



Difficulties in the drafting of legislation according to the *EU acquis* – experiences from Bulgaria

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28 April 2009, Istanbul



MILESTONES OF BULGARIAN PLANT BIOTECHNOLOGY DEVELOPMENT

1985 Central Laboratory of Genetic Engineering (CLGE)

1988 Institute of Genetic Engineering (IGE)

2000 **AGROBIOINSTITUTE (ABI)**
Institute of Genetic Engineering - Kostinbrod
Institute of Floriculture – Negovan
Complex Experimental Station – Samokov

2000 *Bulgarian Centre of Excellence in Plant Biotechnology*
(Excellent Plant Biotech)
(Contract No ICA1-1999-70003)

2005 **AGROBIOINSTITUTE - Sofia**



ABI: BULGARIAN CENTER OF EXCELLENCE IN PLANT BIOTECHNOLOGY

Norman Borlaug Center
NB PSR-DMU

Sub Regional
GMO Center of UNEP

ICGEB
Global Consortium

Foreign Universities
Research Institutes
International
Research Centers
> 50 agreements

MINISTRY OF AGRICULTURE AND FORESTRY
NATIONAL CENTER FOR AGRICULTURAL
SCIENCE

AgroBioInstitute

International Consultative Council

Joint
Projects

Contract
Research

Joint
Ventures

Breeding
Institutes

Bulgarian
Universities

International
Public Funding
EU, NATO
ICGEB, IAEA

RESEARCH AREAS
Genetic resources – in vitro gene bank
Functional Genetics
Biotic and abiotic stress
Ecology – GMP, biocontrol
Bioinformatics; Intellectual rights
*Accredited laboratories – genetic authenticity,
phytosanitary status, quality*

Public and
Governmental
Organizations

Private Business
Multinational companies
SME

AgroBioTech Park

Bulgarian
Private Business
SME

Join Genomic Center



BULGARIAN AGRICULTURE

- The oldest and still the most effective economic sector;
- 40% of the land is an arable land, suitable for:
 - ✓ Intensive agriculture – biotechnology base;
 - ✓ Organic (ecological) farming;
 - ✓ Seed production;
 - ✓ Unique production – wine, grape, tobacco, vegetables, fruits, essential oil crops, herbs, etc.
 - ✓ The land is fully privately owned;
 - ✓ The marketing of the land is expecting to occur in the next one-two years.



WHAT IS THE PRESENT SITUATION OF BULGARIAN AGRICULTURE

- Some of foreign agricultural products dominate;
- The contribution of Bulgarian agriculture in the GNP is 14% (twice less than in 1988);
- Globalization – the danger foreign varieties to dominate; The foreign varieties and hybrids are private sector's owning;
- Need for subsidizing and customs tariff changes;
- Common agricultural policy (CAP) of Europe to be followed.



BULGARIAN AGRICULTURAL SCIENCE

- Natural Center for Agricultural Science:
 - ✓ At present 26 institutes – 4300 persons;
 - ✓ The number is expected to be diminished twice in course of the next few years;
 - ✓ No private institutions yet;
 - ✓ First contracts with the private sector;
 - ✓ 30 to 90% of the arable land still is occupied with varieties and hybrids produced in this country;
 - ✓ Sunflower hybrid Albena averagely occupies more than 30% of the sunflower fields in France in course of twelve years.



WHY PLANT BIOTECHNOLOGY IN BULGARIA

- Continental climate (Very cold winter and very hot summer). Every year losses range from 20 to 60%;
- Climatic and soil variations from region to region, giving rise to a large variation of diseases and pests; Every year losses range from 15 to 50%;
- Plant biotechnology is the most suitable alternative, complementing the drawbacks of traditional plant breeding programs, which are rather labor intensive and time consuming:
 - Diminishing the genetic erosion (at present narrow genetic germplasm);
 - Preservation of genetic germplasm;
 - To enhance the genetic variability;
 - Low environmental impact and sustainable development;
 - New quality, new products, new crops;
 - Improve the efficiency of the breeding programs.



As introduction...

- 1994 – 1st commercialisation of a transgenic plant (FLAVR-SAVR tomato)
- 1995 - Bulgaria signed an agreement with EU, which paved the way of the negotiations for EU accession
- 1996- Bulgaria adopted the first legislative GMO regulation in CEE
- 2000 – Commencement of the negotiations with EU
- 2000 - Bulgaria is the first country that signed and ratified the Cartagena protocol on biosafety
- 2003 – EC recommendation on guidelines for national strategies on co-existence
- 2004 – Interministerial strategic view on co-existence for the Bulgarian agriculture
- 2005 – novel GMO Act



Bulgarian experience, Co-Existence:

Organic farming: current situation

- ❑ Dramatic decrease of pesticide use
- Legal framework in place
- Products: herbs, mushrooms, small fruits, honey, yogurt, milk.
- Number of organic farms- 46/ total number of farms 654 808 (excluding the dairy farms)
- Production- for external market
- Problems with certified organic seeds and plant material
- Huge investments under SAPARD programme

Strongly supportive governmental policy – interest free credits

Genetech biotechnology

- Traditions and regional leadership in plant biotechnologies
- Legal framework in place since 1996
- Deliberate releases of GM maize (42 800 ha) and potato since 1998
- 100 000 ha planted with GM soybean in Romania, approvals for feed and food in Russia
- Independent risk assessment studies
- Economical surveys: GM HT maize bring net benefit of 40% in addition to that of the conventional varieties

No governmental support for research

Co-existence of conventional and organic farming can be achieved on a certain level if adequate labeling threshold values would be implemented
Bulgarian GMO Act: “haste makes waste” story with respect to co-existence



Governmental policy, legislative framework former **GMO** regulation

- **1996- Regulation** on deliberate release into the environment of GM higher plants, produced by recombinant DNA technology- in compliance with EC Directive 90/220
- **1998 – Council** for biosafety of GM higher plants –coordinating and regulatory body under the Regulation. Chairman: the Minister of Agriculture and Forests; expert commissions: on Herbology, Entomology, Food safety and independent commission for Council’s activities control.
- 1999-2004 **field trials**:
- **Small scale** – GM potato, GM sunflower, GM tobacco, GM maize (1998, 2002, 2003, 2004)
- **Large scale-** GM maize (1999, 2000, 2001) – 6 000- 19 000 ha
- **The Council has not granted approval for commercialization of any GM crop**



Present GMO legislative framework in Bulgaria

- GMO Law (Directive 2001/18/EC on deliberate release and placing on the market, 90/219 EEC, amended with 98/81 on contained conditions, 1946/2003 EEC on transboundary movement)
- Ordinance on contained use of GMOs
- Ordinance on deliberate release and placing on the market

Requirement for labelling: over 0.5% of GMOs

- Ordinance on labelling of novel foods – labelling over 0.9%
- Regulation 1829/2003/EC and Regulation 1830/2003/EC – labelling over 0.9%
- Bulgarian Feed and Veterinary Control Act



Bulgarian GMO Law, enacted since June 2005 bans:

- The deliberate release into environment and placing on the market of tobacco, vine, damask rose, wheat, and all vegetable and orchard crops
- applying GMO-based farming “if organic farming is practiced on an adjoining field”
- the deliberate release of any GMOs into the areas included in the National Ecological Network, as well as into the adjoining areas within a zone of 30 km around any such areas.



Bulgarian GMO Law, enacted since June 2005:

- Public register on the permits for deliberate release and placing on the market and register of the area planted with GMOs;
- The GMO farmer is to inform the Ministry of Agriculture and Forestry of the location and size of the areas planted
- The obligation to respect respective isolation distances (provided in Law) is onus to the GMO grower
- The isolation distances for maize, soybean and rape are 800, 20, and 400m, respectively. In comparison, field trials with GM maize (distance of 50 m) have been performed in the period of 1998-2004 on overall 42800,5 ha in different landscape regions in Bulgaria. The adventitious presence of GMOs, if any, in the non-transgenic fields was found to be under 0.5% (Atanassov et al., 2003).



Let's talk about thresholds ...

- For adventitious presence of GMOs in conventional products
 - In EU: 0.9 %;
 - in Bulgaria: 0.5%
- 0.9% threshold for adventitious or technically unavoidable presence of GMOs in the organic products is specified; most organic farmers voluntary apply 0.1% tolerance
- The EC still sustain in adopting EU wide thresholds for adventitious presence of seeds..



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)

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



The main acts determining legislative framework for 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 Medicine (leading authority *MAF*);



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*).

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

MEW — MAF — MH



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).



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*).



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 and
- Executive Agency of Animal Selection and Reproduction.



Control Responsibility of MAF according general GMO law

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



Difficulties / Challenges

- 1. 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*)**
- 2. Prohibited shall be the release in the environment and putting on market of the following GMOs: tobacco, vine, after rose, grain and of all vegetable and fruit crops. (Art. 79 (*) (1) *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*)**



Difficulties/ 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 onmarket 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.



RESEARCH, TECHNOLOGIES, AND INNOVATION

In 5 or 10 years' time agriculture in Bulgaria will determine the development of **BIOECONOMY** which shall influence the development of all other important industries such as **foodstuffs, pharmaceuticals, medicine, energy, textiles, etc.** The future of Bulgarian agriculture on the international market will depend on its ability to meet such challenges as **climate change, demand for new bioenergy sources, natural resources depletion /biodiversity, soils, water, etc./, globalization, increasing competence, demographic changes, scientific and technological inventions.**



To meet these challenges the Ministry of Agriculture and Food started the development of **LONG TERM PROGRAMME FOR AGRICULTURAL PRIORITIES.** It will be uploaded on the Ministry website soon in English. Discussions have been carried out with all possible stakeholders – researchers, administration, agricultural business, and NGOs in Bulgaria.



- Bulgaria is one of the states with the greatest biodiversity in Europe and with a great potential for the development of a competitive bioeconomy. So far, however, it has been underdeveloped.
- The main exported products are raw materials and convenience products while products with high value added are imported to the domestic market. This shows how vulnerable the Bulgaria bioeconomy is and how urgent it is for it to become more competitive, by having the opportunity to produce high value-added products.

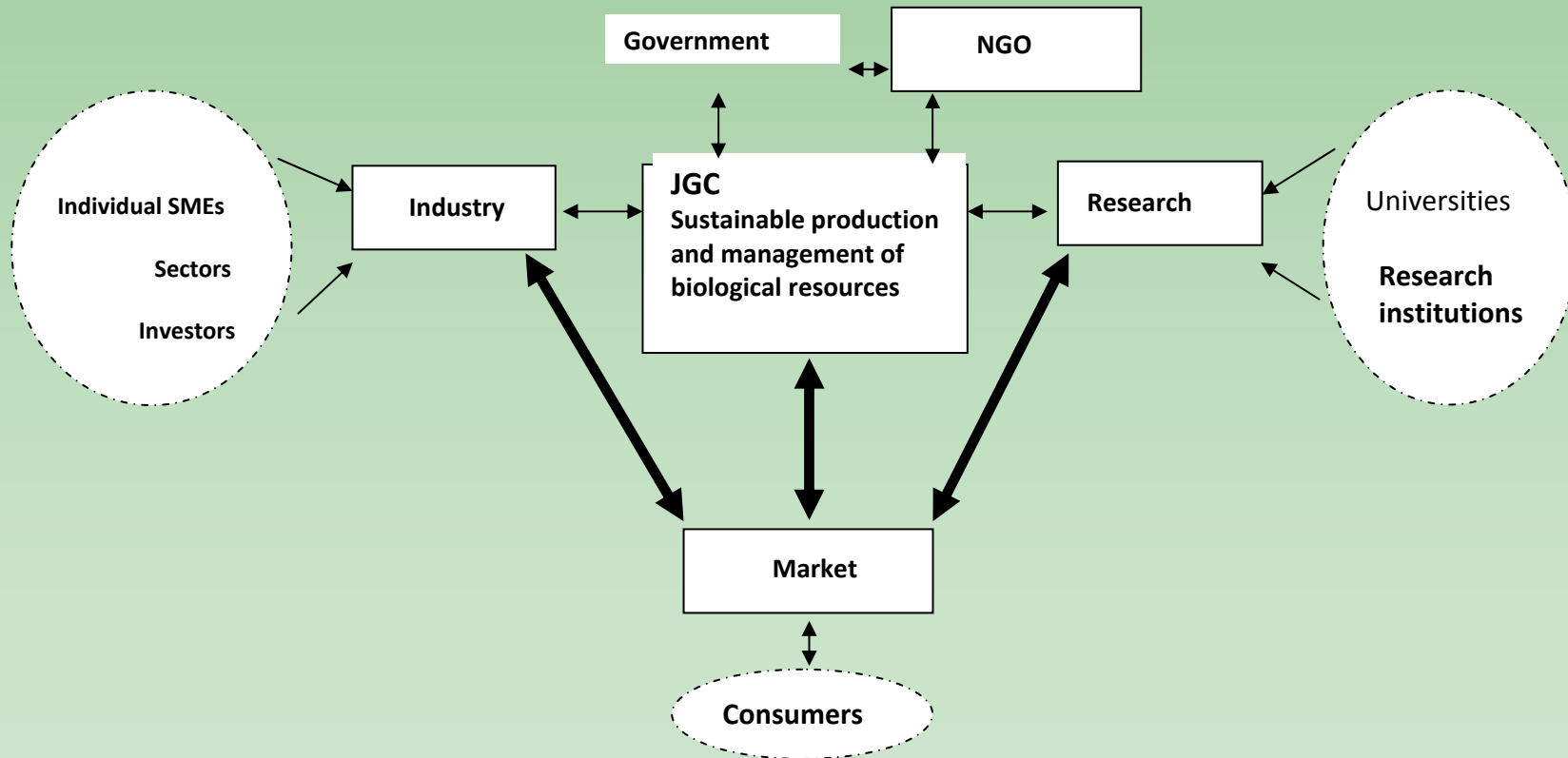


- **Two-dimensional research strategies** have been proposed. One of them is **Transition Research Programme** mainly related to sustainability and consumer requirements for healthy foodstuffs, the development of new **models for agriculture, and an effective regulations for its development.**
- **High-technology Programme** in turn is aimed at competitiveness of the agricultural sector including research of plants and animals, environment, diagnostics, and pharmaceuticals.



- In accordance with the EU priorities, Bulgarian government launched in 2001 the programme **GENOMICS** as one of the five research programmes of national importance.
- To fill and overcome this gap we decided to set up a JOINT GENOME CENTRE as a consortium of academic and university researchers to meet the interests of the private sector (SMEs) in the form of a public-private partnership.







The major goal of the Project for a Joint Genome Centre is to raise the competitiveness of Bulgaria bioeconomy by setting up a key strategic centre to provide all participants, including EC and other partners, and SMEs with access to state-of-art equipment, know-how, new experimental methods and highly skilled staff to create high value-added products. They will be based on the specific and unique Bulgarian biodiversity (micro-organisms, plants, animals, forests, and fish) to benefit agriculture, food industry, cosmetics, organic material industry. The centre will start operation at the end of the first half of 2009.



Conclusions

Bulgarian GMO Act (in force since June, 1st 2005):

- several confusing articles have been adopted in Bulgarian GMO law which are not consistent with CP on Biosafety (case by case approach in RA); EU directives; thus resulting in an unqualified 'ban' on releases and placing on the market **setting up a *de facto* moratorium** of some categories of GMOs
- in discrepancy with the principles of:
 - Science-based approach
 - Proportionality; appropriate scale
 - Stimulating research EC policy

Need for amendments in the Bulgarian GMO Act

- Misperception about the EU policy on GMOs: demand for more accurate decision-making and clearer messages on EC level

We recognize the need of a sound regulatory harmonisation in Europe starting from EC, as a solid groundbase for further Harmonisation of GMO detection and analysis in the region.



THANK YOU !