

# GMOs – policies and regulations since 1972

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# Biosafety - History

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- 1972: First rDNA applications, *E. coli* genes in Simian Virus 40
- 1974: ‘Berg Letter’: **expectations** and **safety questions**: moratorium
- 1975: Asilomar - end of moratorium - safety assessed case by case
- 1976: US: research programs, NIH Guidelines for safety
- 1981: Europe: regulations for rDNA laboratories, research budgets
- 1983: First GM plant: new **expectations** and new **safety questions**
- 1986: OECD rDNA safety recommendations - “Blue Book”

# Biosafety - History

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1986: US coordinated framework for regulation of biotechnology

1992: *Earth Summit, Rio de Janeiro, Agenda 21: Chapter 16:*

if developed judiciously, modern biotechnology can make a significant contribution to strengthening the sustainable production of food, feed and fibre, health care and environmental protection.

1992: Adoption of the Convention on Biological Diversity

- art. 19: share benefits of biotechnology

- art. 8: national biosafety systems

2000: Adoption of the Cartagena Protocol on Biosafety

# EU Regulatory framework - History

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1986: OECD rDNA safety recommendations - “Blue Book”

1986: US coordinated framework for regulation of biotechnology

1987: First outlines of EC Directives on GMOs

1990: EC Directives contained use and release of GMOs

1995: Gaining experience with EU regulatory system: many field trials and market approvals

1997: Decline in permits and market approvals

1998: ‘De facto’ moratorium

# EU Regulatory framework – History

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- 1999: To solve the deadlock, the EU Council of Ministers proposes:
- adopt more stringent rules for placing on the market
  - put in place rules on labeling and traceability
- 2001: Revised EC Directives 2001/18 and 90/219
- 2002: Life sciences and biotechnology — A strategy for Europe
- 2003: New Regulations, e.g:
- 1829/2003 on genetically modified food and feed
  - 1830/2003 on labeling and traceability of GMOs
  - 1946/2003 on the transboundary movements of GMOs

# EU Regulatory Framework for GMOs

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## Regulatory framework since 2003:

- Directives, e.g:
  - 2009/41 on contained use of GMMs
  - 2001/18/EC on the deliberate release of GMOs
- Regulations, e.g:
  - 1829/2003 on genetically modified food and feed
  - 1830/2003 on labeling and traceability of GMOs
  - 1946/2003 on the transboundary movements of GMOs
- Guidance documents, e.g:
  - Information requirements and RA under 2001/18
  - Monitoring and sampling
  - Co-existence

# Environmental Safety – Food/feed Safety

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## Field Trials

- Environmental Safety

## Placing on the Market

- Environmental Safety

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- Food/Feed Safety

# GMOs approved on the market in EU

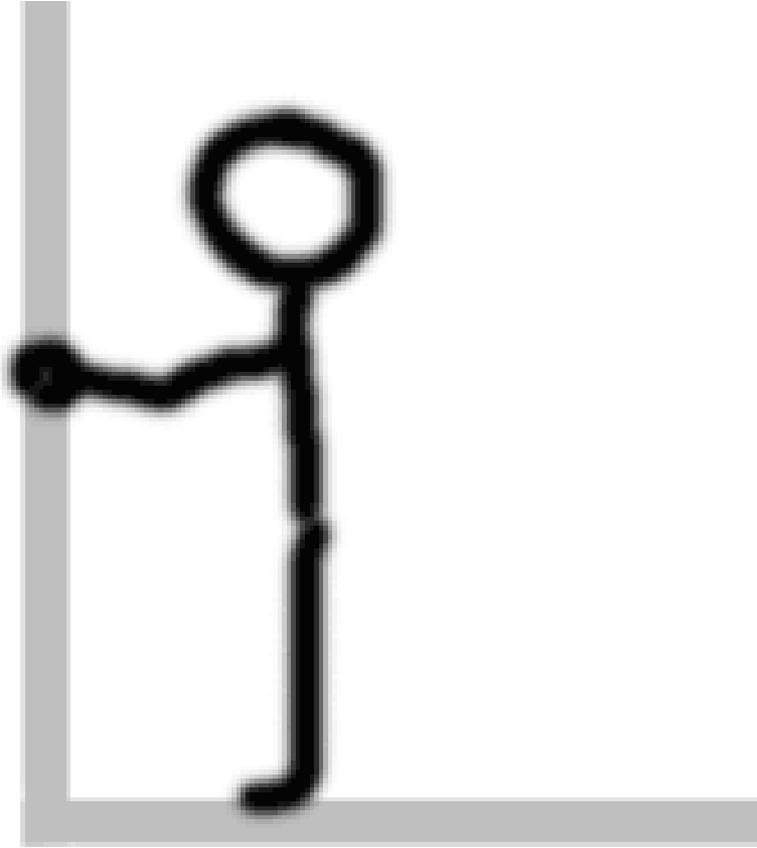
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Authorised under Regulation (EC) No 1829/2003:

- **Maize:** 1507 x 59122, 59122 x 1507 x NK603, MON88017 x MON810, MON89034 x NK603, Bt11 x GA21, Bt11, MON863, MON863 x MON810 x NK603, MON863 x NK603, MON863 x MON810, MIR604, 59122 x NK603, MON88017, MON89034, MON810, T25, MON863 x NK603, GA21, 59122, 1507 x NK603, NK603 x MON810, 1507, MON863, NK603, Bt11,
- **Potato:** EH92-527-1,
- **Rapeseed:** T45, MS8 x RF3, GT 73,
- **Soybean:** MON89788, A2704-12, MON40-3-2,
- **Sugar Beet:** Event, H7-1 ,
- **Cotton:** LL Cotton 25, MON 1445, MON 531, MON 15985 x MON 1445, MON 15985, MON531 x MON1445,
- **Flowers:** Carnation Moonlite,

# Cultivation of GMOs in the EU

Country vs. Year	2007	2008	2009	2010 Bt maize	2010 Amflora	2010 Total
Spain	75148	79269	76057	76575	-	76575
France	21174	-	-	-	-	-
Czech Republic	5000	8380	6480	4680	150	4830
Portugal	4263	4851	5094	4868	-	4868
Germany	2685	3173	-	-	15	15
Slovakia	900	1900	875	1248	-	1248
Romania	350	7146	3244	822	-	822
Poland	327	3000	3000	3000	-	3000
Sweden	-	-	-	-	80	80
<b>Total</b>	<b>88673</b>	<b>107719</b>	<b>94750</b>	<b>91193</b>	<b>245</b>	<b>91438</b>



# EU Regulatory Framework for GMOs

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## Situation in 2011:

1. The EU system does not function:
  - Many decisions not within the legal time frames
  - Some decisions not based on the legal criterion of scientific risk assessment

>>> *the EU is in violation of its own rules*
2. Increasing regulatory hurdles without scientific justification
3. Destruction of field trials

# EU Regulatory Framework for GMOs

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## EU GMO policies have impacts in the EU:

- Public research in Europe is slowing down, moved abroad or stopped altogether
- Impacts on farmers' income and agricultural production in the EU

## EU GMO policies have impacts in the EU:

- Impacts on research
- Impacts on farming

# EU Regulatory Framework for GMOs

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Many proposals to change the situation, e.g:

- Proposal to allow Member States to ban approved products on grounds other than scientific safety assessment

>> most of these proposals are cosmetic and some will make the situation worse, as they will allow politicians to let short term popularity prevail over long term needs.

# Take home messages (1)

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EU Policy makers need to keep reminding themselves that:

- The EU has moved from overproducer to major food importer, which has an impact on global food availability and food prices. The EU **has to** produce more for its own and global food security.
- Mankind will only be able to feed itself without destroying the planet, if farmers can produce more per hectare land and with less impact on the environment. - “Sustainable intensification” (FAO).
- This **cannot** be done by conventional approaches alone.
- Modern biotechnology can contribute significantly to addressing these challenges (*1992 Earth summit!*).

# Take home messages (2)

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EU Policy makers should **continuously**:

- *Assess*
  - The need for regulations
  - The efficacy and efficiency of the regulations
  - Unintended impacts of regulations on research and farming.
- *Monitor:*
  - Progress in science
  - Experiences with GMOs
  - Experiences with regulations