Walls and Bridges

EU authorization requirements for GMOs, One door one key?

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Food safety in general

Safety		Not-regulated	Regulated
	Assessment		
Inherent properties		Art. 14: effect	Category: Additives, GMOs, novel foods
	Ex ante	Self assessment	Authorization
	Ex post	Enforcement	Enforcement
Condition		Art. 14: effect	MRLs, shelf life
	Ex ante	Self assessment	Self assessment
	Ex post	Enforcement	Enforcement





EU regulation of GMOs

- Three core issues
 - Prior authorization based on risk analysis
 - For cultivation
 - For consumption
 - Traceability
 - Labelling
- Related issues
 - Co-existence
 - Intellectual property







The concept of food authorization

- USA 1950s: additives
 - Any substance
- EU 1960s: colors
- EU 1970s: additives
 - Not normally consumed as a food in itself
 - Added for a technological purpose
- EU 1997: novel foods
 - Not consumed in the EU to a significant degree before 1997
- EU 2003: GMO package
 - Reg. 1829/2003 1830/2003





Environmental authorization

- DIRECTIVE 90/220/EEC on the deliberate release into the environment of genetically modified organisms
- DIRECTIVE 2001/18/EC on the deliberate release into the environment of genetically modified organisms
- REGULATION (EC) 1829/2003: integration of both procedures possible
 - 'one-door-one-key'





How did we get to this point?

- 'De facto moratorium'
- WTO litigation



- EU Response
 - Centralization at EU level
 - More efficient procedures





One door one key

- One procedure
 - at EU level, not in every Member State
- One single application
- One procedure: both for food and feed use (consumption)
- One procedure possible: for consumption and cultivation
- One risk assessment covering all risks
- One decision
- Authorization grants access to the entire EU





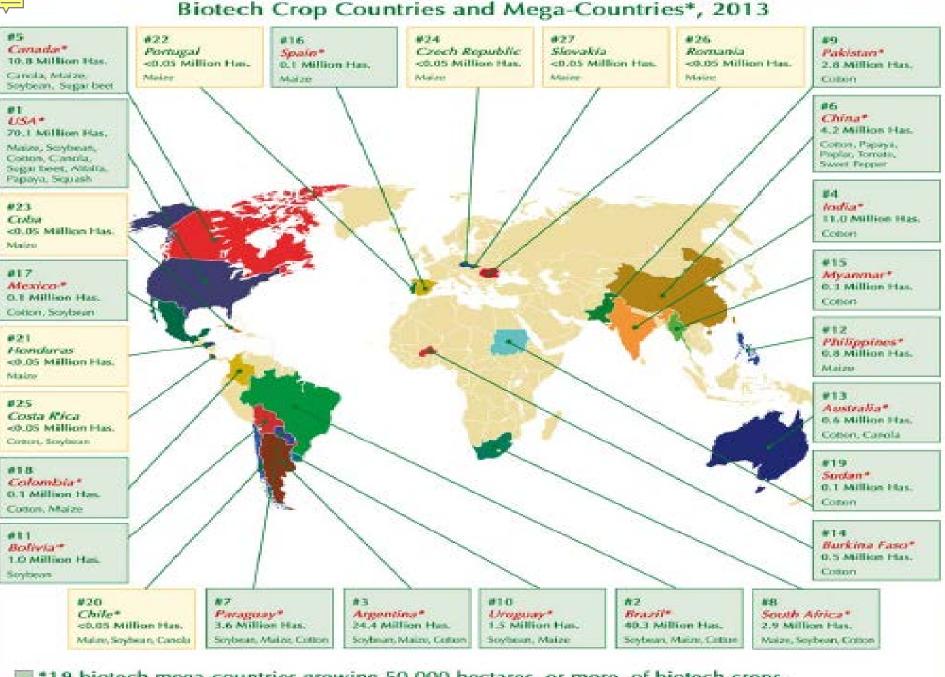
One door one key

- Food / feed: inseparable
- Consumption / cultivation: optional









*19 biotech mega-countries growing 50,000 hectares, or more, of biotech crops.
Source: Clive lames, 2013.

Figures

- Total authorizations for consumption: 43
- Total authorizations for cultivation: 2 1

- GM labeled food on the market: almost absent
- GM labeled feed on the market: up to 95%





Explanation

- Food
 - Consumer preference
 - Labeling
- Feed
 - Costs
 - Labeling no counter incentive





NE Plantaardige margarine.

Bevat 80% vet . Ingrediënten: plantaardige oliën en vetten*, water, 1% zout, emulgatoren (sojalecithine**, E471), droge melkbestanddelen, conserveermiddel (E200), voedingszuur (citroenzuur), aroma's, kleurstof (caroteen), 800 mcg vitamine A en 7,5 mcg D3 per 100 gram.

* geproduceerd met genetisch gemodificeerde soja.

**genetisch gemodificeerd.

Geproduceerd in: Nederland.

Na openen koel bewaren.

art.nr. 5044009

Gemiddelde voedingswaarde	per 100 g
Energie Fiwit	2970 kJ/720 kcal 0 g
WAGENINGEN UNIVERSITY WAGENINGENUR	0 g 80 g

Ten

2

Win

Cultivation

- One procedure
 - All setbacks and delays add up
 - Food safety assessment takes four years
 - Environmental safety assessment takes 10
- One decision
 - Partial problem harvests a full 'no'
- Burdens and risks of procedure
 - Alternative available: export to EU





EU market

- Huge consumer market for GM feed
 - Authorization only possible access
- Not an interesting production market
 - High labor costs
 - High regulatory burdens (environment, zoning)
 - High uncertainties
 - Better go to low wage countries





Conclusion

- Barriers to EU market are high
 - But surmountable in case sufficient economic incentive exists
 - They do for feed consumption
 - They do not for cultivation
- Integrating procedures not successful
- The 'key' needs further improvement
 - EC proposal: more MS freedom not to allow cultivation may lead to more favorable decisions

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See also:

Regulating food law

Fed up with the right to food?

Governing food security

Law, politics and the right to food



A comparative study

Bart Wernaart



Report on the regulatory environment of the European food and dairy sector



Private food law

Governing food chains through contract law, self-regulation, powers standards, audits and certification schemes

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Thank you for your kind attention

Q&A
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Suggestions for further reading

- EU law in general: Klaus-Dieter Borchardt, The ABC of European Union Law, EU 2010 ebook free at http://bookshop.europa.eu/isbin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en_GB/-/EUR/ViewPublication-Start?PublicationKey=OA8107147
- EU food law in general: Bernd van der Meulen, The Structure of European Food Law, Laws 2013, 2, 69–98; doi:10.3390/laws2020069 http://www.mdpi.com/2075-471X/2/2/69
- International food law in general: Bernd van der Meulen, The Global Arena of Food Law; Emerging Contours of a meta-Framework, Erasmus Law Review, Vol. 3, Issue 4 (2010),
 - http://www.erasmuslawreview.nl/files/the_global_arena _of_food_law



