

**Difficulties drafting the GMO
legislation according to
the EU *acquis*
- experiences from Romania -**

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Summary

- ✓ Legislation
- ✓ Institutions: central and local
- ✓ Control of GMO food, feed & seeds
- ✓ Experiences with enforcement
- ✓ Romanian RR soybean story 2000-2006
- ✓ Status of cultivations of MON810 maize > 2007
- ✓ Conclusions
- ✓ Answer to: Implementation of GMO legislation

Legislation status

- ✓ Romania adopted its initial legislation on bio-engineered products **in 2000**
- ✓ This first law was a Government **Ordinance 49/2000**
 - regarding the regulatory process for adoption of some genetically modified crops by Romania's agriculture as **Roundup Ready soybean**
- ✓ **The National Biosafety Commission (NBC)**
 - representatives of relevant regulatory agencies
 - members of public research institutions
 - major role in the decision

Legislation status

- ✓ **Law 214/2002** approving Ordinance 49/2000
 - brought a number of changes
 - **National Biosafety Commission** became the scientific authority with a consultative role
- ✓ Under these new circumstances, decisions regarding environmental release of bioengineered crops (commercial cultivation or experimental purposes), were taking in consideration with the **scientific opinion from the N Biosafety Commission**, would be less susceptible to political influence

214/2002 Biotech law regulated:

- ✓ Contained regulation on the use of Genetically Modified **Microorganisms**
- ✓ **Deliberate release** into the environment of GMOs for any other purposes than placing on the market
- ✓ **Placing on the market** of GMOs as or in product
- ✓ **Import/export** operations with GMOs as or in products

2002 Institutional Framework

1. Ministry of Environment and Water Management
as National Competent Authority (approval)
2. Biosafety Commission (scientific consent)
3. Ministry of Agriculture, Forests and Rural
Development (consent)
4. Ministry of Health and Family (consent)
5. National Authority for Consumer Protection (consent)

Cartagena Protocol on Biosafety

- ✓ Romania signed the Protocol on the
11th October 2000
- ✓ Romania ratified the Protocol on the
11th March 2003 by Law 59/2003
- ✓ The Protocol entered into force on the
28th September, 2003

Implementation of EU regulations

- ✓ Directive 2001/18 EC = Ordinance of Romanian Government 43/2007 (**deliberate release into the environment**)
- ✓ Regulations 1829 and 1830 = Government Decision no. 256/2006 and 173/2006 (**food and feed**)
- ✓ EU recommendation 2003/556/EC = Order 237/2007 under revision (**co-existence**)

43/2007 Institutional Framework

1. Ministry of Environment and Sustainable Development – **National Environment Protection Agency** - competent authority for environmental release
2. Ministry of Environment and Sustainable Development - **National Environment Guard** -
3. Romanian Government - **National Sanitary Veterinary and Food Safety Authority**
4. Ministry of Agriculture, Forests and Rural Development
5. Ministry of Public Health and Family
6. Ministry of Education, Research and Youth
7. **Biosafety Commission** - scientific body
8. **National Authority for Consumers Protection**

Competent authorities GMO food, feed, seed

- ✓ NSVFSA – **National Sanitary Veterinary and Food Safety Authority** (under RG) – competent authority for food and feed
- ✓ NEPA – **National Environment Protection Agency** (under Ministry of Environment and Sustainable Development – authorise the imports into and deliberate release into the environment of living GMOs)
- ✓ NEG – **National Environment Guard** - enforcement of the Romanian environmental legislation
- ✓ MAFRD – **Ministry of Agriculture, Forests and Rural Development** – the control and the certification of the quality of seeds by testing the varieties which are not genetically modified and which can be contaminated with GM varieties
- ✓ NACP – **National Authority for Consumers Protection**-responsibilities for the labelling control
- ✓ IDAH – Institute of Diagnosis and Animal Health – under NSVFSA , **National Reference Laboratory (NRL)**
- ✓ IFB – **Institute of Food Bioresources**

GMO legislation applicable EU legislation

- ✓ **Government Decision no. 173/2006** which sets:
 - the penalties for infringements of the EU Regulations no. 1829/2003 and 1830/2003
 - state the responsibilities of each authority for performing the controls and applying fines
- ✓ **Government Decision no. 256/2006** issued for:
 - implementation of EU Regulation no. 1829/2003.
- ✓ The **Protocol of Cooperation no. 3090/12.07.2006** between the NSVFSA, NACP, MAFRD and NEG in the field of **official control for GM food, feed and seeds**
 - establish responsibilities for the entire GM food, feed and seed chain.

NEG at regional level

- ✓ The **National Environmental Guard (NEG)**
 - specialized body, which operates under the Ministry of Environment,
 - responsible with the effective enforcement of the Romanian **environmental legislation**
- ✓ **NEG structure:**
 - 8 Regional Commissariats
 - 41 Commissariats at county level
 - 1 Commissariat from Bucharest
 - 1 Environment Commissariat of the Danube Delta Biosphere Reserve
- ✓ The **NEG control the cultivation of GM plants** and checks if GM plants is cultivated in forbidden areas such as the natural protected areas

NSVFSA at regional level

- ✓ **42 County Sanitary Veterinary and Food Safety Divisions:** the inspectors involved in the activity of official control on GM food and feed, agronomists, veterinarians, food engineers, biologists, were trained in **legislation, inspection and sampling procedures.**
- ✓ At the level of **Entry Points NSVFSA has 9 BIP's** in which is organised the official control for food safety
- ✓ **“The Guide for inspection and sampling for GMOs”** – developed by NSVFSA, which take into account the provisions of Commission Recommendation 787/2004, **information received during training courses from JRC,** the standards for sampling and testing (ISO 6644:2002; ISO 13690:2001; ISO 5725-1:1997; ISO 2859-0:1999; EN ISO – 542:2001)

NACP at regional level

- ✓ **National Authority for Consumers Protection control:**
 - 12 regional inspectorates
 - 41 territorial offices
 - 1 Bucharest Office for Consumers' Protection
- ✓ **Inspections in food products area, including GMO:**
 - 188 specialists in foodstuffs

DARD at regional level

- ✓ **Divisions for Agriculture, Forests and Rural Development**
 - 42 divisions , one for each county
- ✓ **County DARD inspectors :**
 - conducted checks in the field of GMO growers
 - control of the activity (yearly), approved by MAFRD
 - prepared monthly activity report
 - elaborate minutes of control for mismanagement and measures undertaken
 - prepared the minutes of control in case of sampling
- ✓ **MAFRD** collect reports and prepare notes, information on its **GMO findings through the county inspectors**

GMO national legislation accordance EU legislation

✓ NSVFSA Order no. 94/2006:

Guidelines concerning sampling and analysis of GMO, of GMO as products and products which contain or might contain genetically modified organisms

In accordance with Commission Recommendation no. 787/2004

Control of GMO food and feed

NACP National Authority for Consumers' Protection

- ✓ **Inspectors** 188 specialists in foodstuffs
- ✓ **Central level:**
 - Counselling for food products depart.
 - Market surveillance
 - Counselling for services and products
 - Coordination of the control activity
 - Relation with other authorities food safety
- ✓ **Regional level:** 12 regional inspectorates
 - corporate bodies > 41 territorial offices
 - unincorporated > PC Office Bucharest.

Control of GMO food and feed

NSVFSA:

- ✓ **Central** 5 specialists in the field of GM food & feed.
- ✓ **County** 3 specialists controls for traceability and labelling of GM food & feed.
 - 1 responsible for food
 - 1 responsible for feed
 - 1 supervisor as Director for Food Safety
- ✓ **BIP's** level 2 specialists control for GM food & feed (BIP Constanta – with 4 inspectors)

Legislation in place for seeds

- ✓ MAFRD Order no. 237/2006 - **Authorizing growers of genetically modified plants**
- ✓ MAFRD Order no. 461/2006 - Rules regarding the organization of phytosanitary and the quality controls **at planting material and seeds import-export.**
- ✓ MAFRD Order no. 631/2006 - The control and the **certification of seeds quality** by testing the varieties which are not genetically modified and which can be contaminated with GM varieties.
- ✓ MAFRD Order no. 149/2007 - Rules and techniques norms concerning the productions for sealing, the **control, the quality certification** and the marketing of **cereals seeds**

Established enforcement laboratories

- ✓ National Reference Laboratory (NRL) for GMO in Food and Feed
 - Institute for Diagnosis and Animal Health (IDAH) , state laboratory
- ✓ The molecular biology network of NSVFSA – IDAH
 - 10 state laboratories

Enforcement laboratories

Laboratories approved by MAFRD, who perform GMO analysis of the samples are:

✓ **Institute of Food Bioresources**

- subordinated MAFDR
- RENAR accredited laboratorie

✓ **National Institute of Research for Development in Biotechnologies**

- Stefanesti Arges under accreditation

Food and feed subjected to be controlled

NSVFSA:

Soybean textures – as raw material for feed

MAFRD:

Conventional soybeans and maize MON 810 for commercial purposes & other GMO plants for testing

NACP:

- Checking if the provisions of R 1830/2003 are respected
- Food labelling - mainly for soy products on the market
(soy beans, soy flour)
- The reports on labelling control actions of foodstuffs containing or made of GMOs is sent to NSVFSA

Experiences with enforcement

NSVFSA Annual Activity Report of the controls performed.

For **2007**:

- ✓ 2416 inspections, 20 penalties in amount of 29.000 RON

For **2008**:

- ✓ 2615 inspections, 4 penalties in amount of 3500 RON

For **2009**:

- ✓ 2600 inspections planed

Infringements on traceability are sanctioned by 1000 – 2000 RON

Infringements on labelling are sanctioned by 500 – 2000 RON

Inspectors can take the decision of:

- **temporary withdraw of the products** from the commercialization
- **activity suspension** of the operator breach for 6 months.

Experiences with enforcement

MAFRD

Legislation does not specify the publication of results.

In **2007:**

- 1883 inspections in both conventional soybean growers and maize MON 810 growers.

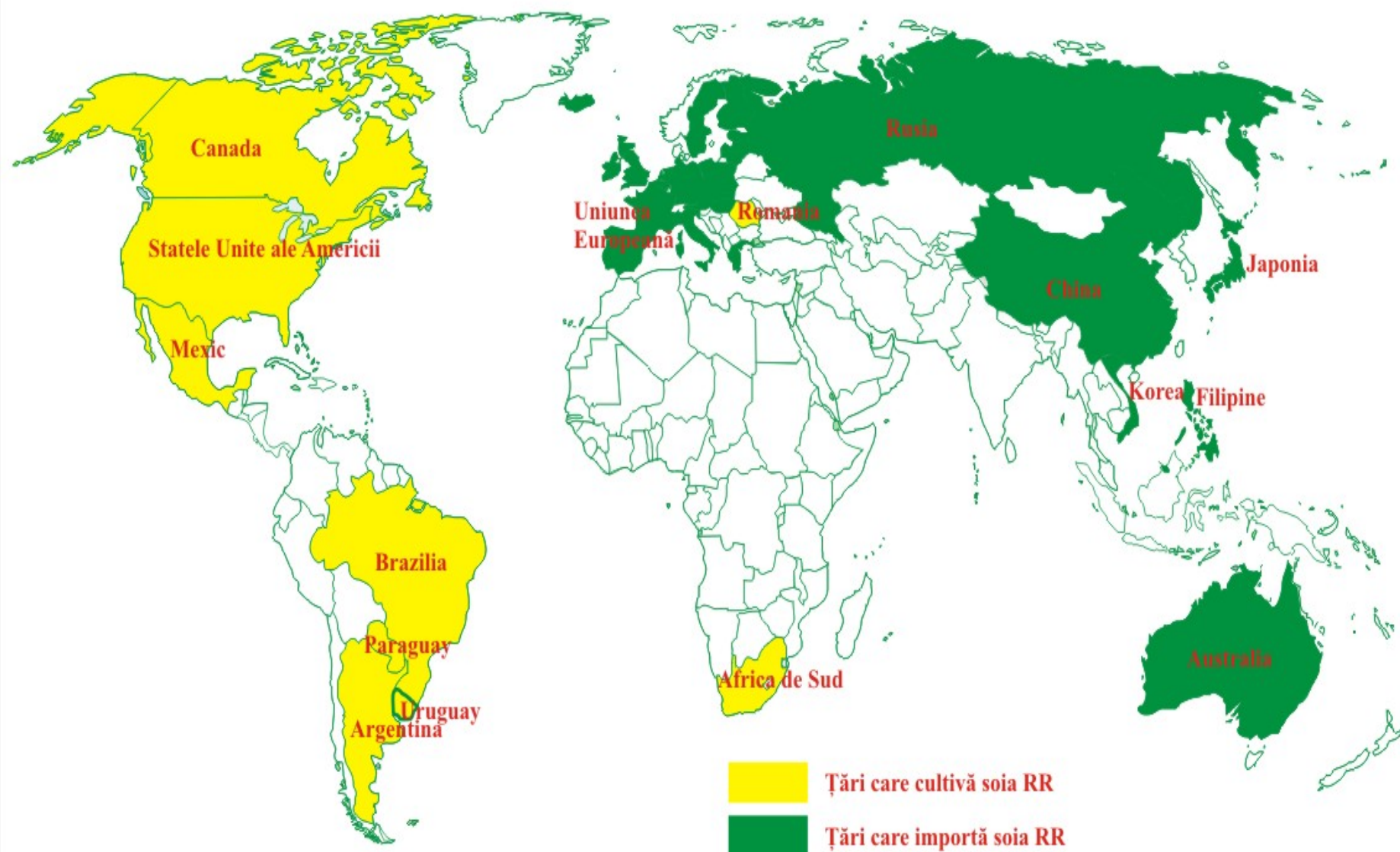
In **2008:**

- 1083 inspections in both conventional soybean growers and maize MON 810 growers

In **2009:**

- > 1000 inspections planed

World area cultivated with RR soybean 2006



Area cultivated with RR soybean

In Romania, the commercial cultivation of RR soybean was approved in 1999.

Beginning with that year, area devoted to this crop expanded constantly, peaking in 2006 at 144 thousand Ha.

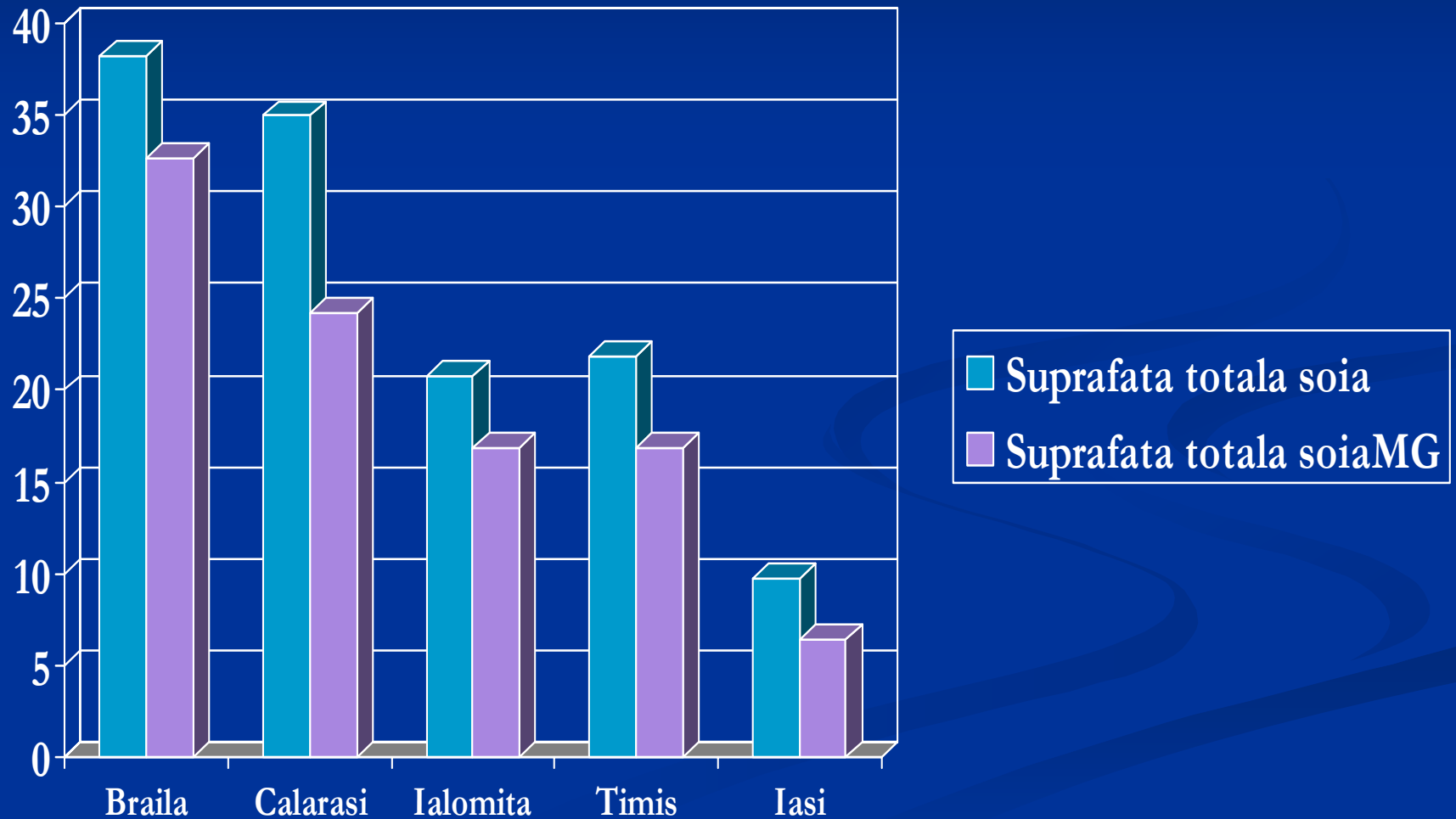
Area cultivated with RR soybean



144 ha cultivated with RR soybean in 2006



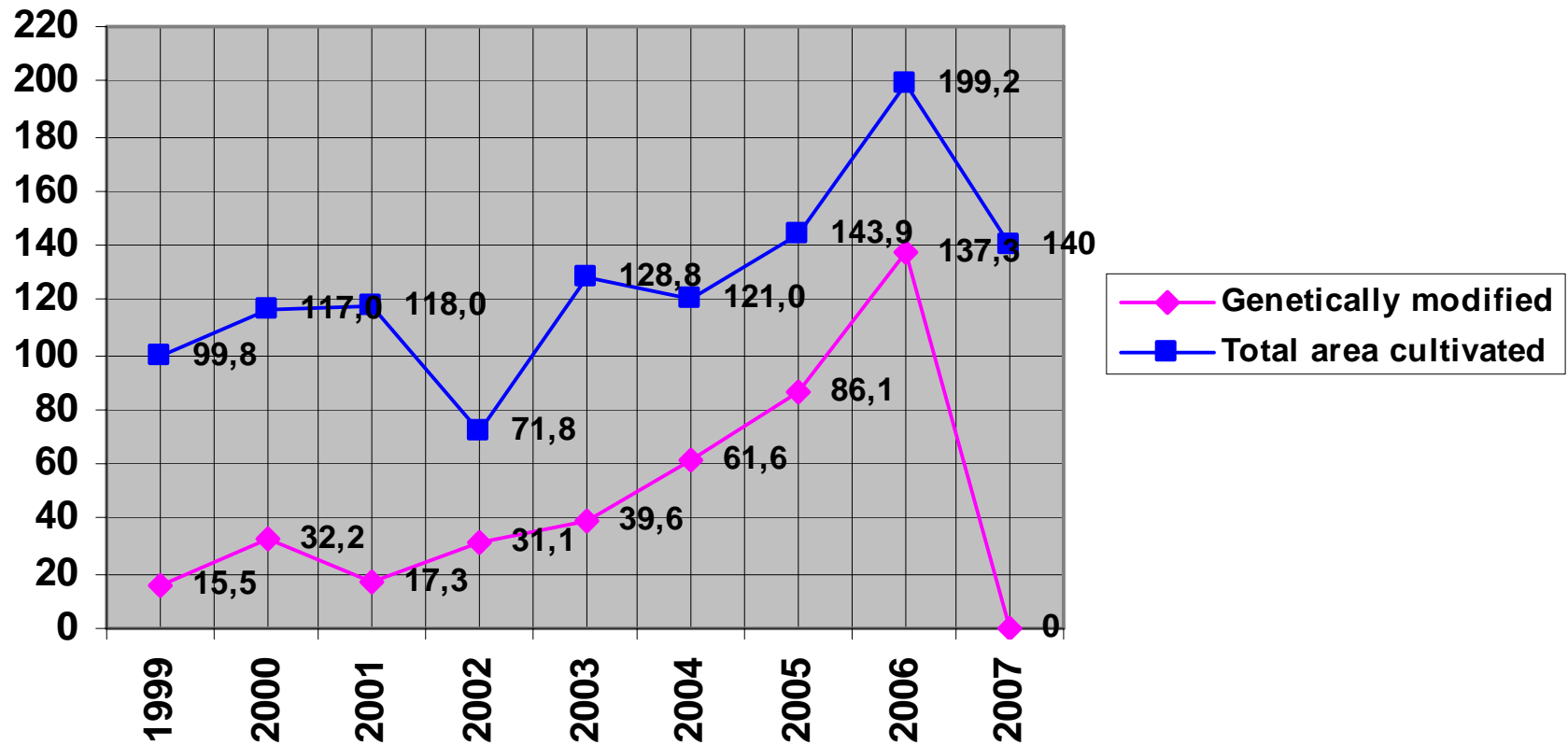
RR soybean in main agricultural counties



Braila county RR soybean in 2006



The evolution of soybean area



Braila county RR soybean in 2007



15 8 2007

The impact of NO RR Soybean cultivation

- ✓ The effects of discontinuing the technology was dramatic for Romania's trade balance:
 - Surface declined from 200.000 ha 2006 to 53.000 ha 2008
 - The import bill for soybean increase from 26 million \$ in 2006 to 75 million \$ in 2007 and 211 million \$ in 2008
- ✓ Romania imported 315.012 t soya bean & oil-cake mostly GM, even from EU countries

Romania soya imports evolution

Year	Seeds		Oil-cake	
	Quantity (t)	Value (USD)	Quantity (t)	Value (USD)
2006 26 M\$	11 945	4 244 413	81 544	21 851 061
2007 108 M\$	68 600	34 022 346	217 039	74 500 459
2008 210M\$	94 361	55 512 308	315 012	155 403 943

Status of cultivation/field trials

- ✓ Romania can commercially grow **ONLY** genetically modified plants approved for market release in EU, as **MON810 maze**
- ✓ In 2007: **289** ha with MON810 maze
- ✓ In 2008: **7166** ha with MON810 maze
- ✓ In 2009: **> 10.000** ha with **MON810 maze**
 - **59 farmers** are using this technology
- ✓ **Field trials with second generation of corn** hybrids with stacked genes are cultivated by Monsanto, Pioneer and Syngenta companies

Conclusions

- ✓ Romania has **implement successfully the legislation** in accordance with the EU *acquis*
 - ✓ **The institutions** , central and local, **are active & efficient**
 - ✓ **GMP - farmer perception is good** but sometime in contradiction with the consumers
 - ✓ Romania having a potential of more **500.000** ha soybean cultivation is harvesting **ten time less 50.000** ha
 - ✓ Inside of exporting 1 million tons we are importing **>315.000 t over 210 million \$**
 - ✓ The **Mon810 maize** has a **good start** for feed cultivation
 - ✓ The existence of a legal framework is the necessary, but not the sufficient condition for adopting right decisions
- An excessive legal framework**, enforced without responsibility, **may have dramatic socio-economic consequences** .



Thank you!

Implementation of GMO legislation in Romania

* **Labelling provision(s) in place regarding GM food, feed, seed and/or environment;**

- ✓ All food and feed with autorisated GMO over 0,9% must be labbeled (HG 173/2006)
- ✓ The labbel contain the text: ”This product contain GMO (and specified the GMO)
- ✓ I is labelled all the conventional seeds with over 0,9% GMO
- ✓ It is labeled all the foods, feeds and seeds over 0,9 GMO

* **Dedicated governmental body and/or competent authority responsible for GMO labelling provisions;**

- ✓ The National Sanitary Veterinary and Food Safety Divisions competent authority for trasability and labelling
- ✓ The National Authority for Consumers Protection (NACP) is a central public administration body that has responsibilities in the labelling control,of foodstuffs, made of or containing GMOs.

* **Enforcement laboratories already established in your Country**

- ✓ National Reference laboratory for food and feed - ICDA - Institute of Diagnosis and Animal Health
- ✓ National Laboratory for seed control - IBA - Institute of Food Bioresources

* **Experiences with enforcement;**

Starting 2007 ANSVSA inspected the traceability and the labeling for food and feed during over 1200 inspections applying 24 penalties

* **Is control exclusively done for public authorities or also for private companies?**

- ✓ University research laboratory - Network of 4 five GMO laboratory Cluj, Bucuresti, Timisoara, Iasi
- ✓ Private laboratory – independent accredited 2, non accredited 3