

20 years after the first draft of the EC rules on GMOs

COST Exploratory Workshop
What role for GM technology in future
competitiveness of European agri-food sector?
5 November 2008, Ljubljana, Slovenia

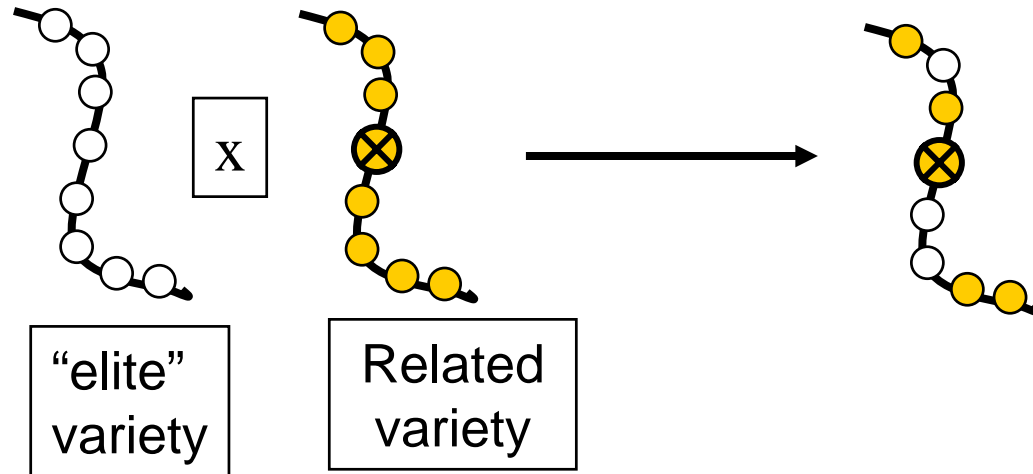
Piet van der Meer

Topics

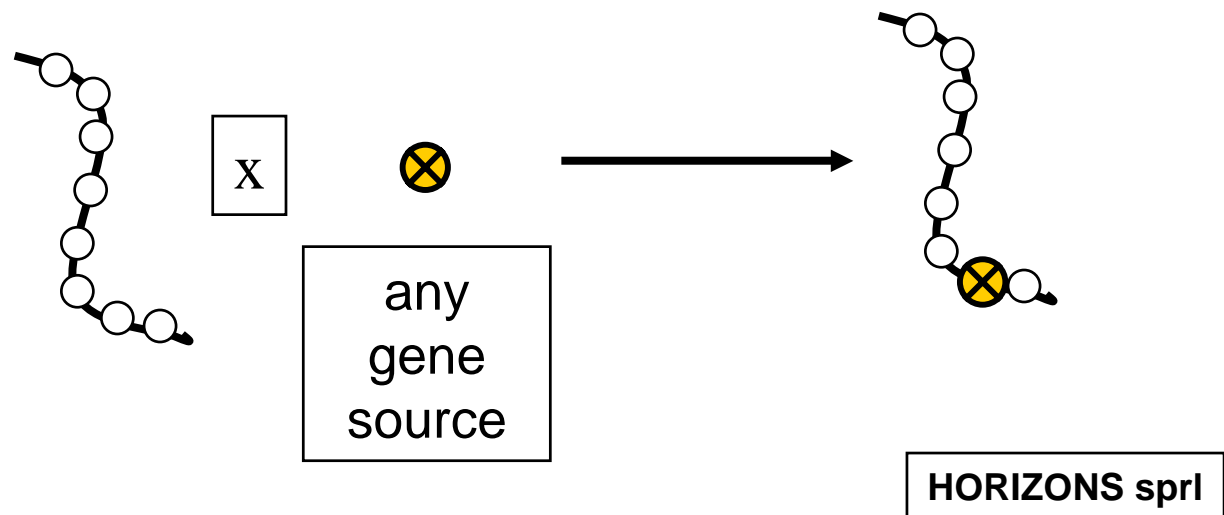
- Background and history – 1972
- History of EU regulations - 1986
- Current situation – 2008
- Introduction to PRRI
- Some thoughts for the discussion

Genetic Modification of Plants

Traditional
plant breeding



Genetic
modification



Genetic Modification of Plants

Technical advantages:

- Specificity
- Speed
- Much greater reservoir of genes

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Potential applications

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Initial safety concerns:

- DNA “going wild”?
- “Insertion” effects ?
- Expression effects – novel traits ?

History

1972: First rDNA applications, *E coli* genes in SimianVirus 40

1974: ‘Berg Letter’: expectations and concerns, moratorium

1975: Asilomar - end of moratorium - safety assessed case by case

1976: NIH Guidelines in the US

1981: National regulations for laboratory work with rDNA

1983: The first transgenic plants

1986: OECD rDNA safety recommendations - “Blue Book”

History

1986: US coordinated framework for regulation of biotechnology

1986: First outlines of EC Directives on GMOs

1990: EC Directives contained use and release of GMOs

1992: UN Agenda 21: Maximise benefits and reduce risks

1995: Gaining experience with EU regulatory system, issuing permits for field trials and market approvals

1997: Decline in permits and market approvals

1998: 'De facto' moratorium

History

1999: the EU Council of Ministers proposed to:

- adopt more stringent rules for placing on the market
- put in place rules on labeling and traceability

2000: Adoption of the Cartagena Protocol on Biosafety

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:
 - 90/219 on contained use of GMMs (as amended by Dir. 98/18)
 - 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
(including risks to humans
and animals as ‘part of the
environment’)

Placing on the Market

- Environmental Safety
- +
- Food/Feed Safety

EU Regulatory Framework for GMOs

Placing on the market of GMOs :

Food and Feed import: Regulation 1829/2003,

- EFSA + involvement of CAs for Food/feed Safety
- Involvement of the 2001/18 CAs for Env. Risk Assessment

Food and Feed and Cultivation: Regulation 1829/2003

- EFSA + involvement of CAs for Food/feed Safety
- Leading role of the 2001/18 CAs for Env. Risk Assessment

Cultivation - Non food (e.g. ornamental flowers): Directive 2001/18

- The 2001/18 CAs for Env. Risk Assessment
- EFSA in advisory role in case of objections - ‘SCP’

GMOs approved on the market in EU

Authorised under Regulation (EC) No 1829/2003:

- Cotton: MON1445, MON15985, MON15985 x MON1445, MON531, Cotton MON531 x MON1445
- Maize Bt11, DAS1507, GA21, **MON810**, MON863, MON863 x NK603, MON863 x MON810, NK603, NK603 x MON810, T25, DAS59122, DAS1507xMON603, DAS59122
- Oilseed rape GT73, Swede-rape, MS8, RF3, MS8xRF3, T45,
- Soya MON40-3-2
- Sugar beet H7-1

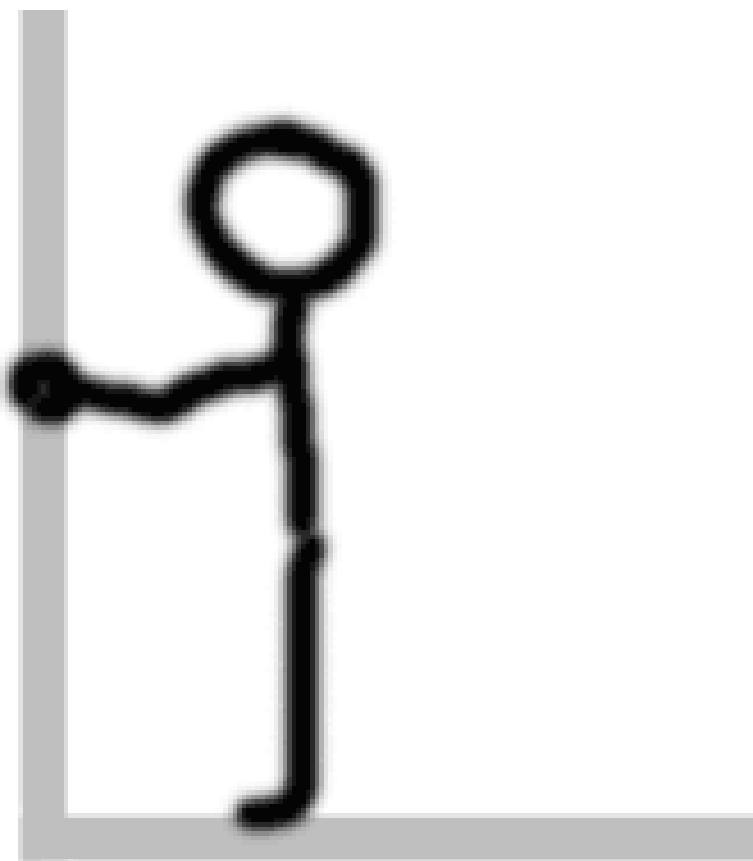
* **Approved for cultivation**

GMOs approved on the market in EU

Cultivation of Bt Maize crops in the EU:

(<http://www.gmo-compass.org/eng/home/>)

	2005	2006	2007	2008
Spain `	53,000	53,700	75,000	79,000
France	500	5,000	21,200	ban
Czech Rep.	150	` 1,300	5,000	8,300
Portugal	750	1,250	4,500	4,800
Germany	400	950	2,800	3,200
Slovakia	0	30	900	1,900
Poland	0	100	300	3,000
Romania*			350	7,100
Total	54,500	62,200	88,900	107,500



EU Regulatory Framework for GMOs

Situation in 2008:

1. The EU regulatory system for GMOs does not function as it was intended to work.
 - Many decisions not within the legal time frames
 - Some decisions not based on the legal criterion of scientific risk assessment
2. All stakeholders involved are aware that the system needs to be improved and have started initiatives to do so.

Developments and activities on EU level

EFSA:

- Updated EFSA Guidance on GM Food and Feed
 - comments before 21 September
- Updated EFSA Guidance Non food/feed guidance
 - Online consultation comments before 16 September
- EFSA Task Force on long term risk assessment and non target organisms as input on the updating of the risk assessment guidelines for cultivation. mandate ends April 2010.
- EFSA position on antibiotic resistance markers expected December 2008

Developments and activities on EU level

The Commission

- Barroso Group of “Sherpas” to the Heads of State discussing the implementation of GM legislation report back by end 2008
- DG Sanco is preparing to translate the updated EFSA guidance for GM Food and Feed in a Commission regulation.
- DG Sanco preparing a technical solution for Low Level Presence for events approved outside the EU and not yet approved in the EU.

Developments and activities on EU level

The Commission

- DG Environment WG examining new breeding techniques.
- DG Env study on socio-economic impacts of GMOs
- DG Environment impact assessment on the adventitious presence of GM seeds in non GM seeds in view of drafting a regulation for AP in seeds.
- JRC: seminar on pipeline of GMOs, 12-13 November 2008, Seville, Spain

Developments and activities on EU level

The Council

- Ad hoc Working Group on GMOs to further discuss possible changes in the environmental risk assessment of GMOs:
 1. Strengthening the environmental risk assessment (DG Env)
 2. Consideration of socio-economic criteria
 3. Improvement of the functioning of the scientific assessment
 4. EU thresholds for adventitious presence of GM seeds
 5. Consideration of “sensitive and/or protected” areas

Developments and activities on EU level

Member States, e.g:

- France: conferences: e.g.
 - colloque de l'Académie des Sciences - September 2008
 - Séminaire sur l'évaluation du risque; Conférence du Gene
- Austria.
 - Study on the application of the Precautionary Principle.
 - High Level Coordination meeting on GMOs.
- Netherlands:
 - 2 October symposium on definitions of GMOs
- Slovakia:
 - Preparation of biosafety strategy

Developments and activities on EU level

Other organisations

- COST: workshop “What role for GM technology in future competitiveness of European agri-food sector? “ 5 November, 2008, Ljubljana, Slovenia
- PRRI
 - o PRRI letter to EU Commissioners – effect on R&D
 - o comments on EFSA updated Guidance
 - o PRRI informal meeting on risk assessment
6-7 November 2008, Brussels Belgium

PRRI - Background

- ❑ Tens of thousands public sector scientists worldwide conduct biotechnological research to strengthen sustainable agricultural production, improved health care and environmental protection.
- ❑ National policies and regulations define which role public research **should** and **can** play.
- ❑ International agreements, such as the Cartagena Protocol on Biosafety, steer national policies and regulations.

PRRI - Background

For long, public researchers working in modern biotechnology have not been represented in international negotiations

Consequently:

- The voice of public research has not been brought to the negotiation table in an organised way
- Confirmation of the misperception that modern biotechnology is the domain of a handful big multinationals.

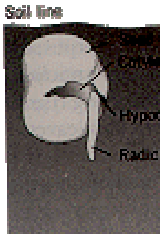
The Public Research and Regulation Initiative (PRRI)

PRRI is established in 2004 with the objective to offer a forum for public researchers involved in biotechnology through which they are **informed about** and can **participate in** international negotiations that are relevant to biotechnology.

PRRI aims to:

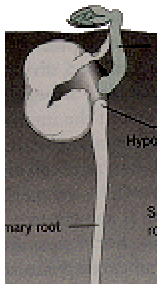
1. Educate public researchers about international regulations
2. Bring science to international negotiations as well as views on the impacts of regulations on public research

PRRI - the first four years



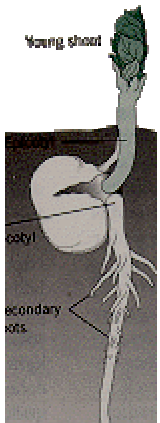
Planting the seed - (2004)

Raising awareness in international meetings



Germination (2005 – 2006)


‘Try out ‘ participation in two Meetings of the Parties to the Cartagena Protocol



Growing and branching - (2006 – 2008)

2008-2009: Focus on EU regulations

Joining PRRI: www.pubresreg.org



Public Research & Regulation Initiative

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JOIN US

PRRI Members are regularly provided with an update on the recent activities of the Public Research and Regulation Initiative. Membership is open to all researchers working in the public sector and is free of charge.

Public sector scientists
Public researchers who wish to be informed about and actively involved in the PRRI activities, such as providing comments and feedback on draft discussion papers, are welcome to register as a PRRI member. Once registered, name, organisation and country will be included on the PRRI membership list.

Public sector scientists who additionally wish to participate in one or more of the Working Groups are invited to inform the Steering Committee through the Secretariat.

Other stakeholders
Other stakeholders such as: policy makers, government officials, journalists, NGO's and the general public, that would like to receive regular updates, can indicate their interest by contacting the Secretariat.

Title: *

Prof.
Dr.
Mr.
Mrs.
Ms.
MSc.

First name: *

Middle name:

Surname: *

Email-adress(es):

Thoughts for the discussion

- The EU regulatory framework can work well, (also for PMPs).
- EFSA opinions are scientifically robust.
- The main problem is political, not scientific or technical.
- Encouraging number of initiatives to improve the system, but:
 - o More transparency and coordination of the various activities
 - o Address political issues in one place – e.g. Sherpa
 - o Address specific technical problems in one place, based on proper science.

Thoughts for consideration

- While the regulatory framework is in place:
 - Apply the rule of law – decisions need to be given in time and on the legal basis of scientific assessment - EFSA
 - Don't change the rules while playing the game
- While revising the regulatory framework: More involvement of the public research sector – e.g PRRI
- Inform the EU Council of the concerns raised in the COST workshop – relevance for future discussions on synthetic biology, nano-technology etc.

Hvala!

Piet van der Meer

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