

GMOs – policies and regulations since 1972

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Biosafety - History

- 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

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

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

- 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

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

Field Trials

- Environmental Safety

Placing on the Market

- Environmental Safety

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- Food/Feed Safety

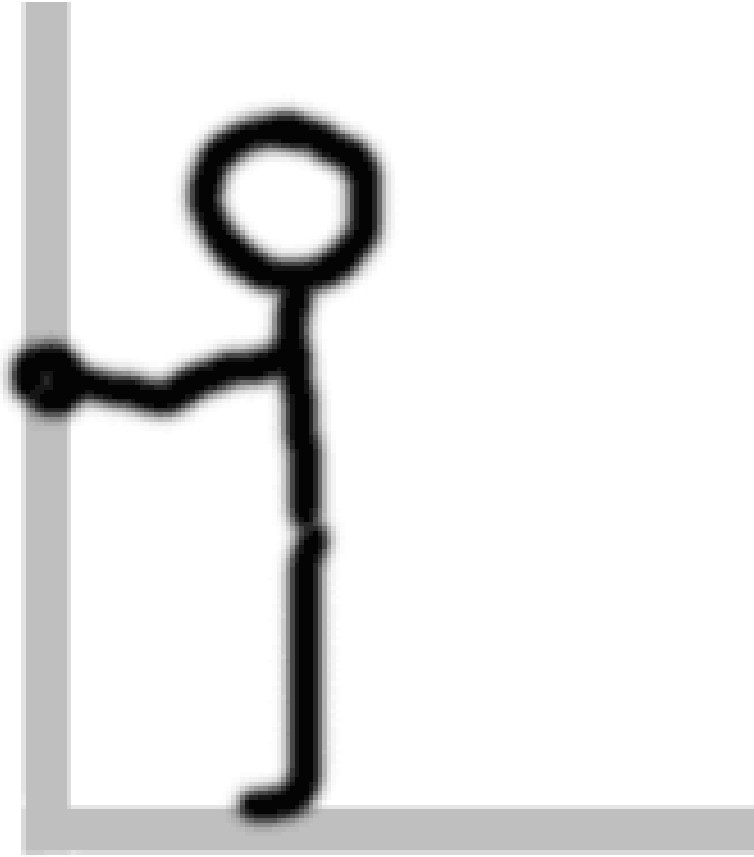
GMOs approved on the market in EU

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
Total	88673	107719	94750	91193	245	91438



EU Regulatory Framework for GMOs

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

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

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)

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)

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