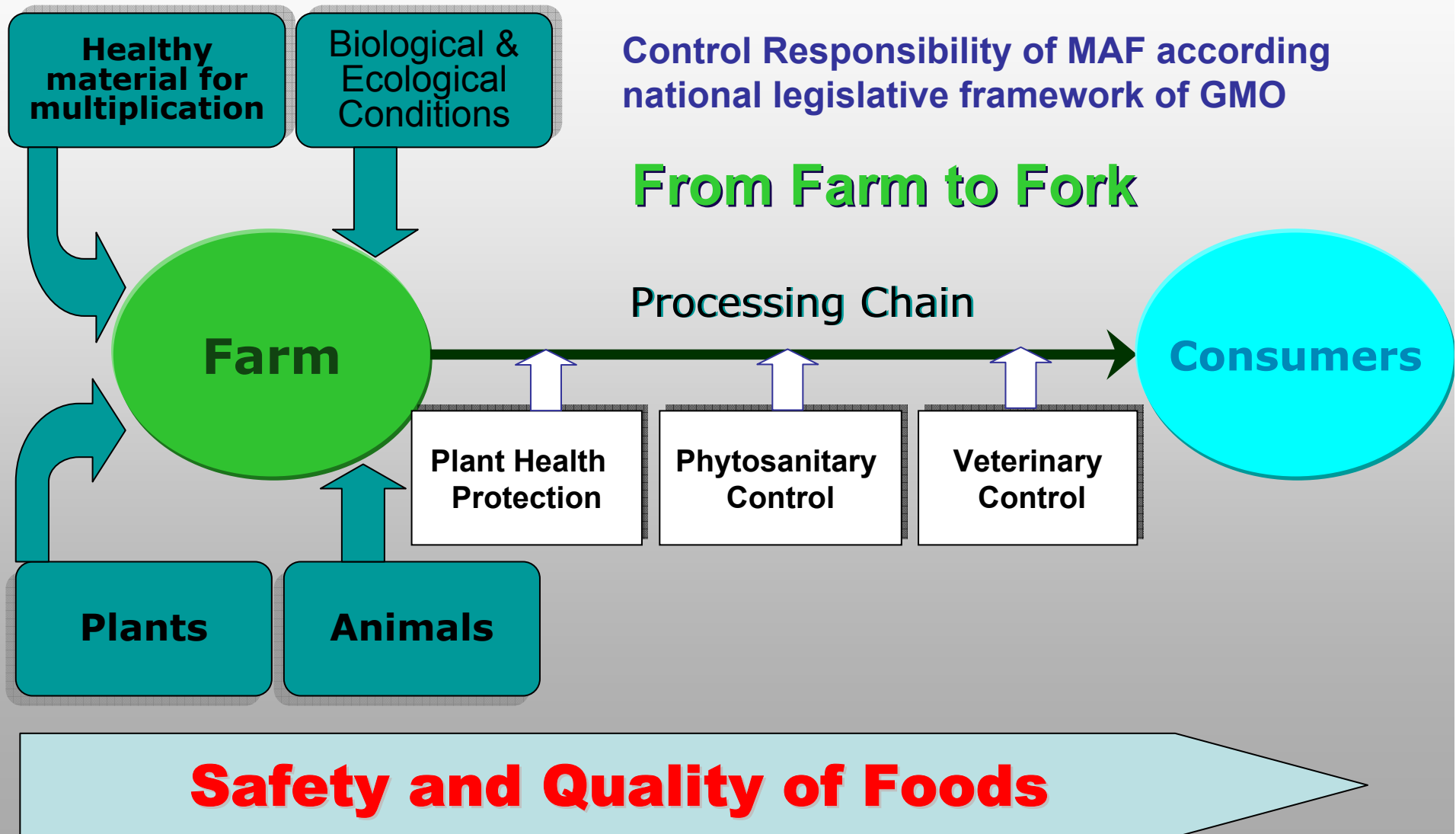
- Food of animal origin
- Seeds and planting material
- Feed and feed stuffs
- Veterinary medicines
- Plant protection products

**GMO inspections:**

- Field inspections
- Plant inspections (especially millers, feed plants, meat processors, seed plants, farms)
- Transport inspections ( trucks, ships, trains)
- Border inspections



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## **Laboratory network of MAF for GMO control**

R&D Center – GMO laboratory of AgroBioInstitute (Genomic Center)

Control laboratories:

- Central laboratory of Executive Agency Plant Variety Testing, Approbation and Seed Control;
- Central laboratory of National Veterinary Medical Service;
- Central laboratory of National Service for Plant Protection;
- Private accredited laboratories.



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## Challenges

**1. Prohibited shall be the release in the environment and putting on market of the following GMOs: tobacco, vine, oil rose, grain and of all vegetable and fruit crops. (Art. 79 (\*) (1) Law for GMO)**

### MILESTONES OF BULGARIAN PLANT BIOTECHNOLOGY DEVELOPMENT

- |             |  |
|-------------|--|
| <b>1985</b> | <b>Central Laboratory of Genetic Engineering (CLGE)</b>  |
| <b>1988</b> | <b>Institute of Genetic Engineering (IGE)</b>  |
| <b>2000</b> | <b>AGROBIOINSTITUTE (ABI)</b><br><i>Institute of Genetic Engineering - Kostinbrod</i><br><i>Institute of Floriculture – Negovan</i><br><i>Complex Experimental Station – Samokov</i> |
| <b>2000</b> | <b>Bulgarian Centre of Excellence in Plant Biotechnology</b><br><b>(Excellent Plant Biotech)</b><br><b>(Contract No ICA1-1999-70003)</b>   |
| <b>2005</b> | <b>AGROBIOINSTITUTE - Sofia</b>  |



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## Challenges

- 2. Prohibited shall be the release of GMOs on the territories, included in the National Ecological Net in the meaning of the Law on the Biological Diversity, as well as on the adjoining territories including 30-kilometers band surrounding them. With regard to genetically modified cotton plant the adjoining territory shall cover 400-meter zone. ( Art. 80. (suppl. SG 43/08) *Law for GMO*)**
- 3. The Minister of the Environment and Water shall refuse to issue a permit for releasing GMOs in the environment in the presence of a contiguous field with a biological manner of production. (Art. 52.(2) *Law for GMO*)**
- 4. Prohibited shall be the release in the environment and putting on the market of GMOs containing marker genes for antibiotic resistance. (Art. 81. *Law for GMO*)**



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## Challenges

5. **The permit shall be issued for a term not longer than 5 years.** (Art. 67.(3) *Law for GMO*)
6. **Geared for direct processing, in which occasionally appearing or technically unavoidable traces of GMO exist, for which an issued permit for putting on market has been obtained, and are in quantities not more than 0.5 under cent or in as defined by the ordinance of Art. 45 smaller quantity.** (Art. 74.(3) 2. *Law for GMO*)
7. **Official Authority interaction.**



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**MAF demand and fields of choice for collaboration with JRC**

- 1. Synchronization of Bulgarian legislative framework for GMO with European.**
- 2. Implementation of an efficient monitoring plan for GMO by MAF:**
  - Scientifically base risk assessment of commercial cultivation of GMO, marketing of feedstuff and food of animal origin;
  - Efficient GMO control and inspection activities;
  - Laboratory control.

**JRS support for infrastructure and administrative capacity building**



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**THANK YOU FOR ATTENTION**