

# Regulatory and Political Climate of Biotechnology in the EU

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Constance Cullman



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# Global Operations



**Rapid worldwide expansion.**

**Facilities in more than 40 countries**

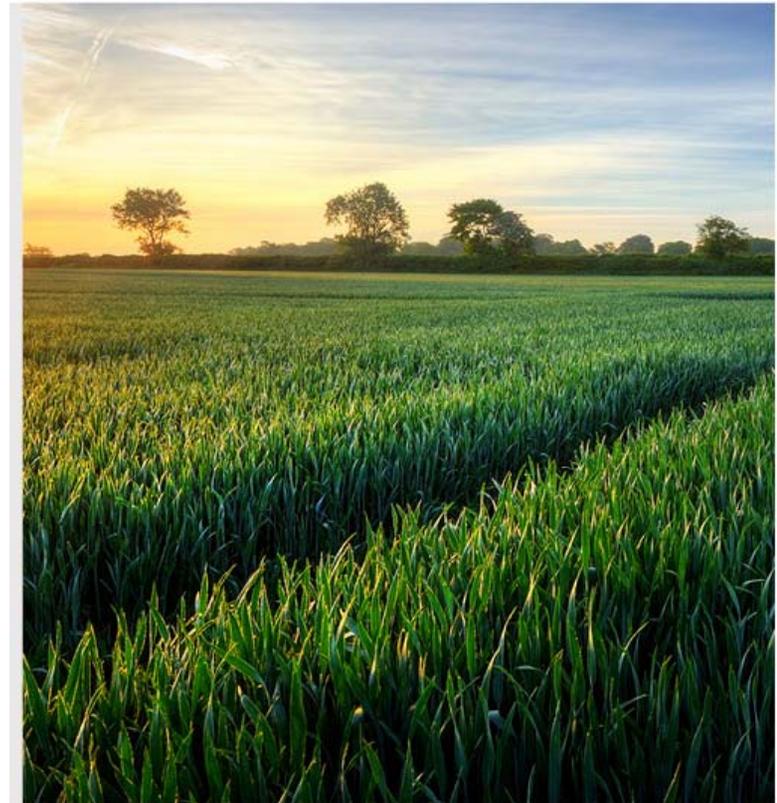
**Products sold in more than 130 countries.**

**More than 7,700 employees worldwide.**

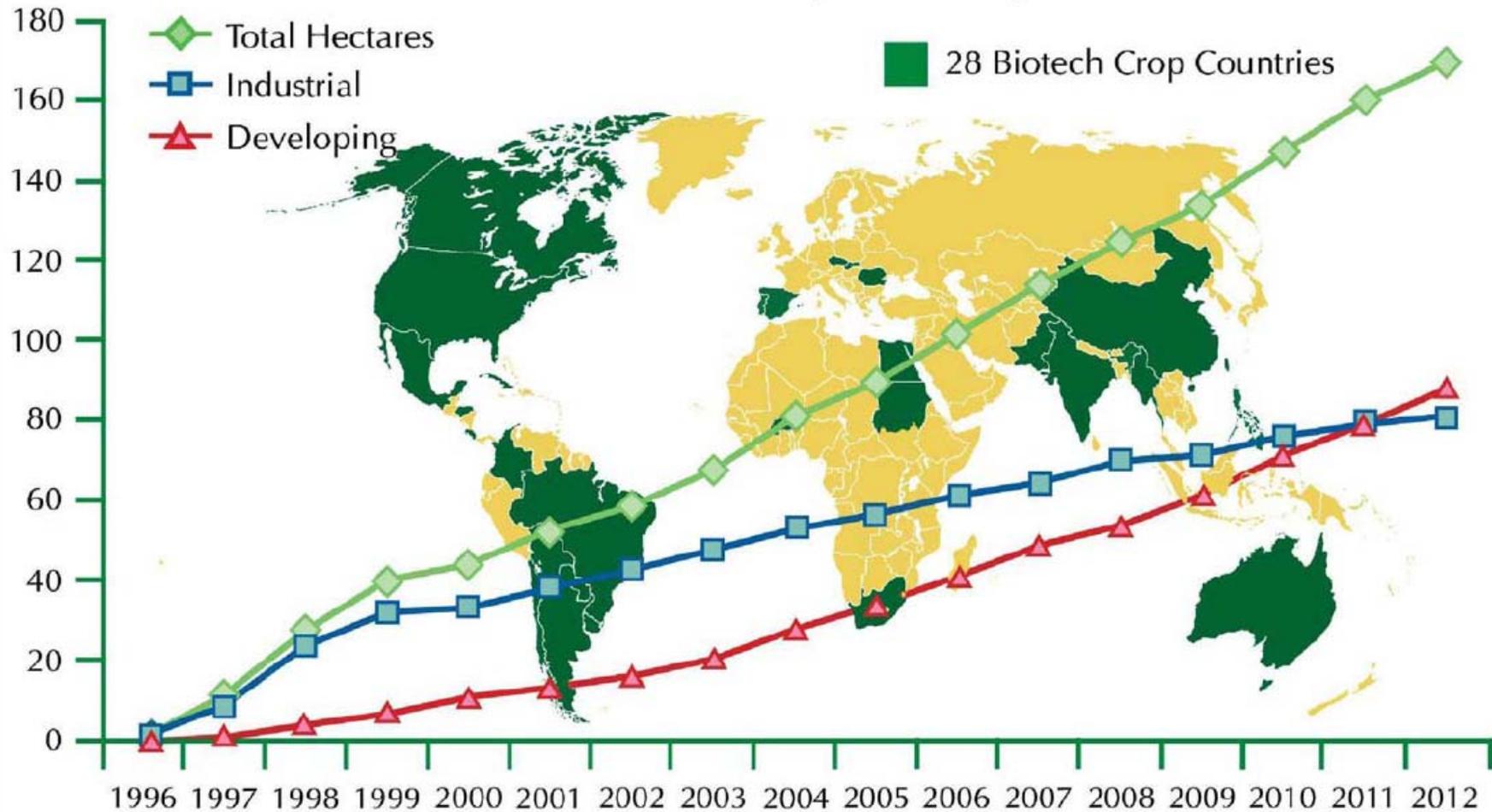


# Overview

- Biotechnology – The Global Picture
- Status in the EU
- EU Regulatory Framework
- Political Aspects
- Trends
- Conclusions



## GLOBAL AREA OF BIOTECH CROPS Million Hectares (1996-2012)



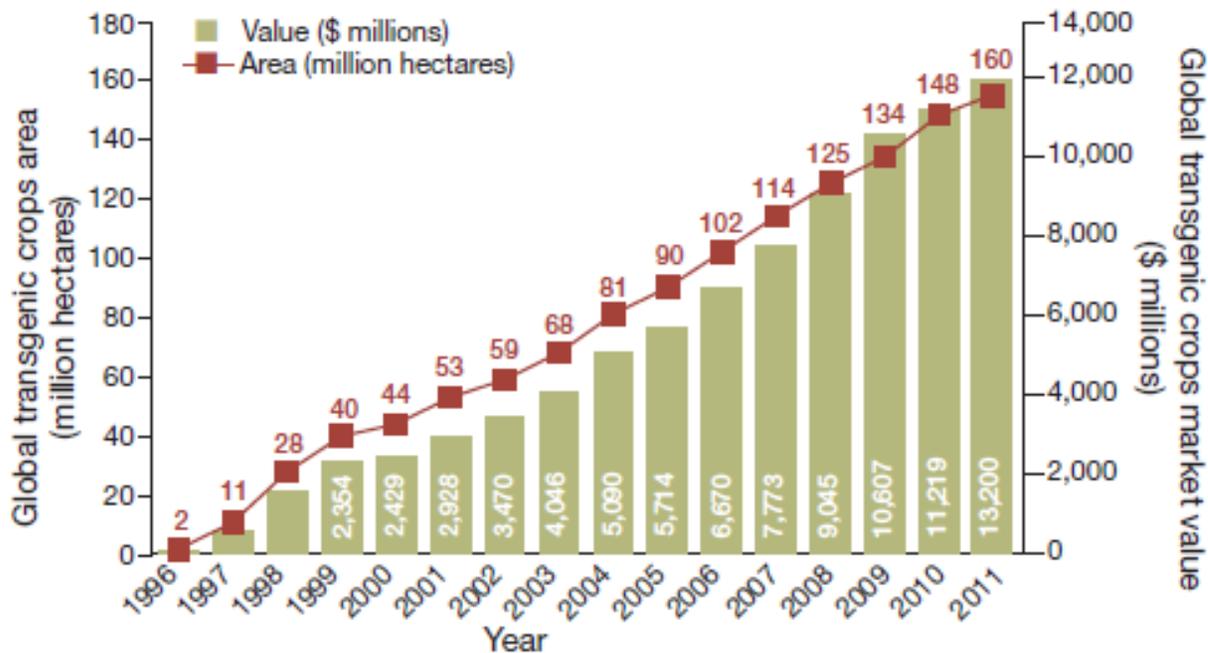
*A record 17.3 million farmers, in 28 countries, planted 170.3 million hectares (420 million acres) in 2012, a sustained increase of 6% or 10.3 million hectares (25 million acres) over 2011.*

Source: Clive James, 2012.

# Rapid Growth of Global Transgenic Seed Market

## Historical global area and value of transgenic crops

Transgenic acreage grew 8% in 2011, now representing 36% of the global seed market.



Source: International Service for the Acquisition of Agri-Biotech Applications. Value data are explicitly from seeds and licensing revenue rather than from 'crops' themselves.

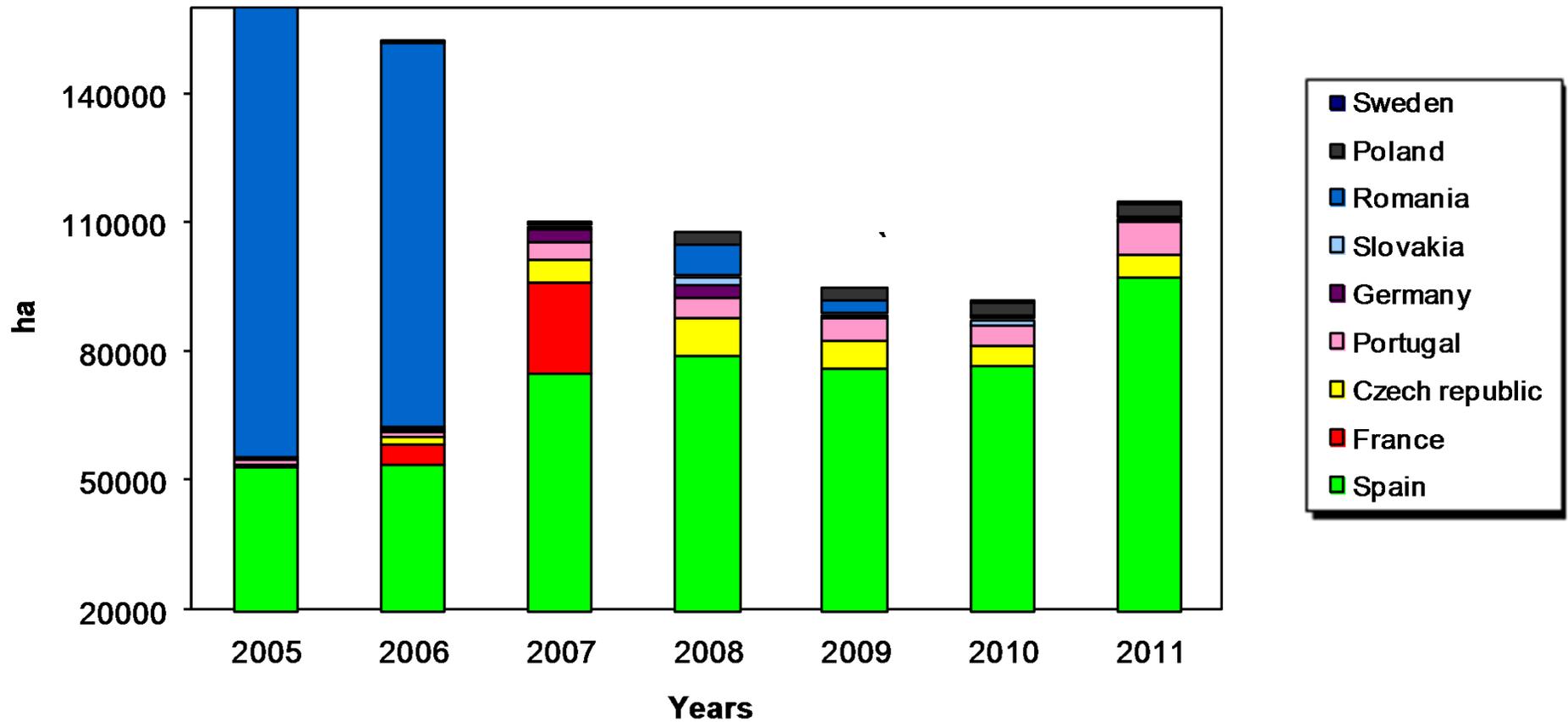
Source: Marshall, A. (2012) Existing AgBiotech Traits continue Global March. *Nature Biotechnology* 30, 207

# Biotechnology in the European Union



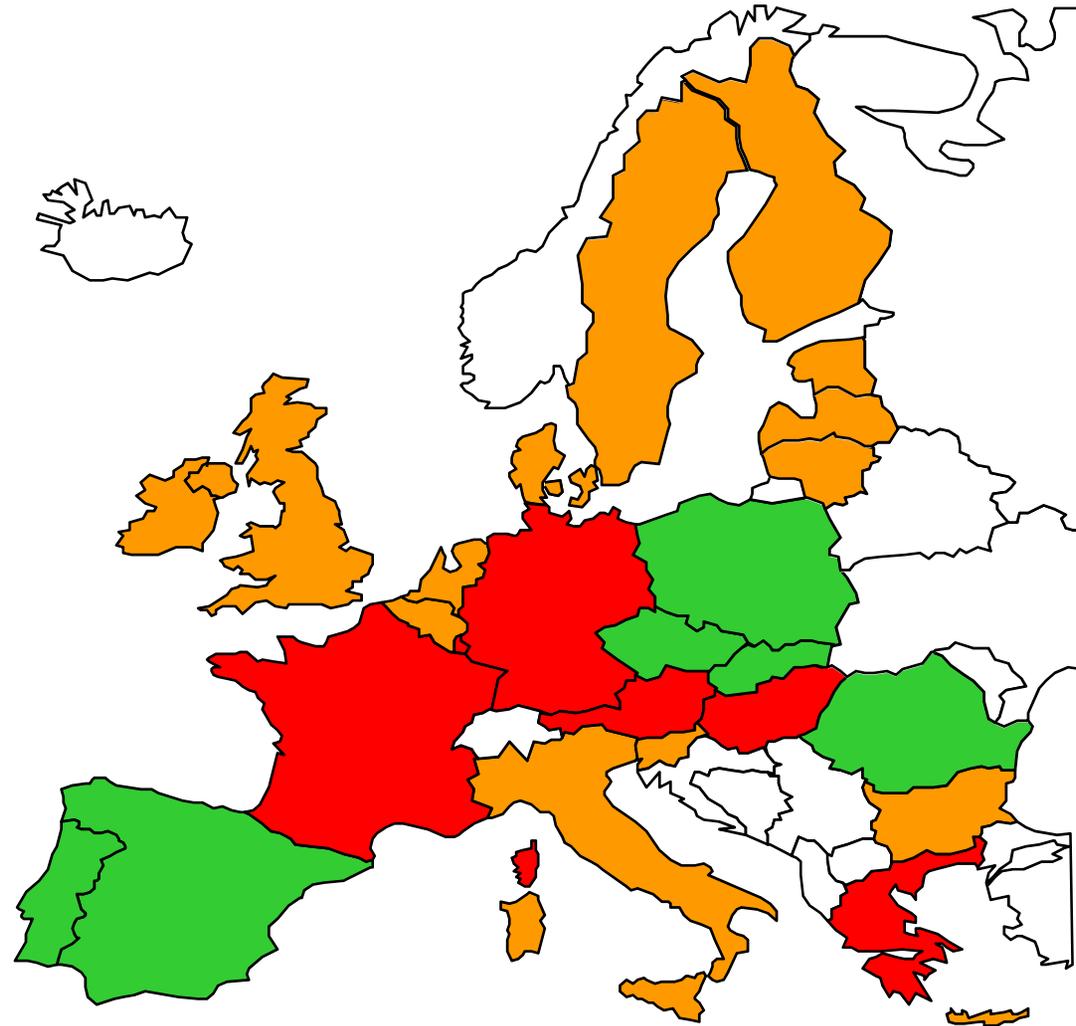
# Evolution of biotech cultivation in the EU

## Biotech crop cultivation in the EU

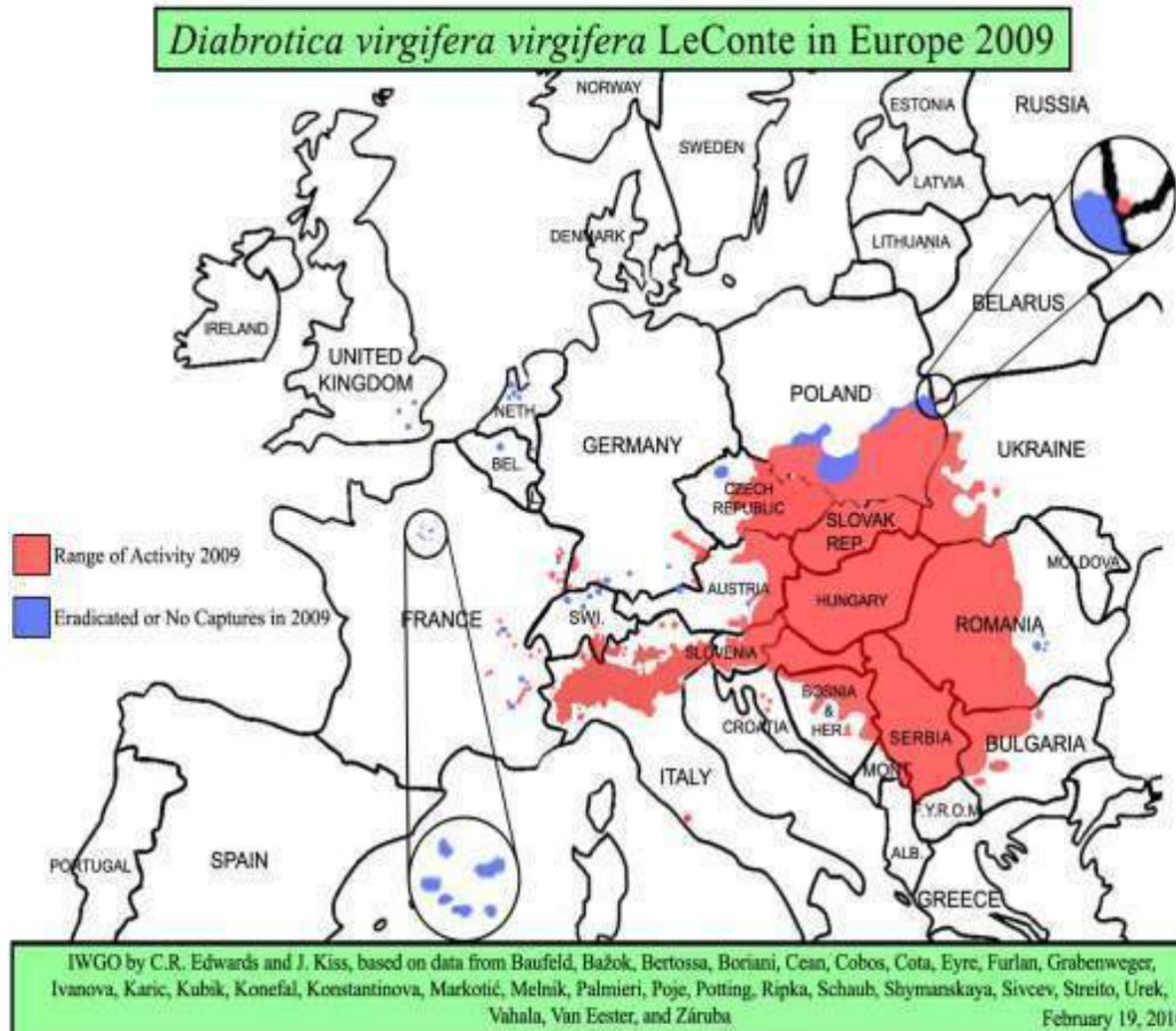


Source: James, C. (2011) Global Status of Commercialized Biotech/GM Crops

# Cultivation of biotech crops in the EU

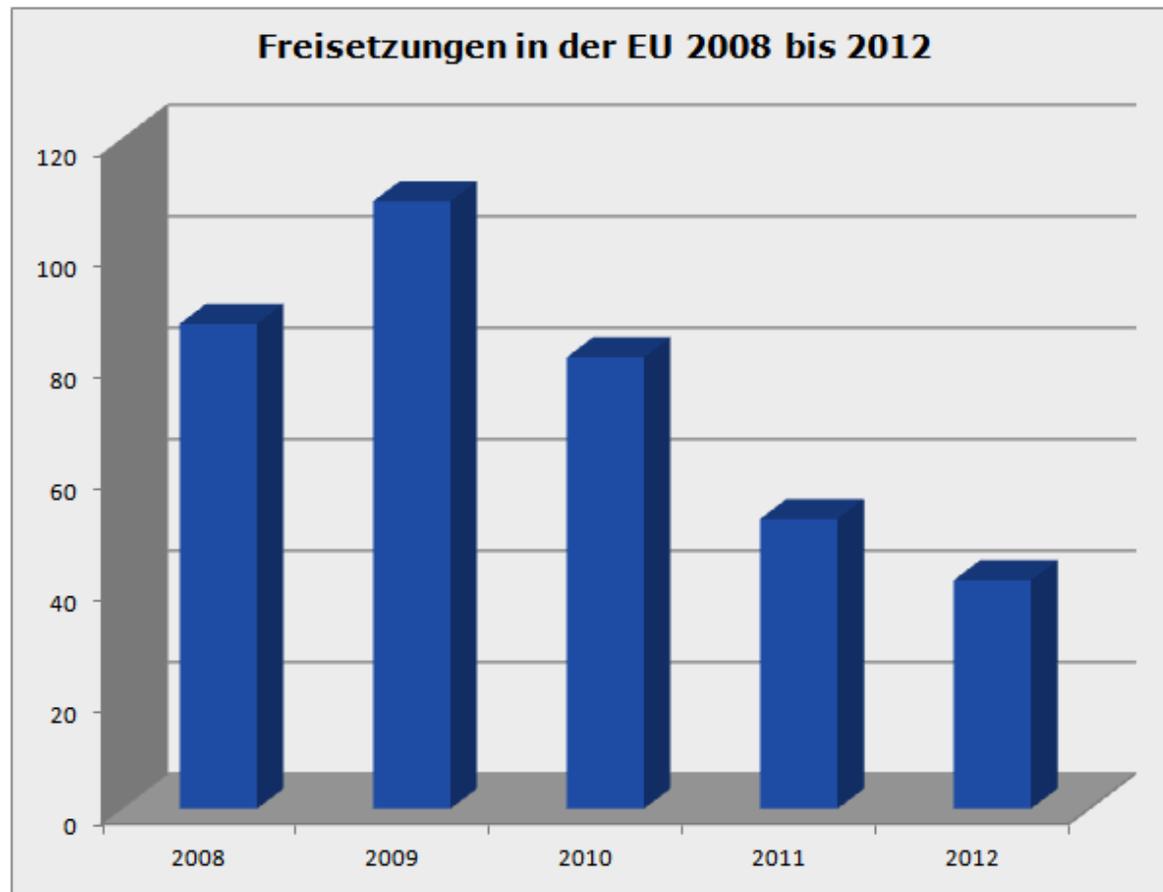


# A growing problem: Corn rootworm moving through Europe



**3 GM Maize products with corn rootworm resistance have been in the EU approval system since 2005...**

# Number of field trial requests in the EU is declining



<http://www.gmo-safety.eu/news/1416.plant-research-europe-genetic-engineering-field-trials.html>

# The EU regulatory framework for biotech...



# A completed legislative framework

## *Cultivating biotech crops:*

- Directive 2001/18 on the deliberate release of GMOs into the environment
- Coexistence Recommendation (2010/C 200/01):
  - Guidelines to ensure coexistence of GM crops with conventional and organic farming

## *EU Principles:*

- Safety (case-by-case evaluations)
- freedom of choice
- labeling and traceability



# A completed legislative framework

## *Using Biotech Food or Feed*

- Regulation 1829/2003/EC on genetically modified food and feed
  - foods that are biotech and processed foods derived from biotechnology
  - applies to food and feed and addresses effects on human or animal health
- Regulation 1831/2003/EC
  - Traceability/ labeling of biotechnology, traceability of food/ feed products produced from biotechnology
- Regulation 1946/2003 on the transboundary movements of biotechnology
  - EU Principles: Safety, freedom of choice, labeling and traceability

# Products approved in the EU

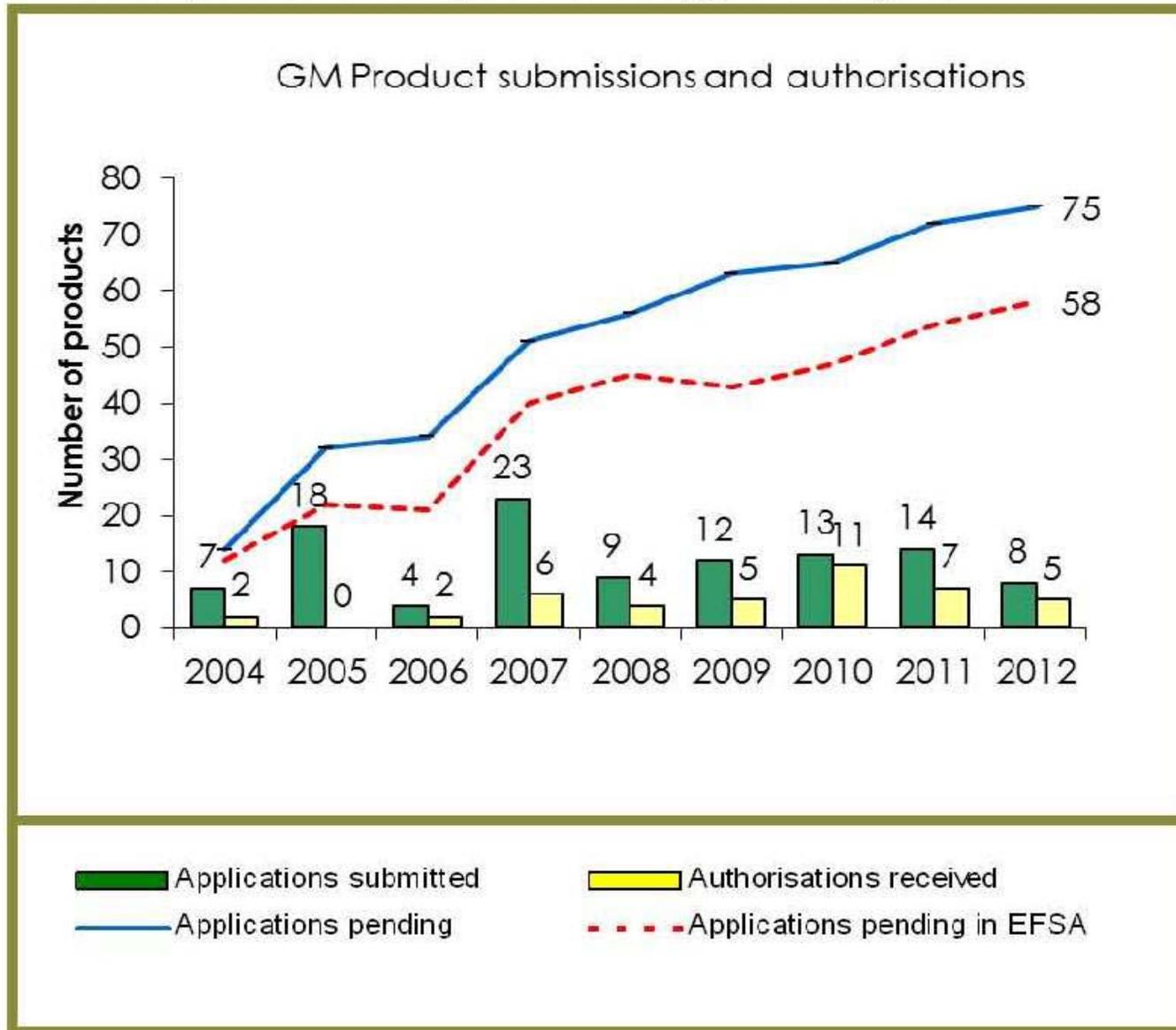
The EU has approved 46 biotech events for import, only two for cultivation

- **Import**
  - > Maize: 26
  - > Oilseed rape: 3
  - > Soybean: 8
  - > Cotton: 8
  - > Sugar beet: 1
- **Cultivation**
  - > Maize: 1 (1998)
  - > Potato: 1 (2010)



# Biotech Product Submissions and Authorizations

The GM product backlog of the EU approvals system



Source: EuropaBio, 2012

# 75 Biotech Products are currently in the EU approval process



## 23 products for cultivation

- > 17 maize
- > 3 potato
- > 1 soybean
- > 1 sugarbeet
- > 1 cotton



## 52 products for food, feed, import & processing

- > 17 maize
- > 12 cotton
- > 15 soybean
- > 7 rapeseed
- > 1 rice



## Timelines for GM products with a positive EFSA safety opinion and awaiting Commission action:

Timelines not compliant with EU law		Timelines compliant for the moment		Products for EU cultivation	
Product	Application Received by EFSA <sup>iv</sup>	Publication of EFSA Opinion	Months (m) and days (d) waiting for the Commission to schedule first vote <sup>v</sup> : maximum: 3 months	Months (m) and days (d) waiting for the Commission to schedule second vote <sup>vi</sup> : maximum: 2 months	Days after Council/ Appeal vote - waiting for approval
1507 maize (c)	11/2000	03/03/2005	voted after 47 m 22 d (25/02/09)	44 m 11 d and counting	
Bt11 maize (ipc)	05/1996	19/05/2005	voted after 45 m 06 d (25/02/09)	44 m 11 d and counting	
LL Rice62 (ffip)	08/2004	30/10/2007	60 m 06 d and counting		
NK603 maize (ffipc)	08/2005	11/06/2009	40 m 25 d and counting		
MON810 maize (ffipc) (renewal)	06/2007	30/06/2009	40 m 06 d and counting		
MS8xRF3 rapeseed(ff) (renewal)	06/2007	22/09/2009	37 m 14 d and counting		
GT73 oilseed rape(ffip) (renewal)	06/2007	15/12/2009	34 m 21 d and counting		
MON863 maize (ffip) (renewal)	06/2007	30/03/2010	31 m 06 d and counting		
MON89034x1507xMON88017x59122 maize (ffip)	10/2008	27/09/2010	25 m 09 d and counting		
MON89034x1507xNK603 maize (ffip)	02/2009	27/09/2010	25 m 09 d and counting		
MON531 cotton (ffip) (renewal)	06/2007	16/09/2011	13 m 20 d and counting		
MON88017 maize (c)	04/2008	10/11/2011	11 m 26 d and counting		
MON1445 cotton (ffip) (renewal)	06/2007	16/12/2011	10 m 20 d and counting		
GA21 maize (ffipc)	07/2008	16/12/2011	10 m 20 d and counting		
MON 531xMON1445 cotton (ff) (renewal)	06/2007	28/03/2012	7 m 8 d and counting		
MON 40-3-2 soybean (c)	11/2005	21/06/2012	4 m 15 d and counting		
Bayer MS8, RF3& MS8x RF3 oilseed rape (ffip) (extension of scope)	23/06/2010	26/09/2012	1 m 10 d and counting		
MON87705 soybean (ff)	25/02/2010	30/10/2012	0 m 5 d and counting		
<b>Accumulated undue delay per column</b>			<b>446 m 20 d</b>	<b>88 m 22 d</b>	
<b>ACCUMULATED UNDUDE DELAY<sup>vii</sup></b>			<b>534 months 42 days = 44.6 years</b>		

ff=food, feed, industrial use

i=import

p=processing

c=cultivation

Source: EuropaBio, 2012

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## Regulatory Hurdles

- The EU process for biotechnology product authorization takes substantially longer than comparable systems
- For cultivation consideration, the authorization system has never been properly implemented
- Several EU governments vote against EFSA scientific determinations for political reasons
- Every year twice as many biotechnology products enter the system than exit
- New assessment requirements lacking scientific basis are frequently introduced for political reasons
- In 2012, the EU's Rapid Alert System for Food and Feed detected 40 unauthorized events: 31 rice incidents from China, India and Pakistan, and 9 papaya incidents from Thailand

# Negative effects of overregulation on innovation



- High regulatory costs – major market barrier for small firms
- Brain drain – the best researchers and labs go to more welcoming places
- No incentives for SMEs operating in field
- Block for certain types of innovation, especially for small market crops or traits
- European seed firms competitiveness decline (access to high-yielding germplasm)
- Field trial research is significantly lagging

# EU heavily dependent on imported protein

**EU27: Soy imports and domestic = 35mlnt/year**

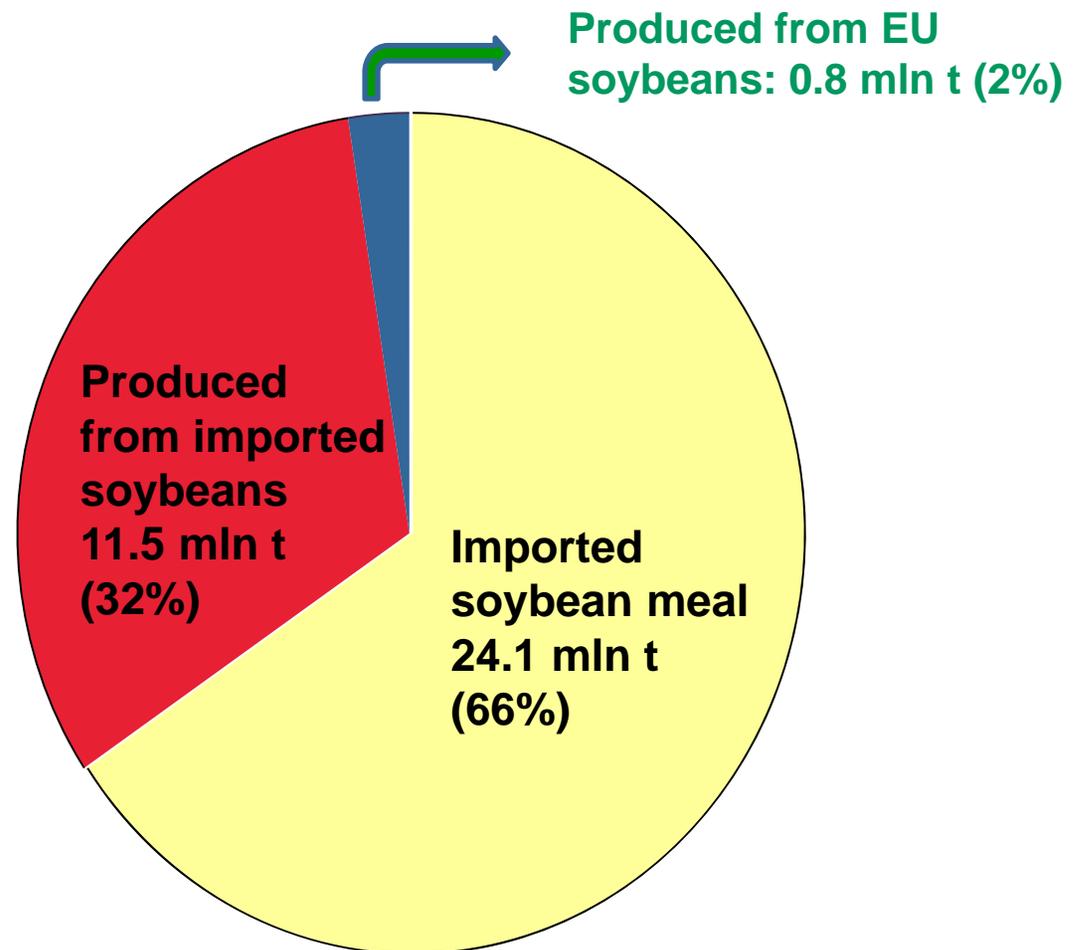
**60 kg = amount of imported soy per EU citizen**

**Soy is used for animal feed particularly.**

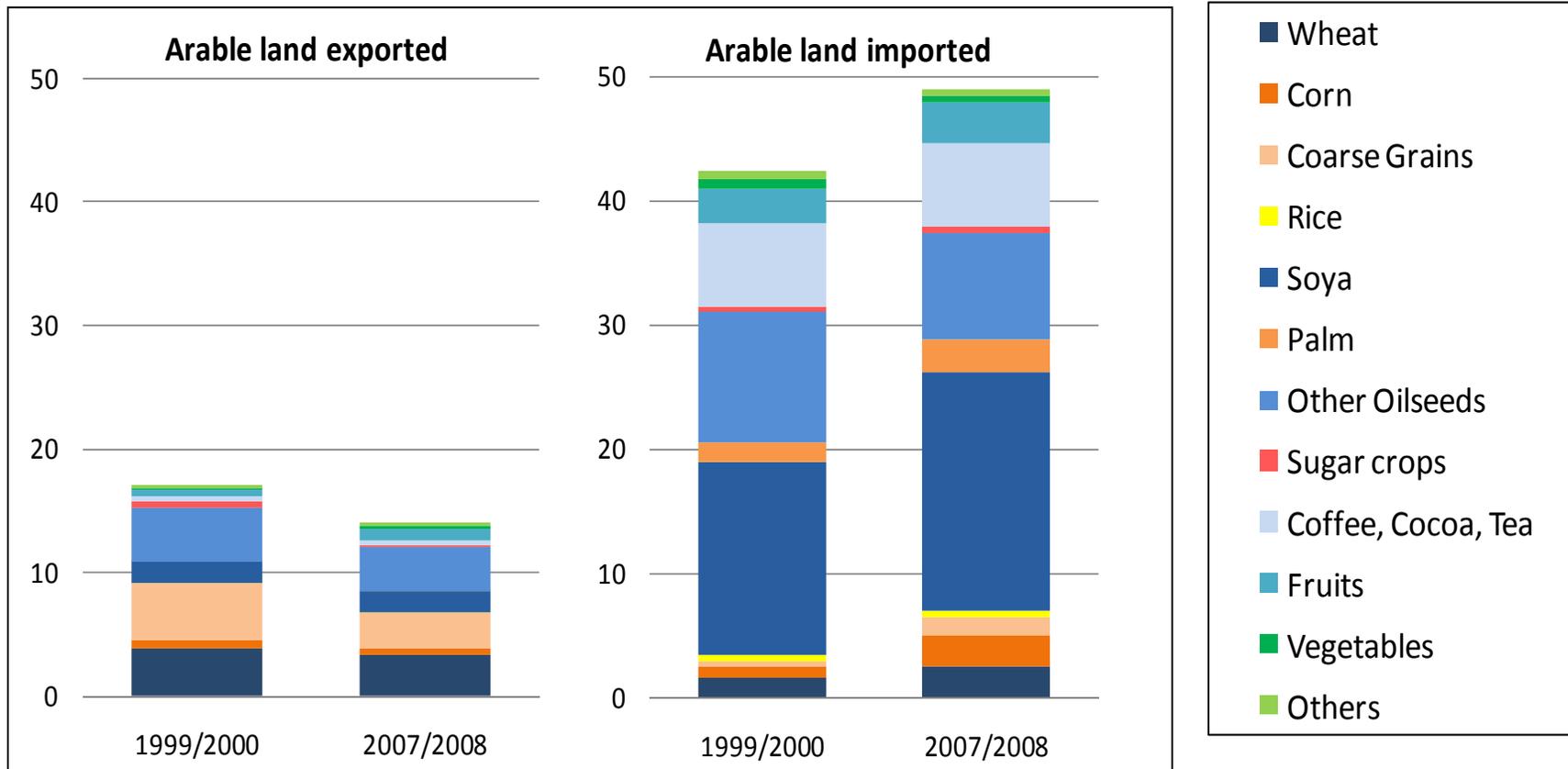
**90% of imported soy is from biotech crops.**

**Non-biotech soy becoming difficult to source.**

**Increasingly costly (e.g. \$85/t premium.)**



# Trend: EU 'importing' more land



EU uses 35 million hectares outside EU to feed 500 million consumers

# Estimated benefits to EU of adoption of biotech crops each year

TABLE 8

Estimated benefit to EU of adoption of transgenic crops per crop cycle

Crop	Area, Mha	Trait	€/ha		€M	
			min	max	min	max
Maize <sup>a</sup>	8.5	IR			157	334
Cotton	0.26	IR	50	150	13	39
Soyabean	0.5	HT	10	38	5	19
Oilseed rape	6.5	HT	30	49	195	318
Sugarbeet	1.46	HT	50	150	73	219
<b>Total</b>					<b>443</b>	<b>929</b>

Benefits for other crops based on benefits from similar crops elsewhere in the world.

<sup>a</sup> Benefits for maize from Table 4, based on published outcomes for Bt maize in EU, but obtained before recent increases in pressure arising from spread of WCR.

Benefit to EU farmers if they were allowed to grow available GM crops (estimate)

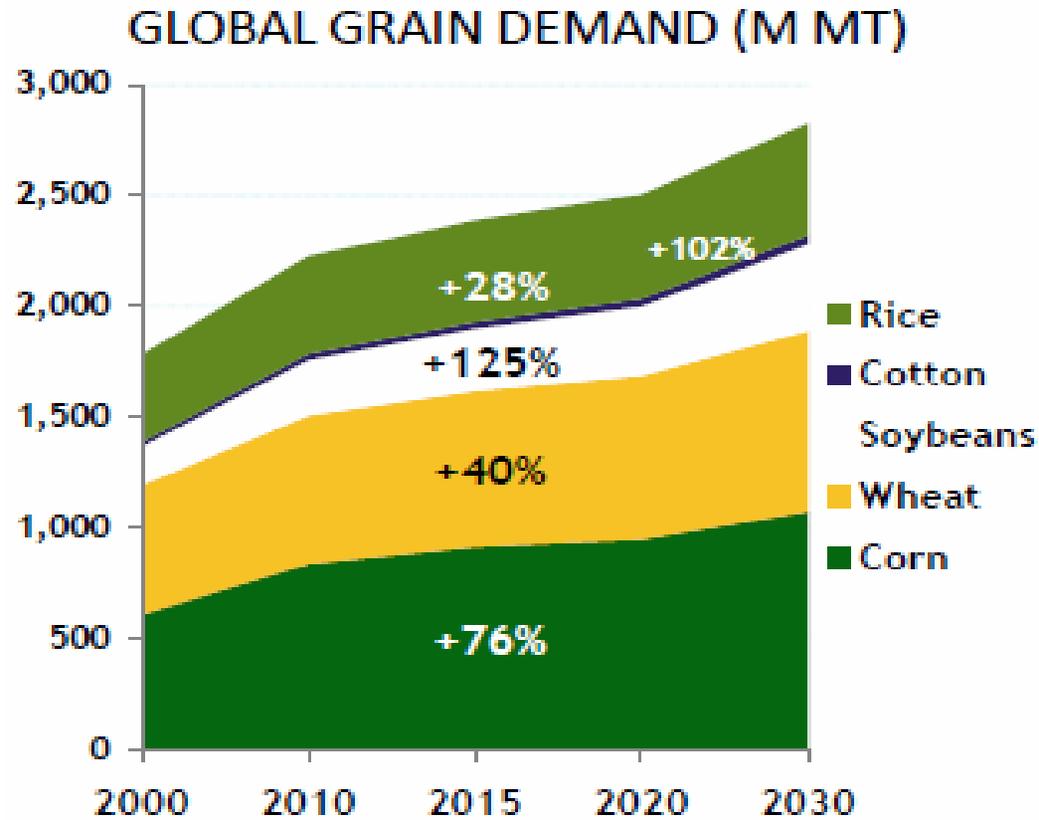
**€443 and €929 million each year.**

Source: The impact of the EU regulatory constraint of transgenic crops on farm income; Julian Park, Ian McFarlane, Richard Phipps and Graziano Ceddia, New Biotechnology; March 2011

# Global trends



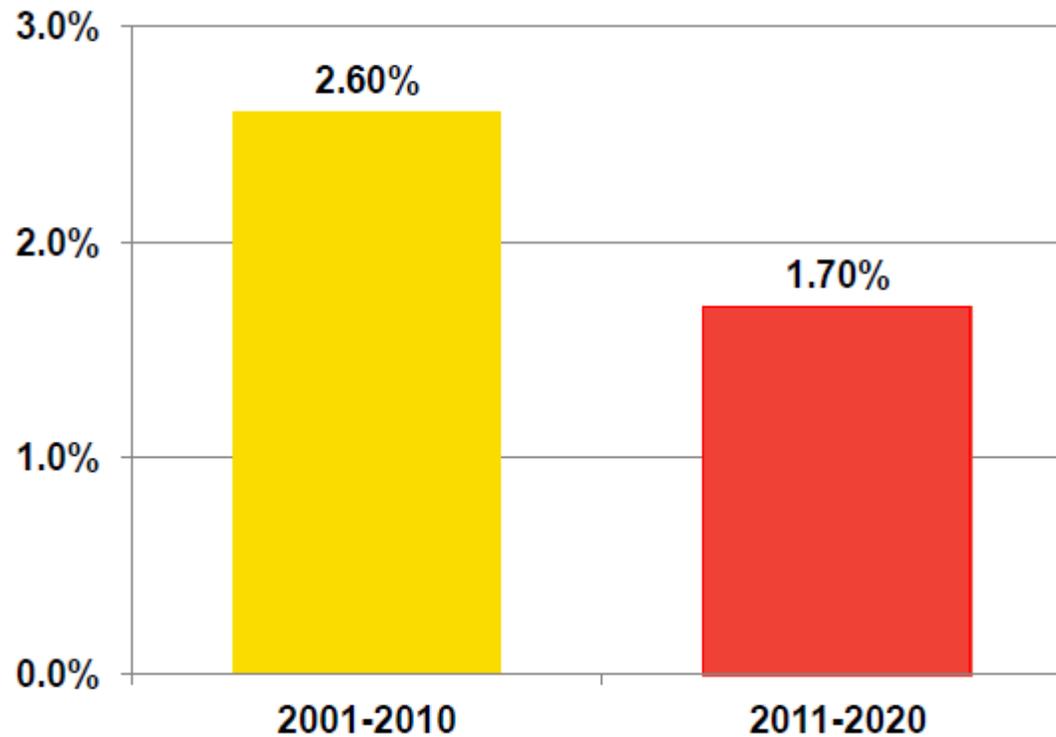
# Dramatic Growth in Demand



Source: FAO world agriculture towards 2015/2030. summary report HIS Global insights

# Slower global output growth

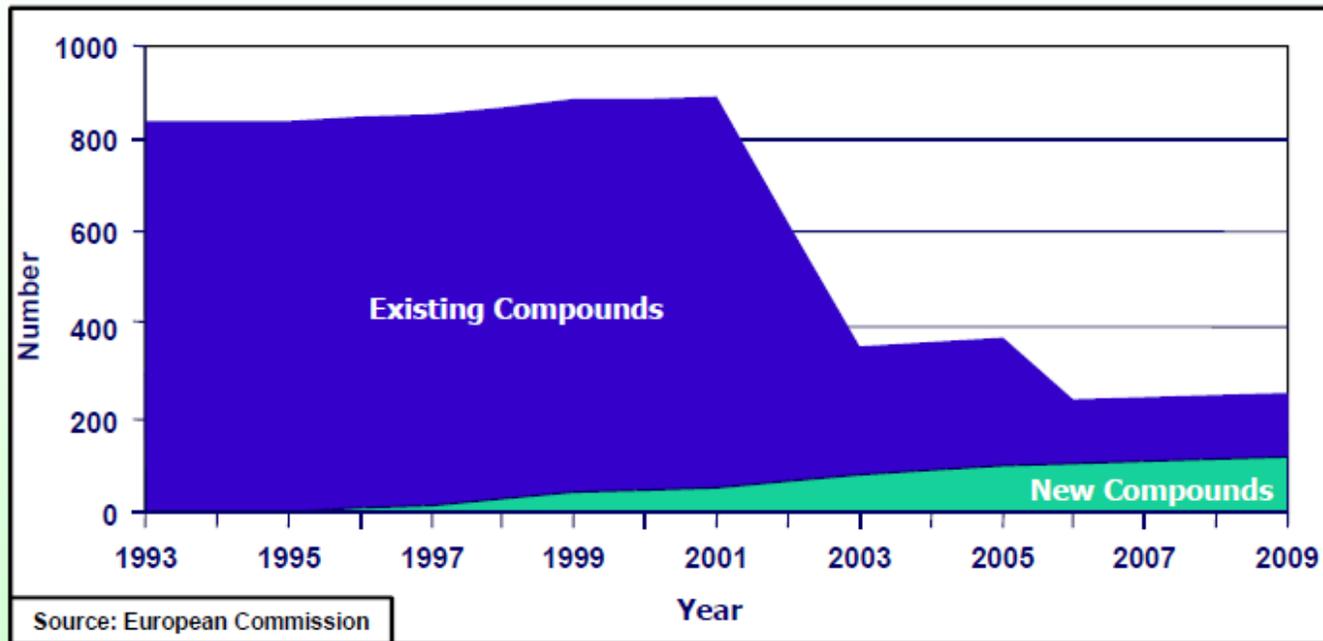
## Global agricultural production growth



Source: W. Jones – OECD -Food security: contribution to the global food supply and the increasing need of biomass for various uses

# Crop protection – The big picture

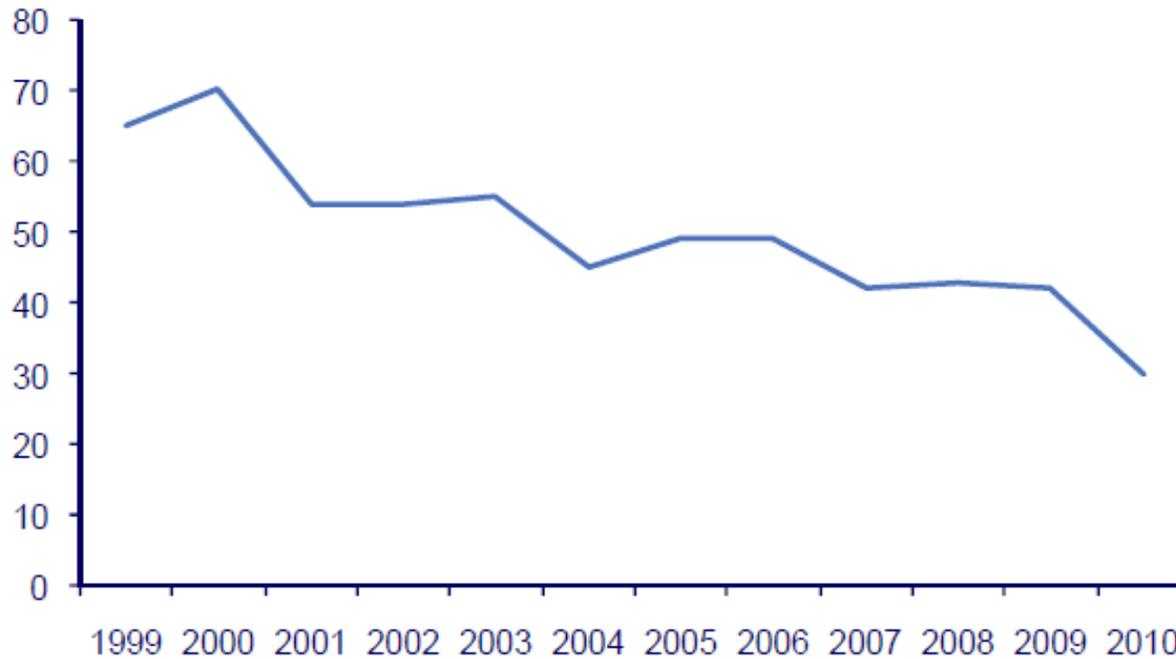
## Number of pesticide substances



# Crop protection – The big picture

## *Agrochemical Active Ingredients in Development*

a.i.s in development

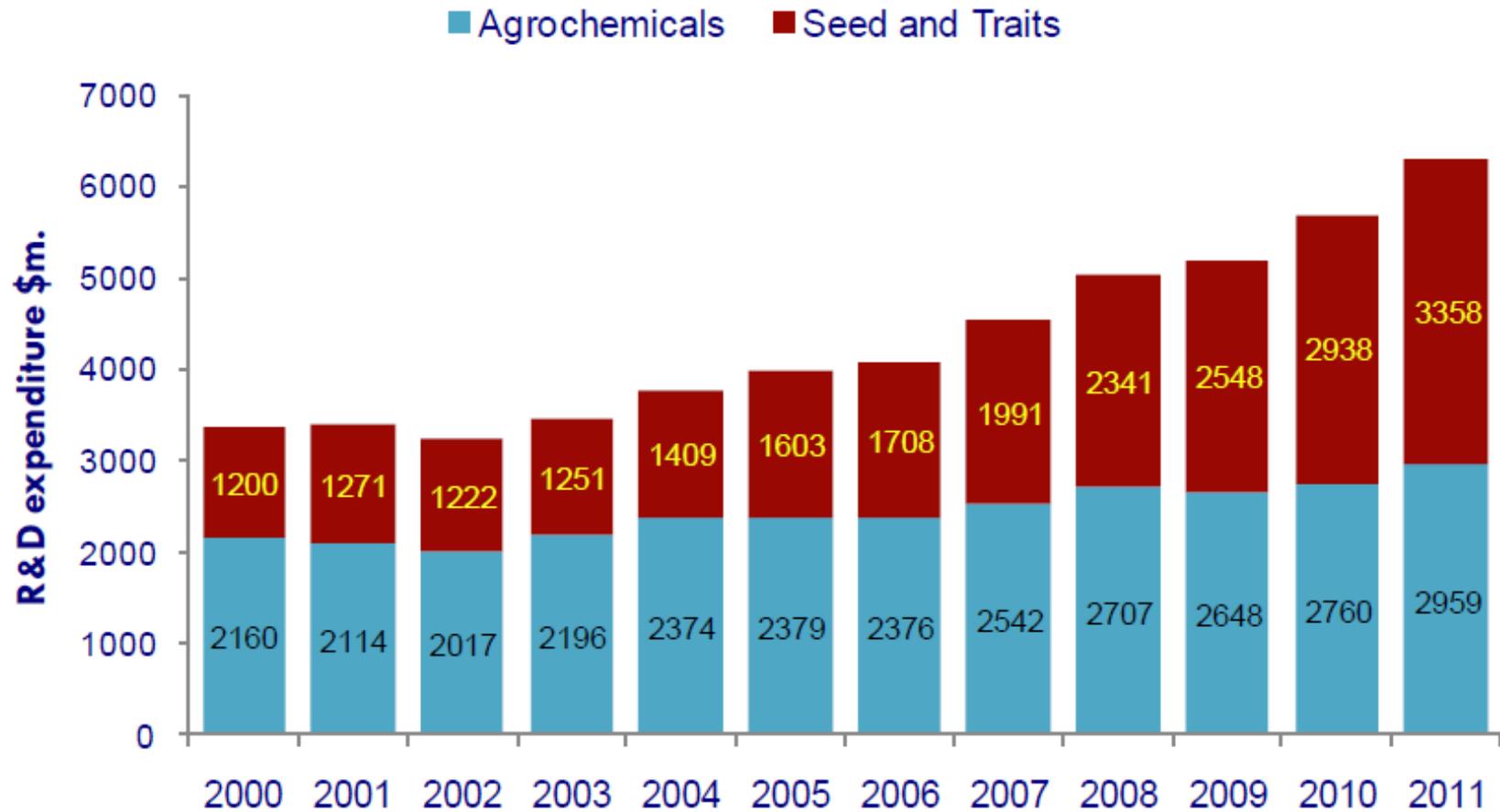


November 2011

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## Total R&D Expenditure by the Leading Agrochemical Companies



Source: Trends in Industry R&D – April 2012 PhillipsMcDougall Newsletter – AgriService

# Conclusions

- Success has led to increased global investment and adoption
  - Most rapidly adopted crop technology in recent history
  - Second generation traits are beginning to emerge
  - New breeding techniques close to adoption
- Current EU regulatory framework technically workable however political intervention in the process has impeded predictable implementation
- Europe risks becoming innovation backwater
- More international coordination is needed



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# Thank You!

Special thanks to  
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