Approvals of GMOs in the European Union

**Analysis • Global Comparison •
Forward Projection • Impacts • Improvements**

Analysis: Main findings

- Authorisation system for GMOs not working as it should
- There is a significant backlog
  - Every year, twice as many GM products enter the system than exit it.
  - Almost twice as many product applications in the system, than have exited it
- EU process takes substantially longer than comparable systems
- Slow process cannot be explained by safety concerns alone
  - EC takes 11 months (on average) to put products to the vote. Law foresees 3
  - New assessment requirements lacking scientific basis are introduced
- For cultivation, the agreed process has never been correctly implemented
- Some governments vote against EFSA scientific advice for political reasons

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Summary: Conclusions

State of play

1. **The authorisation system for GMOs in the EU is not working as it should.**
2. **The EU process for GM product authorisation takes substantially longer than comparable systems.**
3. **The Commission takes 11 months (on average) to put products to the vote. Legislation foresees 3 months.**
4. **For GM products for cultivation, the authorisation process has never been correctly implemented.**
5. **Some EU governments vote against scientific experts at EFSA for political reasons.**
6. **Every year, twice as many GM products enter the system than exit it.**
7. **New assessment requirements lacking scientific basis are introduced for political reasons.**

Impacts and looking ahead

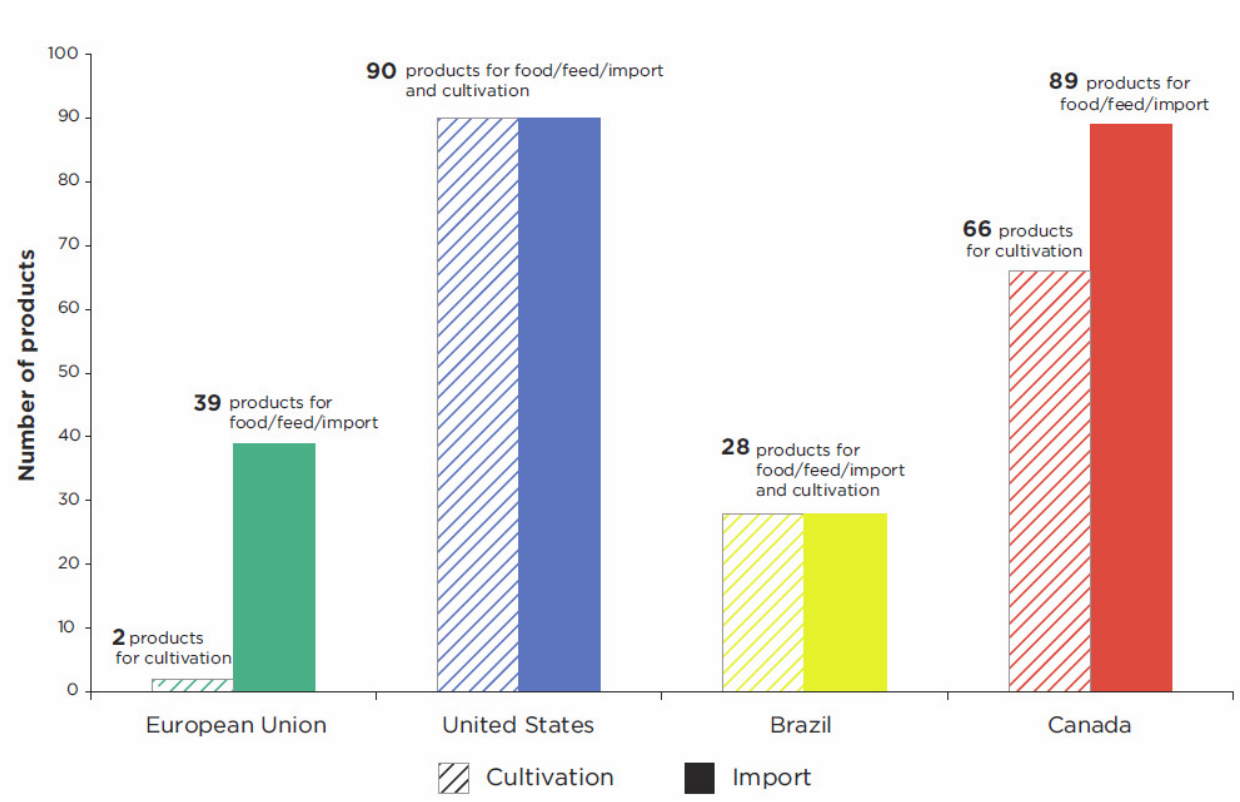
1. **Prediction: 93 GM products are expected to be in the EU process in 2015.**
2. **Trade problems and economic costs resulting from asynchronous authorisations will increase.**
3. **Countries exporting commodities to the EU are less inclined to wait for EU approvals.**
4. **European farmers suffer competitive disadvantage resulting from the authorisation delays.**
5. **Efficiency gains are possible without impacting thoroughness, completeness or independence of assessment.**

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Summary: Recommendations

1. The EU's declared fight against bureaucracy should be extended to the field of GMO approvals.
2. The European Commission should put GM products to the vote without delay, as prescribed in EU law.
3. Targets should be set to deal with the backlog. Efficient application processing should be a higher political priority.
4. Occasions for Member States to vote on products should no longer be cancelled.
5. Member States should play by the rules they agreed on = base their voting behaviour on EFSA scientific opinion.
6. On cultivation, the system should be based on farmer and consumer choice within an EU science-based system.
7. New risk assessment requirements should only be added if EFSA scientists deem this necessary.
8. New elements of EFSA guidance should not be applied retroactively.
9. EFSA can improve clarity, certainty and predictability regarding to guidance for applicants.
10. New requirements for applicants should only apply if included in formally adopted, updated guidance document.
11. New applications should not require additional data on products already assessed as part of previous assessments.
12. Stacked product applications should be reviewed in parallel with individual component single applications.
13. A fast-track safety assessment should be available for products assessed and on the market for years.
14. Products that already received an EFSA opinion should follow a simplified procedure.

Analysis: Approved GM products



The solid part of the bar charts reflects the number of products approved for cultivation: 2 in the EU, 90 in the US, 28 in Brazil and 66 in Canada.

The striped part indicates the number of products approved for food/feed uses and import.

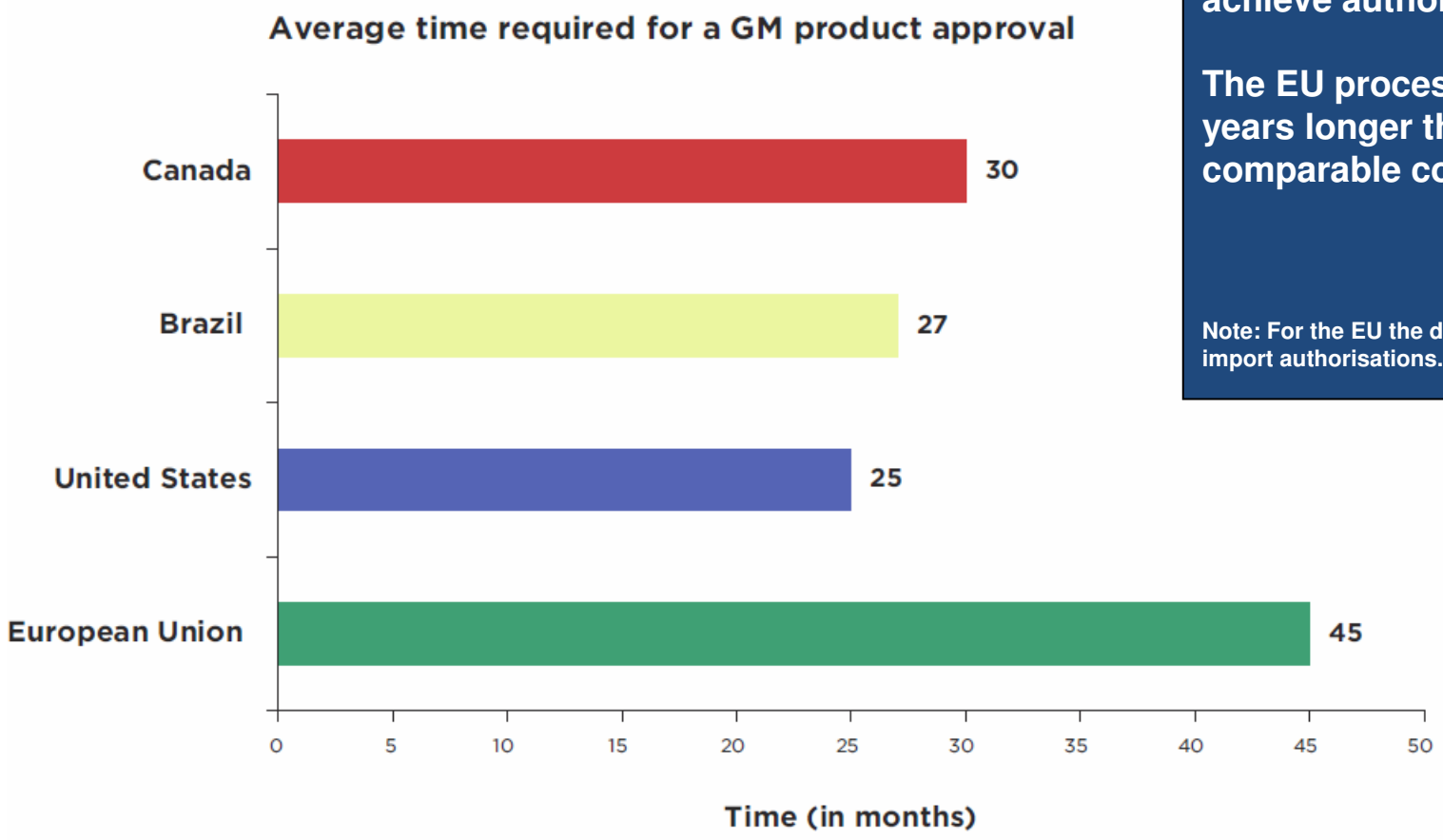
In the US and Brazil, the products approved for food/feed uses and import are also authorised for cultivation.

Note 1: Of the 39 approved GM products in the EU, 12 are stacked products; GM products with more than one GM trait and 2 are renewals. The EU is one of the few regions where it is compulsory to submit separate applications for stacks and renewals.
Note 2: Canada includes Plant Novel Traits (PNT), some of which are not GM. (status August 2011)

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Analysis: Timelines of four regions

- From submission to final approval -



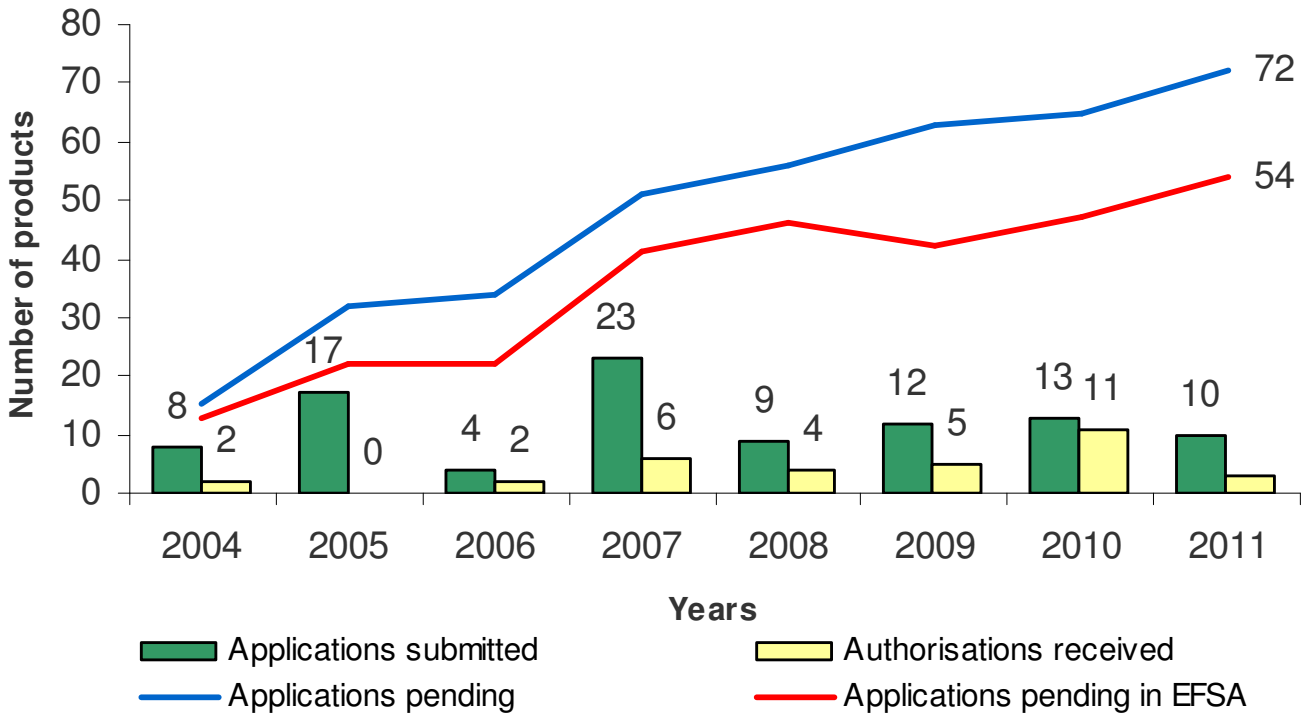
The average time required to achieve authorisations.

The EU process is 1.5 to 2 years longer than in comparable countries.

Note: For the EU the data only applies to import authorisations.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Analysis:
Applications vs. authorisations



The chart shows that the number of GM products pending approval in the EU system increases every year.

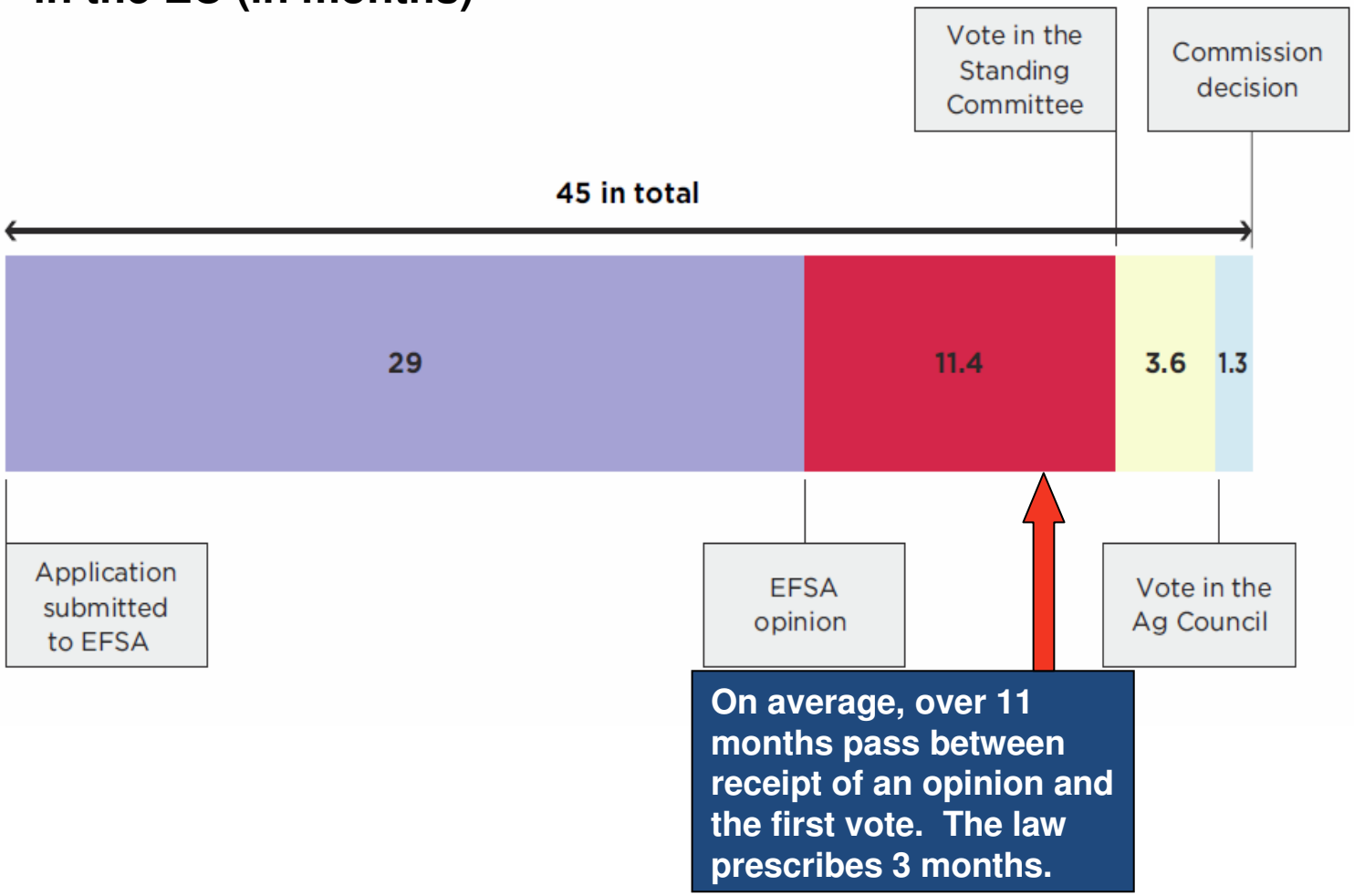
Every year more applications are submitted than authorisations received.

Status : 31 August 2011

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Analysis: EU authorisation time

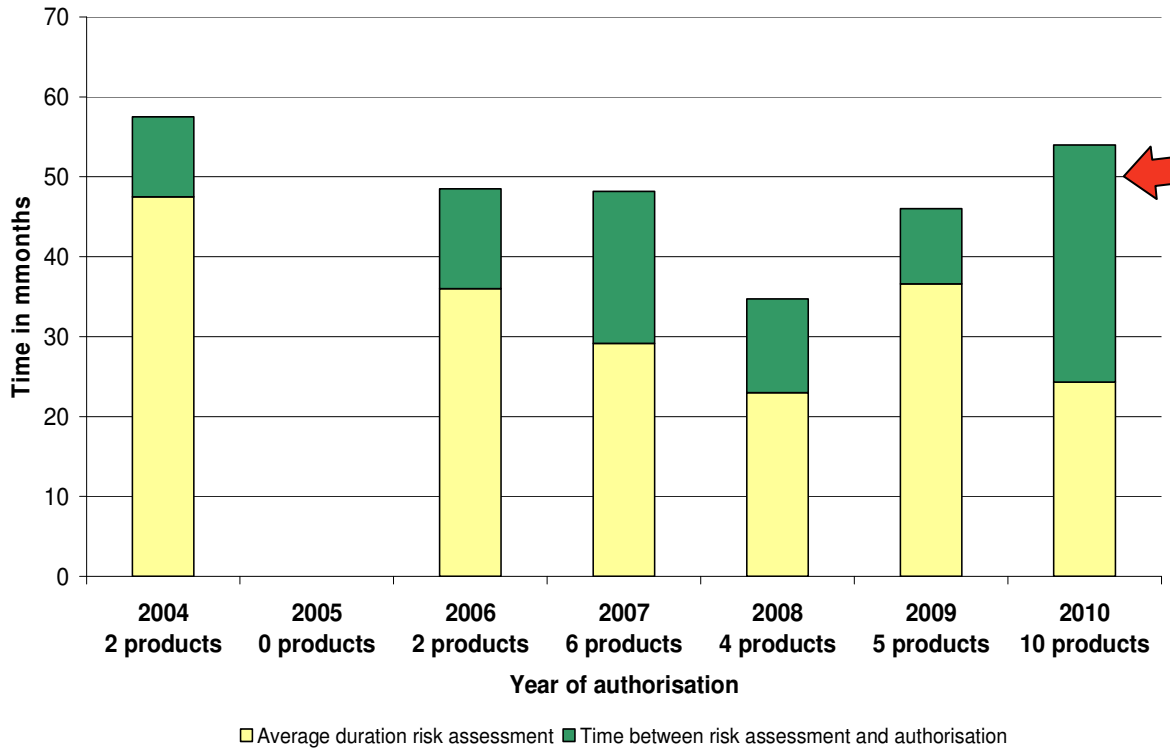
Average duration of GM food and feed products authorisation in the EU (in months)



The chart shows that the average time it takes to assess and process an import application is 45 months.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

EU authorisation timelines



The chart shows the average time it takes to approve a GM import product is increasing.

Over 50 months in 2010 (less than 40 months in 2008).

Notes:
In 2010, eight out of the 10 products approved were stacks and one was a renewal. Only one new product for import was approved in 2010.

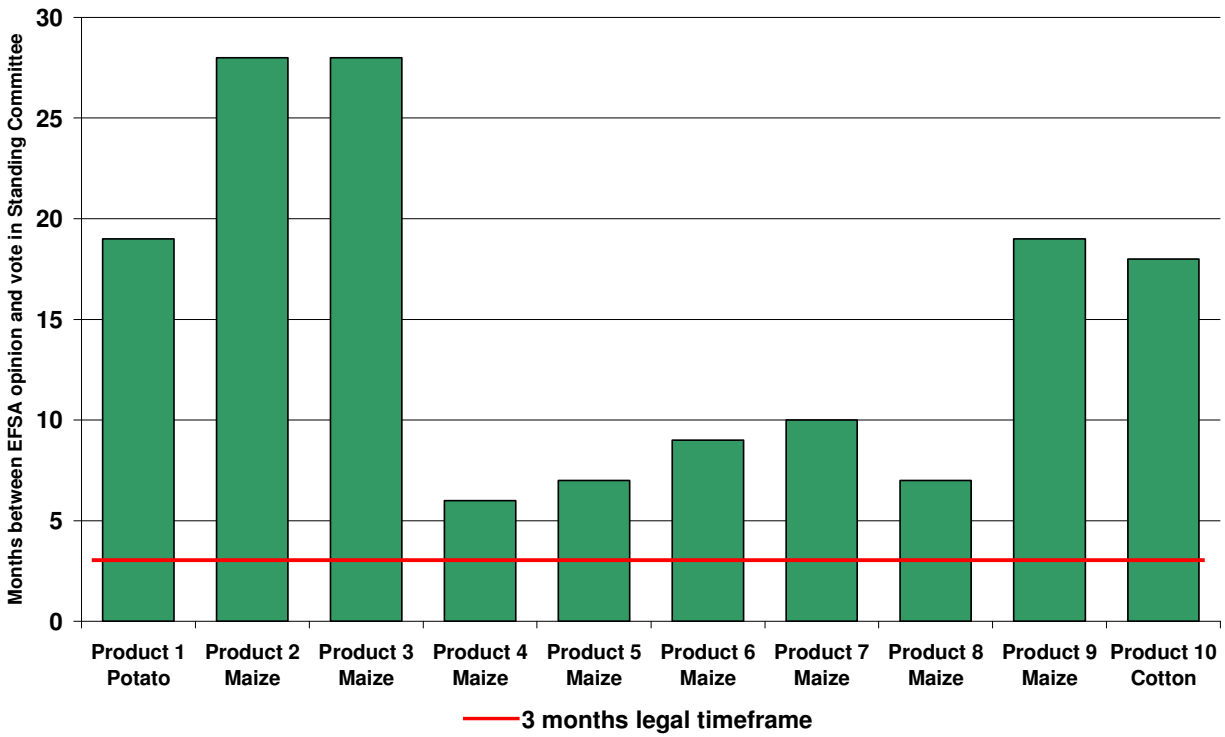
This chart includes all import products (not products for cultivation in the EU). No products were approved in 2005.

In 2011 to date, only three products were approved.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

EU authorisation timelines

Timelines of the last 10 GM products approved for import



Green bars show the number of months between EFSA opinion and the first Member State vote.

In all cases the legal timeframe of 3 months – the red line – was exceeded.

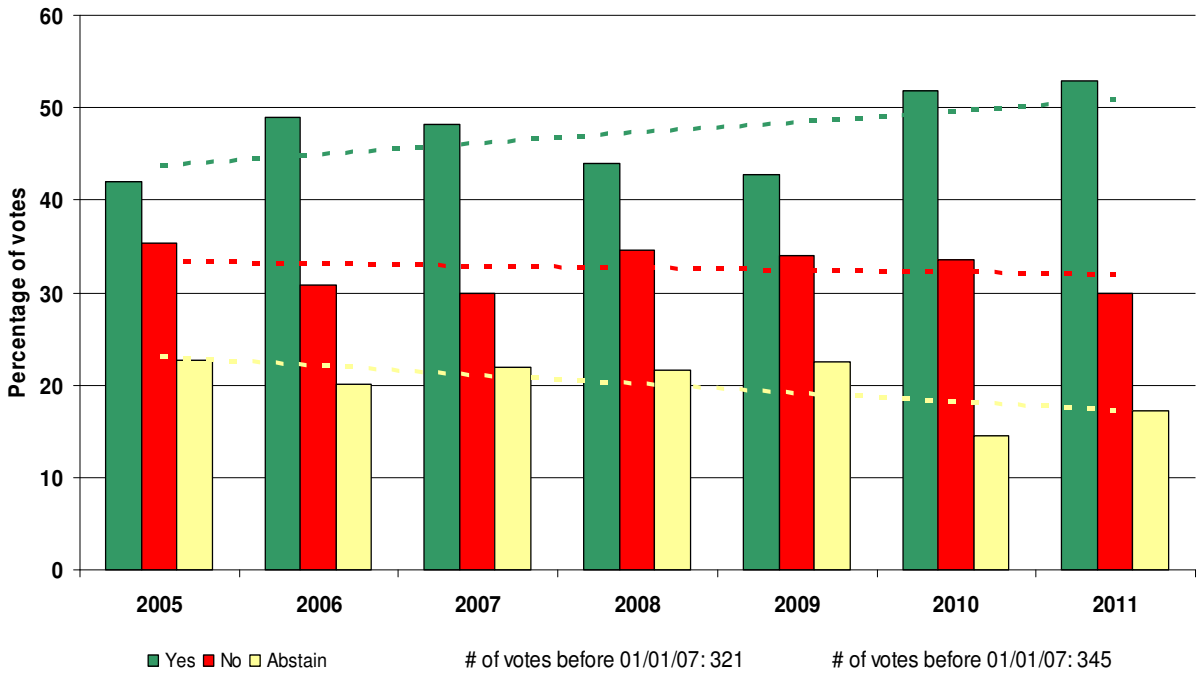
Even for products that move faster than average the number of months is more than double the legal timeframe.

Note this chart excludes renewals.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

EU authorisation voting

Member States voting behaviour since 2005

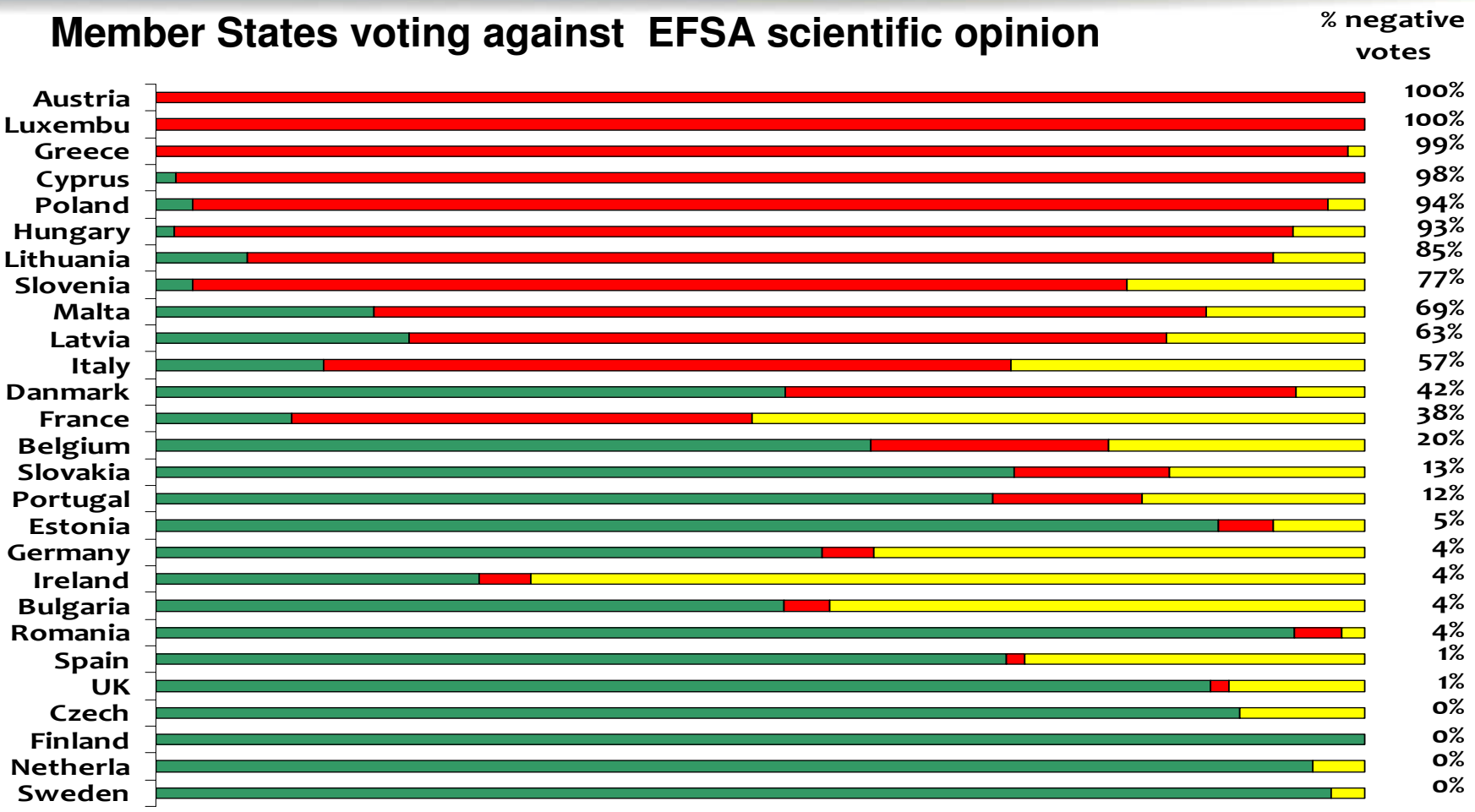


The chart shows that

- **Since 2010, over 50% of votes cast are in favour of approvals.**
- **There is a clear increase in the percentage of votes cast in favour of GMOs.**
- **The voting against GMOs and abstentions are decreasing.**

"Approvals of GMOs in the European Union". Report available from EuropaBio.

EU authorisation voting

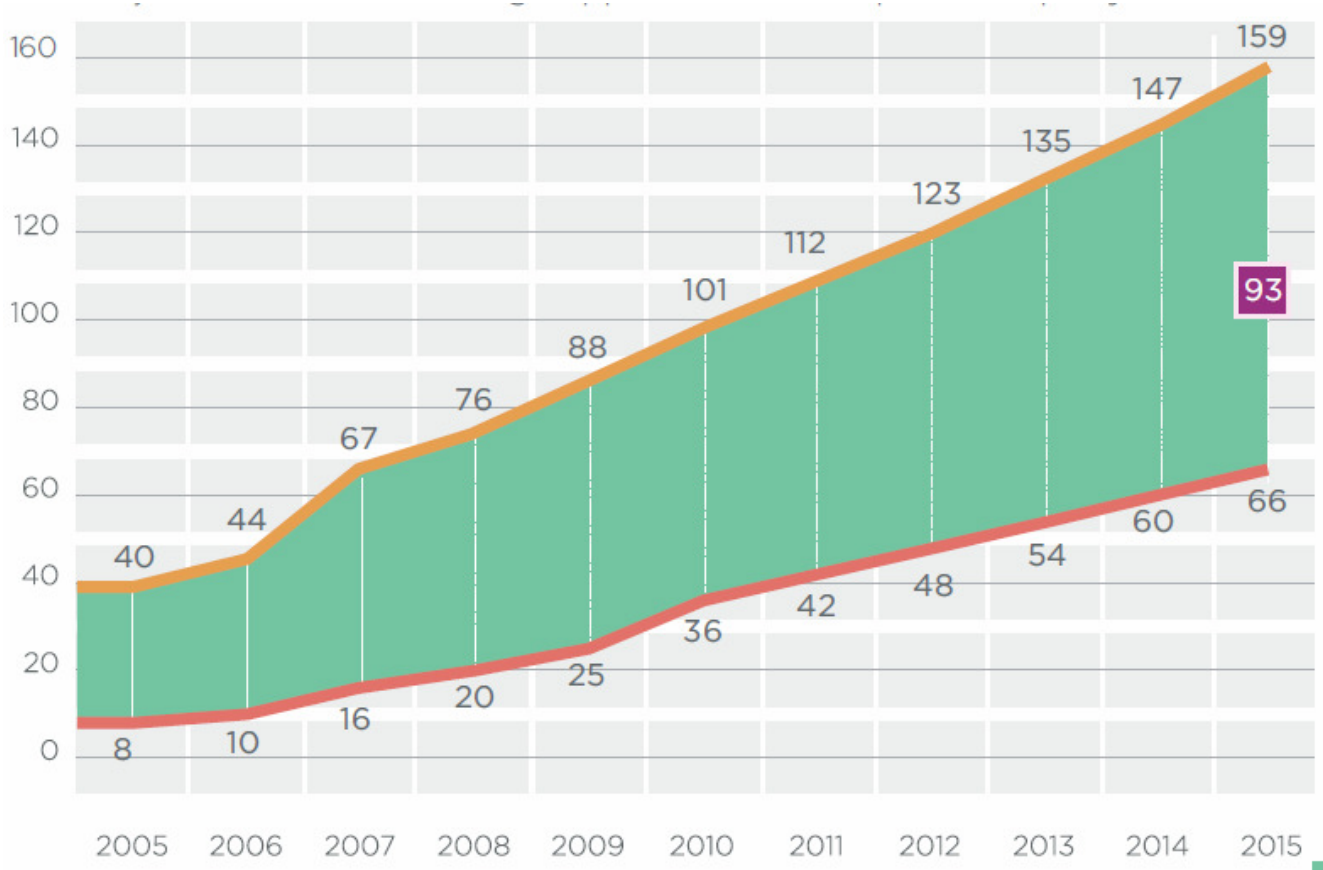


The chart shows that 10 countries vote against the EFSA scientific opinion ranging upwards of 63% of the time.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

EU authorisation system

- state of play assuming 6 approvals per year-



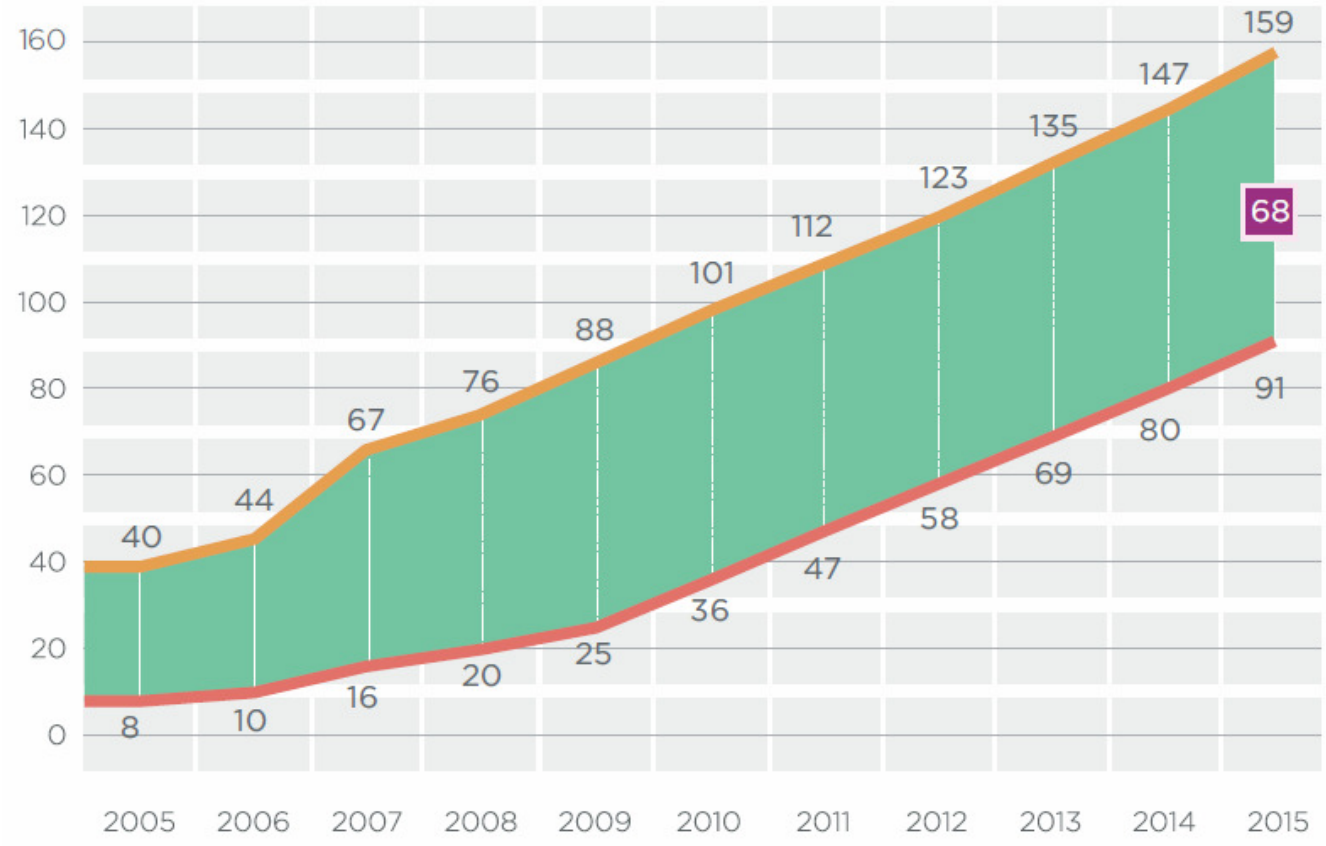
If the average annual authorisation rate of 6 products remains unchanged, there will be at least 93 products in the system by 2015.

Note:
6 products per year is the average approval rate of the last 5 years.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

EU authorisation system

- state of play assuming 11 approvals per year-



If the average annual authorisation rate is 11 products, there will be at least 68 products in the system by 2015, the same total as at the start of 2011.

Note:
11 products per year is the rate of 2010, which was a record.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Forward projection

Status to end 2010

- 101 products submitted to the EU authorisation system
- 36 products approved
- 65 products in the EU authorisation system (8 new submissions in 2011, actual total now 73)

Prediction for 2015

- 20 individual new events
- 4 renewals
- 22 stacked events
- 12 events developed for local markets, not seeking an approval in the EU

93 products in the system in 2015 (assuming average 6 approvals per year)
68 products in the system in 2015 (assuming average 11 approvals per year)

EVEN IF THE APPROVAL RATE ALMOST DOUBLES THE BACKLOG REMAINS UNCHANGED

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Impacts

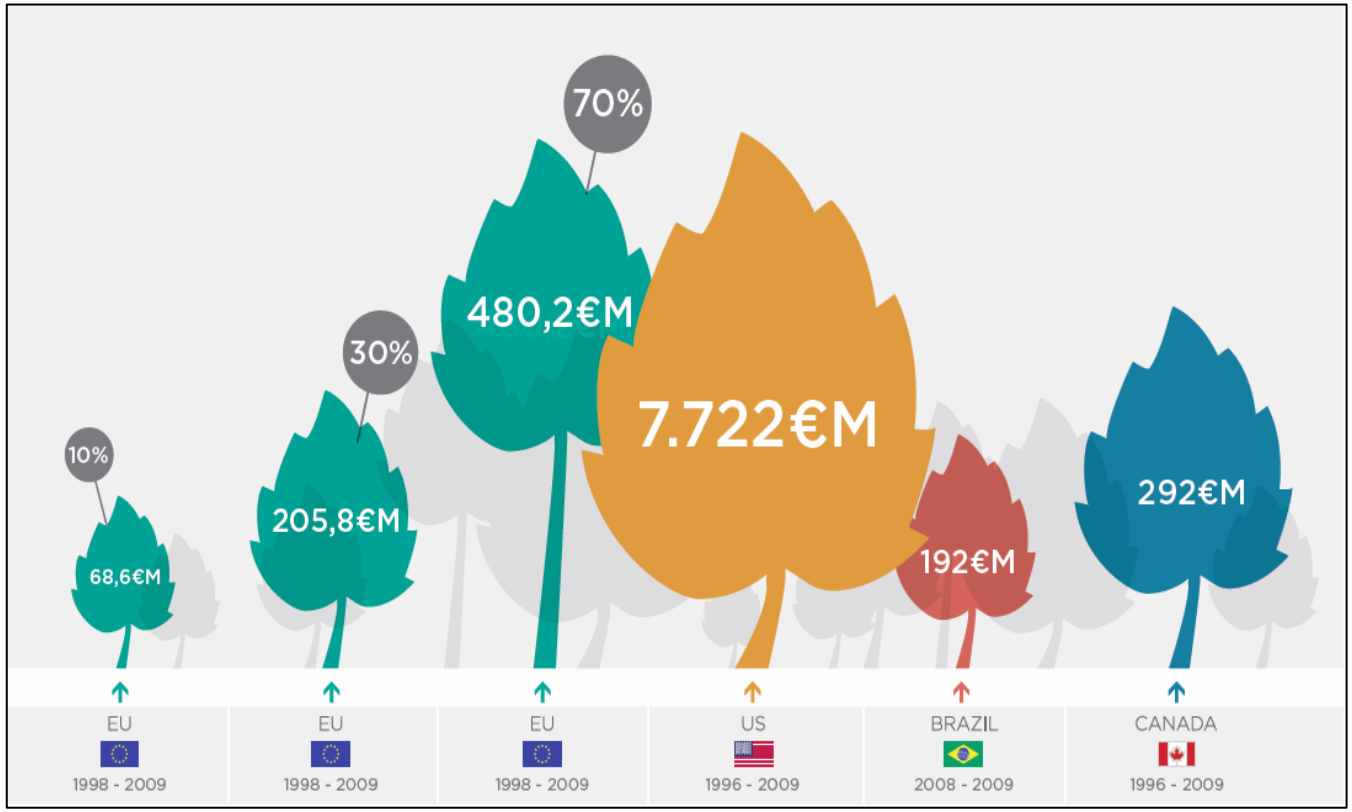
- Increasing likelihood of presence of non-authorised GMOs in imports leading to trade problems and economic costs resulting from asynchronous authorisations
- Countries exporting commodities to EU less inclined to wait for EU approvals
- European farmers suffer competitive disadvantages resulting from the authorisation delays
  - Benefits foregone due to no access to GM crops estimated at €443-€929 million yearly
  - Higher feed prices
- "Brain drain" of scientists and SMEs, as safe technologies are rejected
- Reduced consumer confidence in the safety assessment and the overall approval process

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Impacts of the EU system

- farmers in Europe -

GM crop farm income benefits in the EU under 3 scenarios



% Percentage of area where farmers would gain an economic benefit from growing GMOs

Data in this chart based on Park, J., (2011) The impact of the EU regulatory constraint of transgenic crops on farm income.

The chart shows additional farmer revenues for 4 areas due to GM crop use.

For EU farmers, the chart shows additional revenues they could have had if allowed to grow available GM crops (1998-2009).

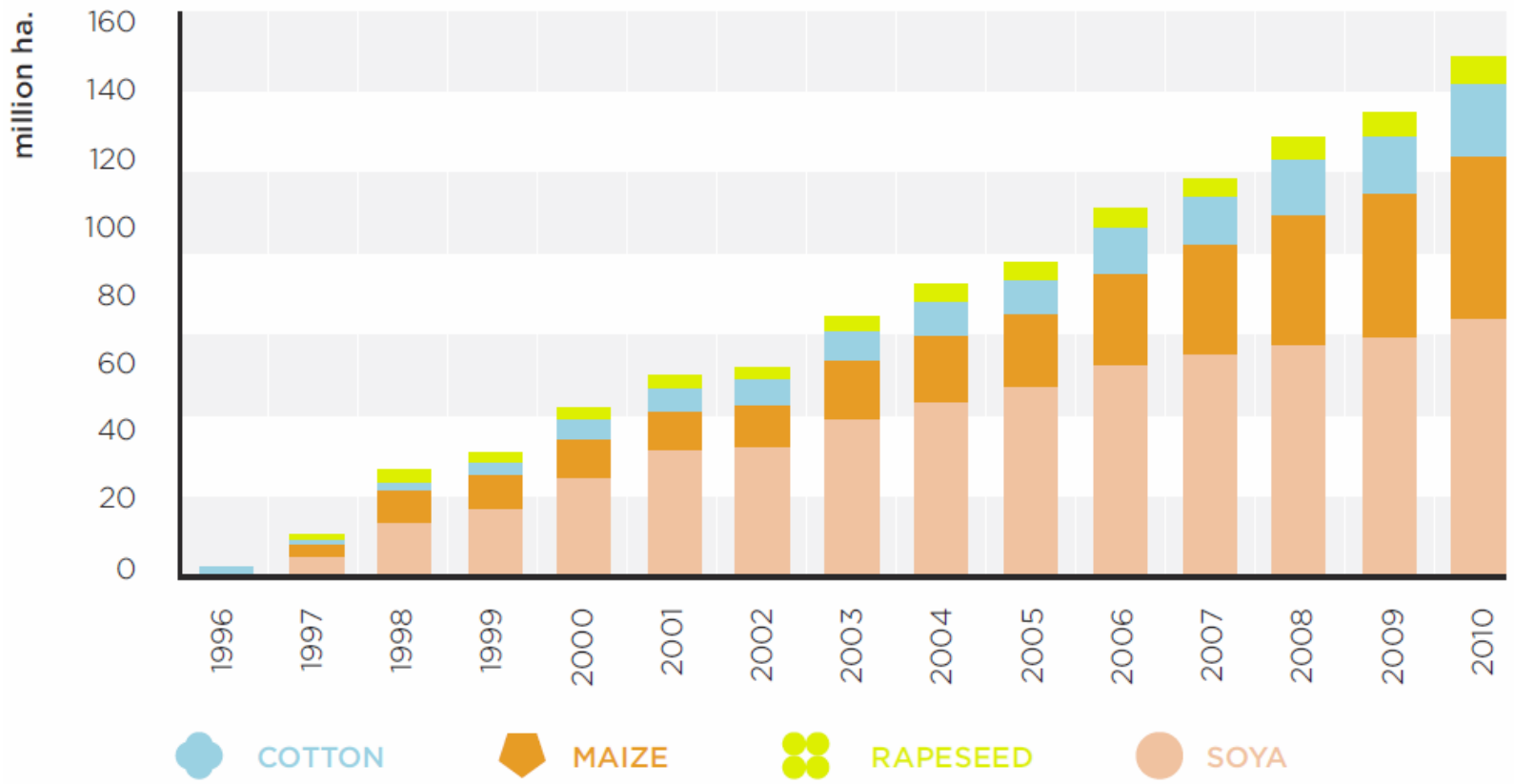
- At a 10% adoption rate they could have accrued benefits of €68 million.

- At a 30% adoption rate they could have accrued benefits of €205 million.

- At a 70% adoption rate they could have accrued benefits of €480 million.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

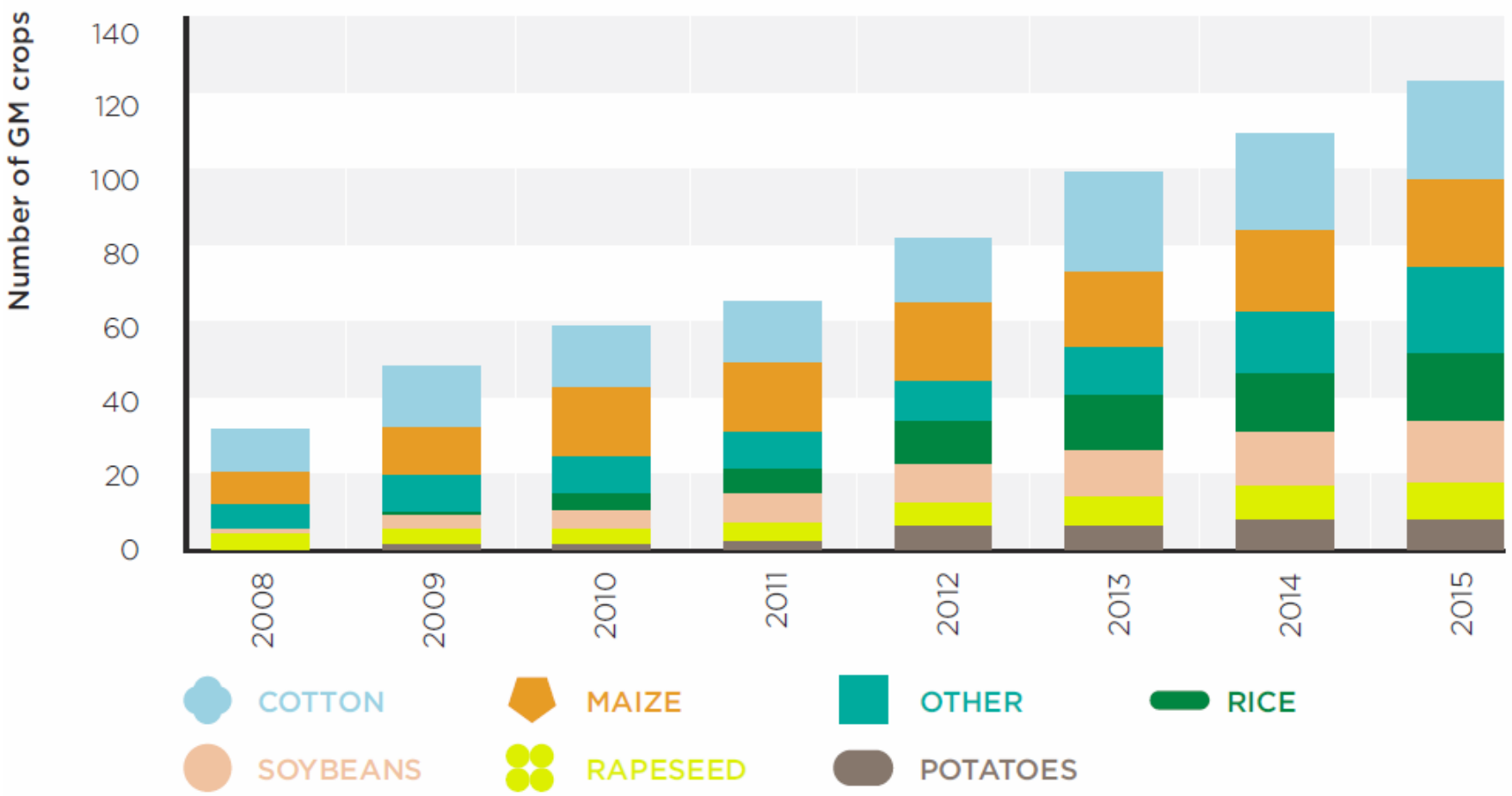
Trend: Global planting of GMOs



- Accumulated GM hectarage 1996-2010 exceeded 1 billion hectares for the first time in 2010
- 87-fold increase in hectarage between 1996 and 2010 = biotech fastest adopted crop technology
- Number of countries planting biotech crops soared to a record 29, up from 25 in 2009

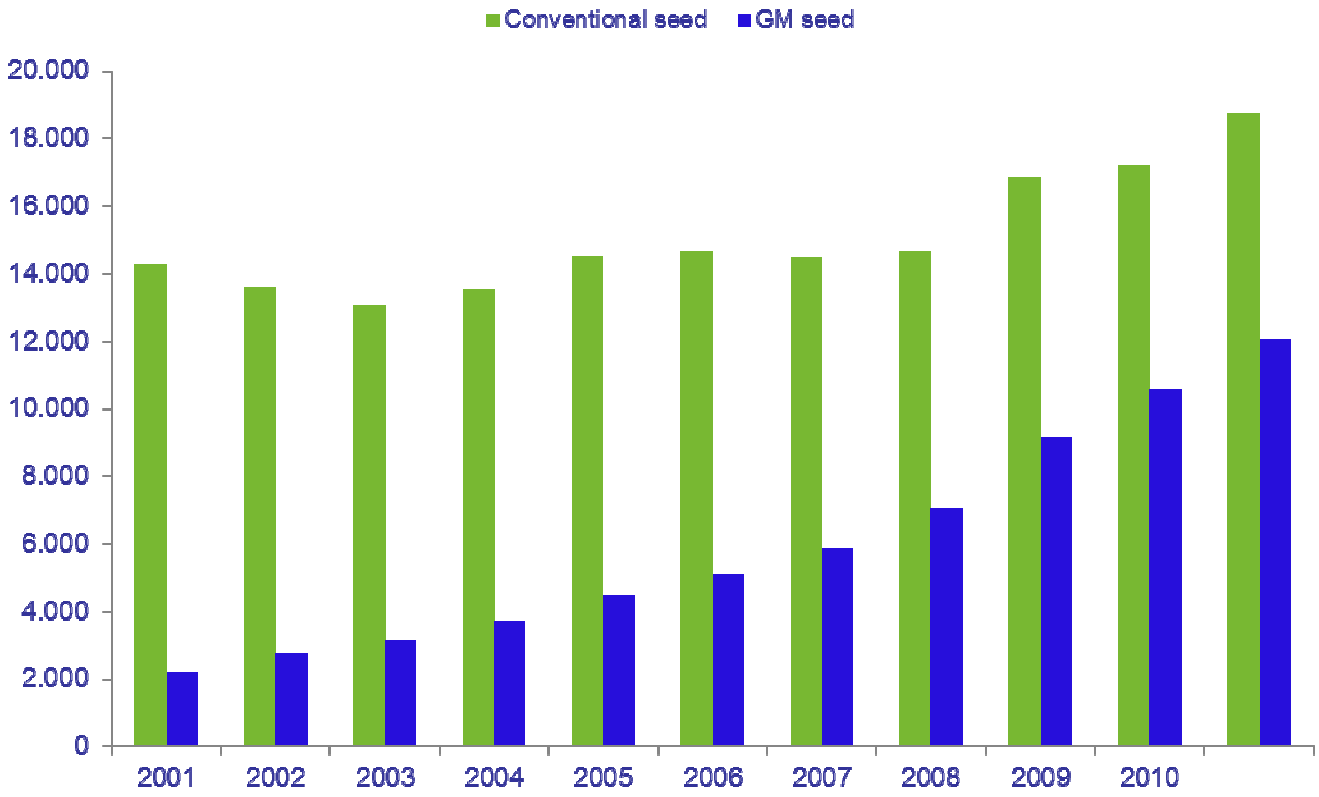
"Approvals of GMOs in the European Union". Report available from EuropaBio.

Estimate of future GM crops worldwide



"Approvals of GMOs in the European Union". Report available from EuropaBio.

Trend: GM vs. commercial seed sales

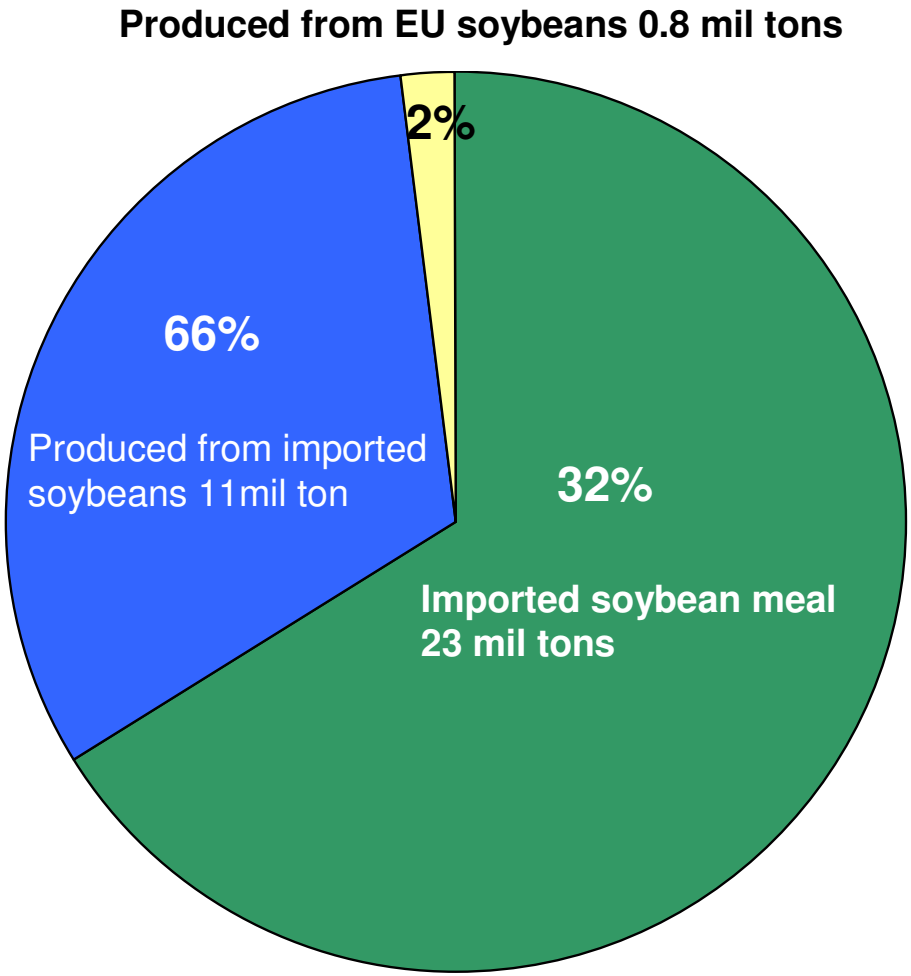


The graph shows that commercial sales of GM seeds for the main commodity is growing fast, as compares conventional seeds.

Source: Philips McDougal

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Trend: EU soybean imports vs. EU domestic production



The graph shows that only 2% of soybean consumption in the EU is produced from soybeans grown in the EU.

The remaining 98% is to be imported.

Source: USDA, ACTI

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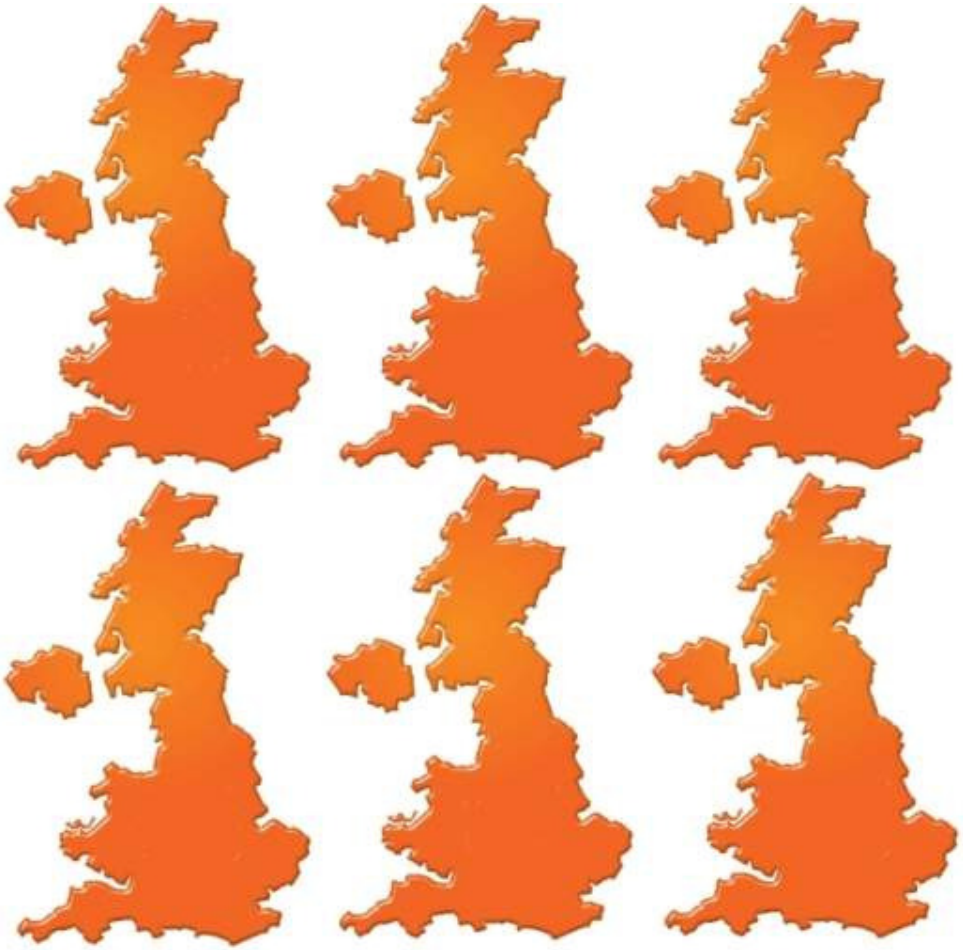
Comparison of 2010 GM cultivation Worldwide vs. EU

Global area of biotech crops

148 million ha in 2010



EU area of biotech crops

91,438 ha in 2010

Equivalent to less than the area of Greater London

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Cultivated in EU: Insect-resistant Bt maize MON 810

- Authorised in EU since 1998
- Protection against European Corn Borer
- Cultivated in: Spain, Czech Republic, Romania, Portugal, Slovakia, Poland
- Illegal bans in 7 countries: France, Germany, Hungary, Greece, Austria, Luxembourg and Bulgaria

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Room for growth in EU

- 25% of EU maize is affected by the European Corn Borer
- But only 1% of EU maize is Bt today
- There is a need for cultivation of this crop in areas affected by ECB
- More crops are available to meet other needs but are blocked/delayed in the EU approval system

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Insect-resistant Bt maize increases competitiveness

- ✓ Improved crops
- ✓ Increased yields
- ✓ Increased income
- ✓ Cost savings
- ✓ Reduction of energy use
- ✓ Controlled targeting of pests

Europe record example: Spanish Farmers ↑ yield by 10%

Worldwide 1996-2009: Farmer income ↑ $64.7 billion with significant, additional environmental benefits

Cumulative economic benefits: Developing countries (49%) > industrial 51%)

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Cultivated in EU: Amflora potato

- Starch potato for industrial use: paper and textile industry, glues, construction material
- Approved March 2010 after more than 13 years…
- First cultivation approval after 12 years in the EU
- Cultivated in 2010 in Germany, Czech Republic, Sweden
- Only amylopectin is produced instead of a mixture of amylopectin and amylose
- Added value of € 100-200 million through optimised production

"Approvals of GMOs in the European Union". Report available from EuropaBio.

GM soybeans in Romania provided economic success

- '90s less/less soybean – '99, only 120,000 ha
- '99 RR soybean introduced, glyphosate resistant
- RR soybean - 137,000 ha out of 190,000 in 2006
- Farmer advantages - 18% average yield gains
  - easy control of weeds
  - reduction in expenditures
  - higher selling price
  - safer and larger yields
- National farm $ increase '99 -'06 =$44.6 million
- RR soybean cultivated elsewhere since 2007

"Approvals of GMOs in the European Union". Report available from Europ

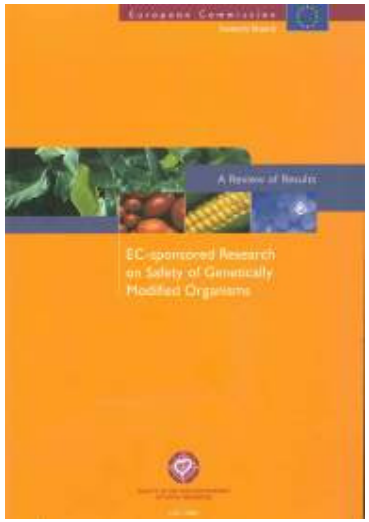
GM soybeans in Romania provided economic success

ROMANIA JOINS EU IN 01/01/2007
GM SOYBEAN IN ROMANIA DISALLOWED

- Soybean area decreased dramatically to 44,000ha after 2010
- Direct negative impact on grain production
- Lost profit at farmer level: €11 in 2007 and €19 million in 2008
- State tried to support production with €8 million in 2008
- Romania again became a net importer of soybeans
- In 2009, $137.3 million spent on imports to fulfill soy needs

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Public sector GMO Research in Europe



"EC-sponsored Research on Safety of Genetically Modified Organisms" (1985-2000)

"The use of more precise technology and the greater regulatory scrutiny probably makes GMOs *even safer than conventional plants and foods*."

"A decade of EU-funded GMO research" (2001-2010)

- **50** EU projects
- more than **400 independent research groups**
- European research grants of some **EUR 200 million**

Biotechnology, and in particular GMOs, are not *per se* more risky than e.g. conventional plant breeding technologies

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Lost income: what if EU farmers were all allowed to grow GM maize?

GM maize in the EU

In 2009, 94,850 ha of GM maize was cultivated in 6 EU countries; Spain, Czech Republic, Portugal, Slovakia, Romania and Poland

Benefits that might accrue to EU farmers adopting GM maize

- Reduction of pest damage
- Higher yields
- Input saving

Net benefit with estimated total value to EU farmers between: **€157 to €334 million each year**

Estimated increase annual income if GM maize was planted across EU

Country	From €M	To €M
Bulgaria	3.6	5.4
Czech Republic	4.6	9.2
Germany	25.7	42.4
Greece	1.2	5.9
France	34.2	85.5
Italy	40.6	108.2
Hungary	6.2	12.6
Austria	12.0	16.8
Poland	11.9	29.9
Portugal	1.4	2.4
Romania	12.1	21.5
Slovakia	3.6	5.9
Total	**€157 million**	**€334 million**

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

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Lost income: What if EU farmers were allowed to grow GM cotton?

GM cotton worldwide

- 16.7 Mha of Bt cotton grown worldwide in 2009, almos half of 33 Mha of world cotton cultivation

GM cotton in the EU

- No Bt cotton is permitted for cultivation in EU
- Greece/Spain have significant conventional cotton production

Benefits for EU farmers adopting GM cotton

- Wherever cotton is grown in the world, it is vulnerable to damage caused by bollworm *Earias insulana*

Economic advantage per ha to EU farms would be in between **€50/ha to €150/ha**.

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

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Lost income: What if EU farmers were <u>all</u> allowed to grow <u>GM soybean</u>?

GM soyabean worldwide

- 77% of the 90Mha of soybean grown globally in 2009 was transgenic

GM soyabean in the EU

- No transgenic soya now permitted for cultivation in the EU
- Conventional soyabeans are grown in 9 EU countries, with a total acreage of only 0.5 Mha

Estimated economic advantage would be between **€5 to €19 million** mostly because of input savings.

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

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Lost income: What if EU farmers were all allowed to grow GM oilseed rape?

GM oilseed rape worldwide

- HT canola cultivation in 2009 represented about 20% of the 31 Mha of rape cultivation worldwide

GM oilseed rape in the EU

- Transgenic oilseed rape is not yet approved for field scale cultivation in the EU
- About 6 Mha planted with oilseed rape in 2009

Benefits to EU farmers adopting GM oilseed rape

- GM canola offers higher gross margins than its conventional counterpart

Net benefit of between **€30 and €49/ha**. Potential annual benefits to EU farmers of between **€195 and €318 million**.

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

Lost income: What if EU farmers were <u>all</u> allowed to grow <u>GM sugarbeet?</u>

GM sugarbeet worldwide

❖ HT sugarbeet recently introduced in US/Canada to help farmers deal with weed pressure

GM sugarbeet in the EU

❖ GM sugarbeet is not yet approved for cultivation in the EU

❖ In 2008, 101 Mt of conventional sugar beet was produced from 1.46 Mha of cultivation

Benefits to EU farmers adopting GM sugarbeet

❖ Savings from adoption of HT sugar beet are likely to be in the range €50-€150/ha

Annual economic benefit for growers over the current 1.46 Mha would be in between **€73 and €219 million.**

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

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Estimated benefits to EU of adoption of GM 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[a]	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
Total					443	929

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

Benefit to EU farmers if they were allowed to grow available GM crops is estimated at

€443 and €929 million each year.

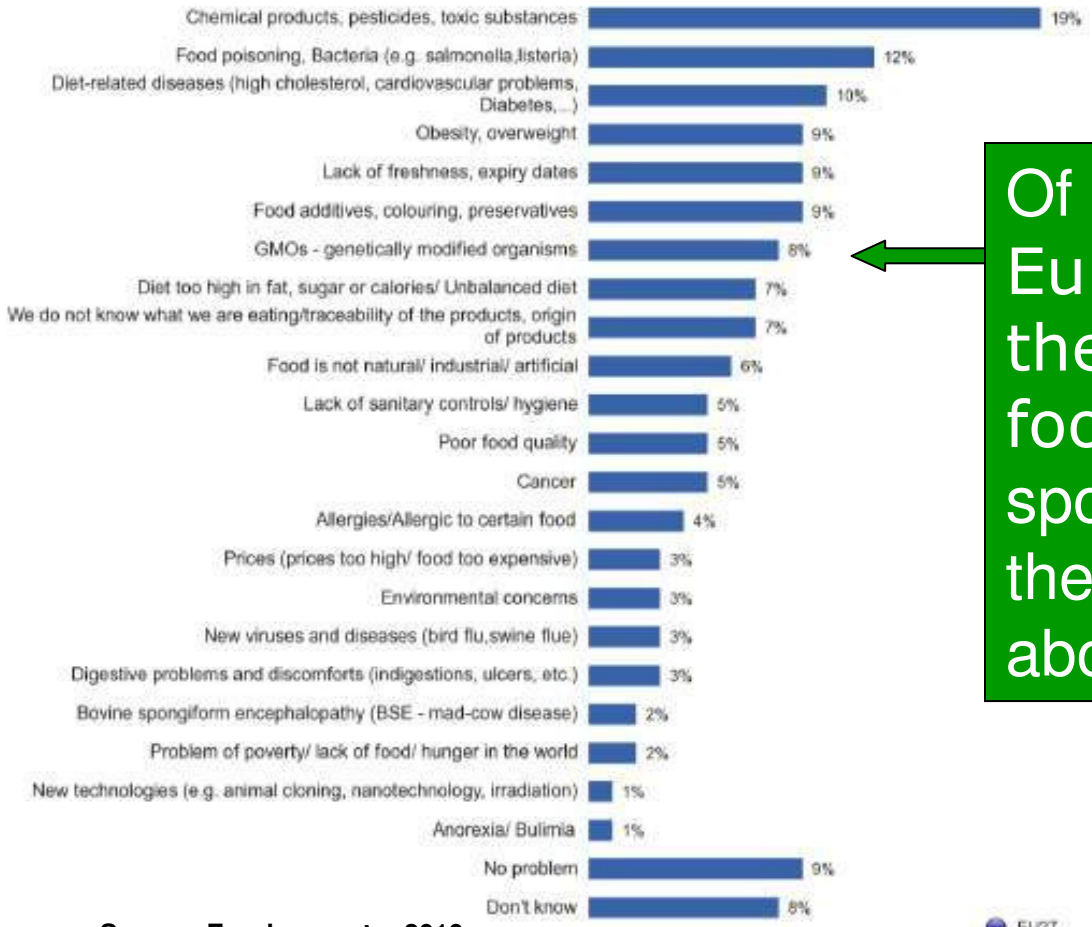
Source: The impact of the EU regulatory constraint of transgenic crops on farm income; Julian Park, Ian McFarlane, Richard Phippsand Graziano Ceddia, New Biotechnology; March 2011

"Approvals of GMOs in the European Union". Report available from EuropaBio.

2010 Consumer opinion about food according to EC

Graph: 2.1 – Spontaneous responses to problems and risks associated with food

QF3. Could you tell me in your own words, what are all the things that come to your mind when thinking about possible problems or risks associated with food and eating? Just say out loud whatever comes to mind and I will write it down. Anything else?

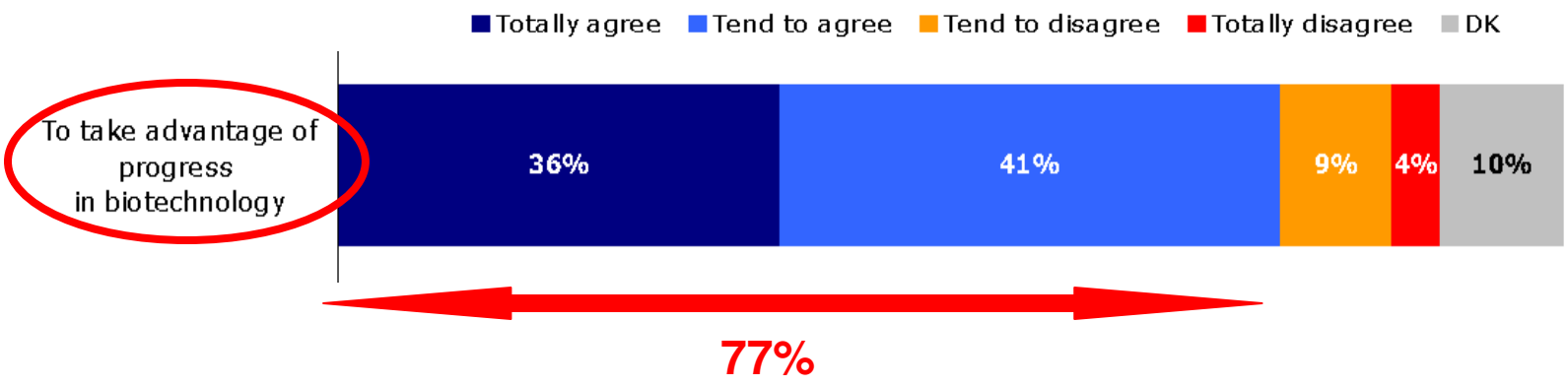


Of all the worries Europeans say they have about food, **only 8%** spontaneously say they are worried about GM in food

Source: Eurobarometer 2010

2010 Biotechnology and Public Perception according to EC

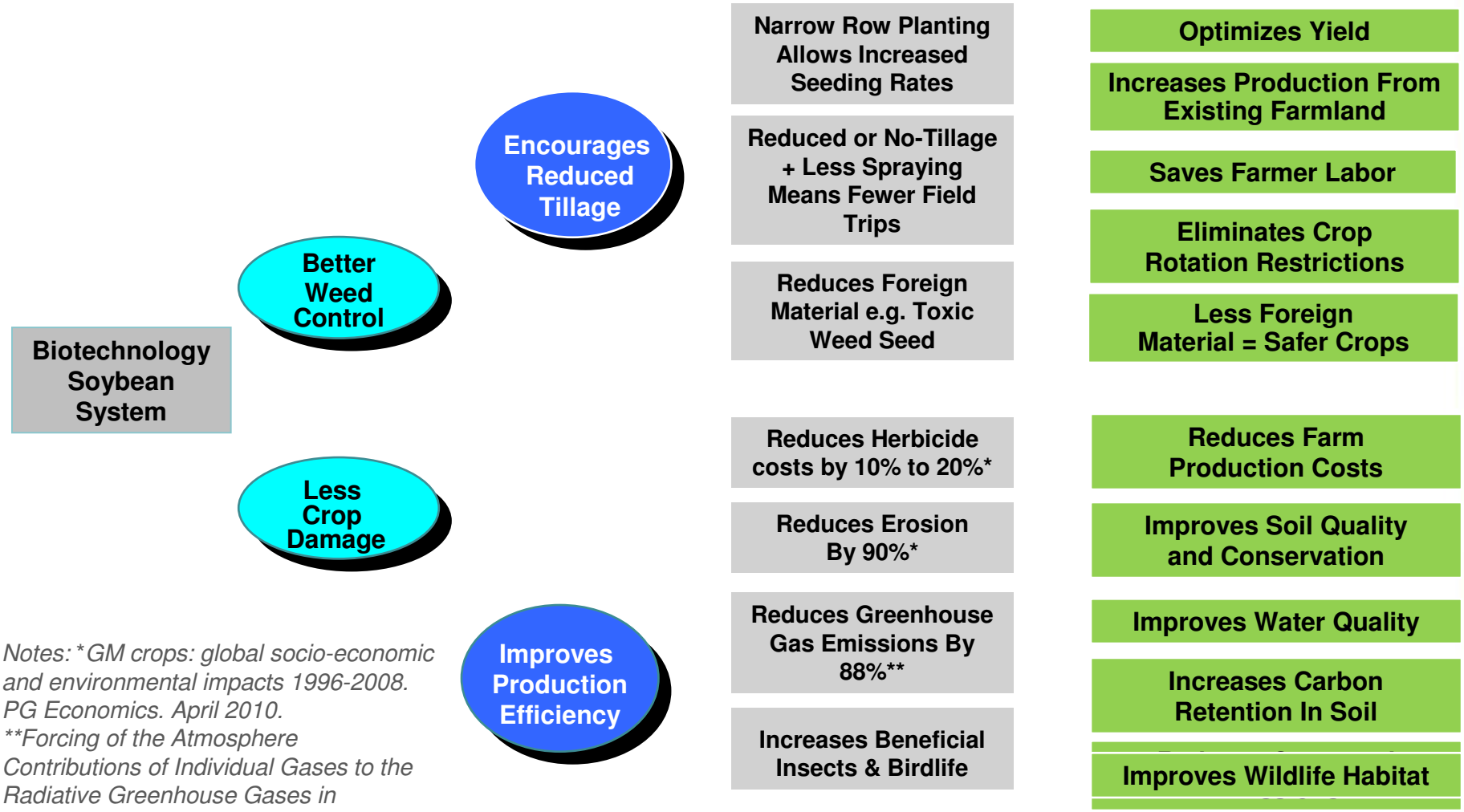
QB11 Please tell me whether you agree or disagree with each of the following statements regarding farmers in the European Union : The European Union should encourage its farmers...
- EU



77% of EU citizens are in favour of taking advantage of biotechnology in agriculture

Source: Eurobarometer 336 (2010) Europeans, Agriculture and the Common Agricultural Policy

Why farmers grow biotech soybeans



*Notes: *GM crops: global socio-economic and environmental impacts 1996-2008. PG Economics. April 2010.*
***Forcing of the Atmosphere Contributions of Individual Gases to the Radiative Greenhouse Gases in Intensive Agriculture.. Science 289:1922 (2000).*

Source: David Green, Greenhouse Communications, Virginia. And Economist magazine 2011.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Farmers get yield gains from GM

Spain

- 13 years of BT corn experience
- cumulative 535,000 hectares
- yield increases between 6-10%
- up to € 122 more per hectare
- 2/3 benefits for farmers/ consumers

EU Commission JRC Report

Source: Anove, JRC

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Environmental gains from GM

Preserved biodiversity

- higher yields = less conversion of natural land to crop production
- if no longer access to biotech = 12.4 m ha extra area to offset yield loses
- studies indicate GM crops have not decreased crop diversity

Reduced soil erosion

- biotech crops = little or no-till practices
- conserve soil moisture/reduce erosion

Lower CO2 emissions

- in 2009 GM crops facilitated 17.7 billion kg reduction of CO2 emissions = removing 7.8 million cars from the roads for 1 year

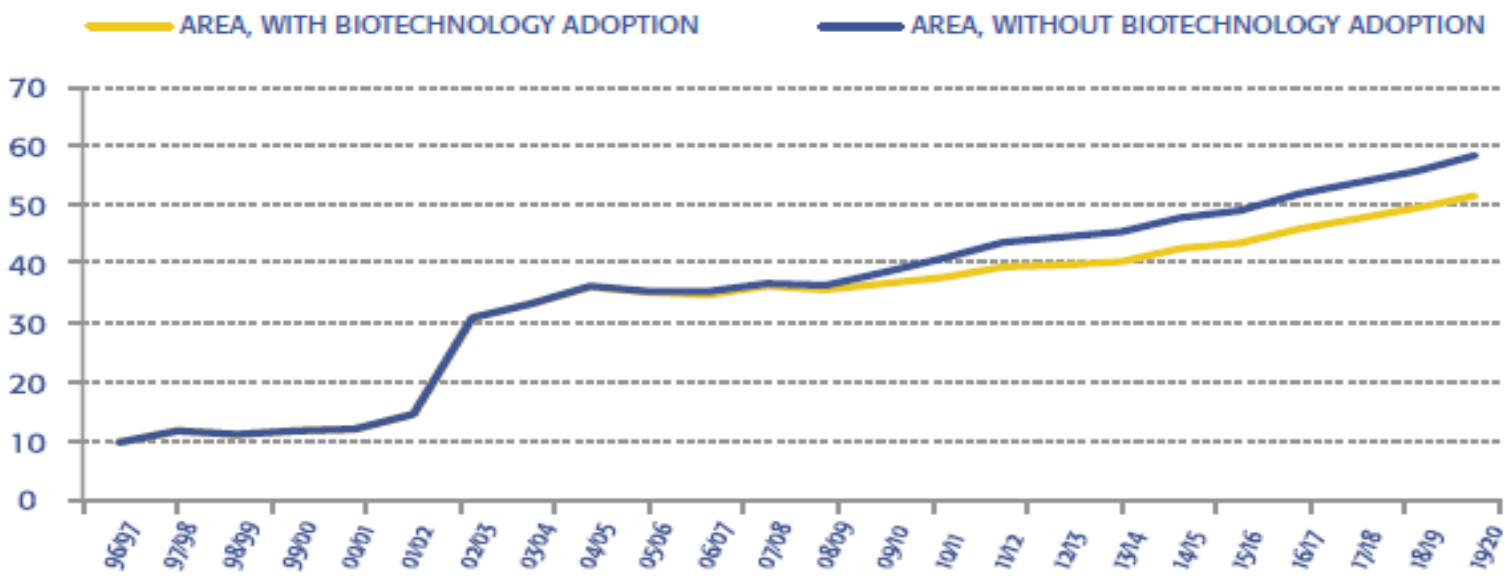
Reduced input use

- more targeted or reduced pesticide spraying

Sources: Brookes, G. and P. Barfoot. 2011 Forthcoming
"Impacts of GM crops on biodiversity" , Janet E. Carpenter, Magazine *GM Crops*.

GM crops save land

Increase in planted area, with the non-adoption of agricultural biotechnology

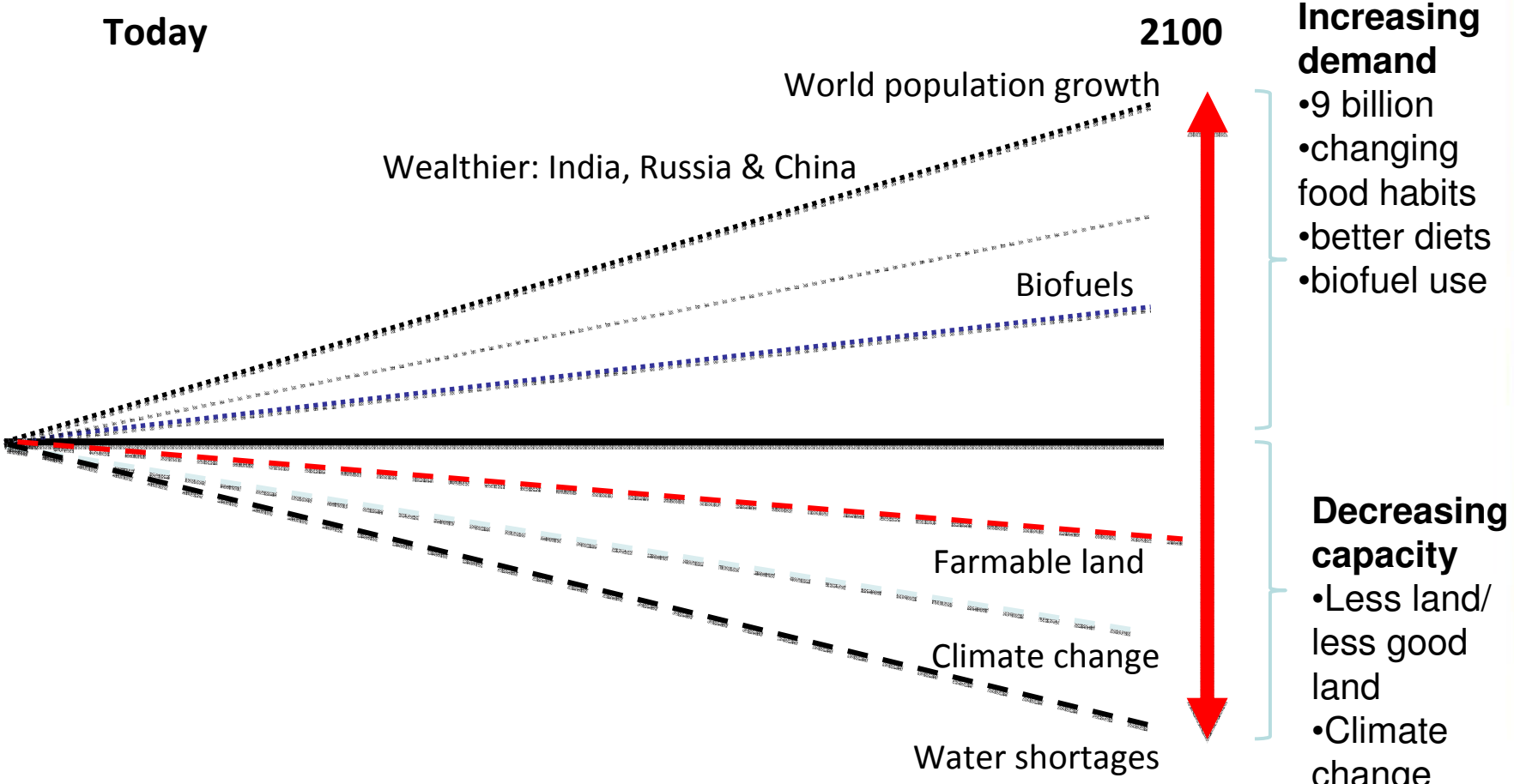


Source: CÉLERES®. Figures in millions of hectares.

http://www.celeres.com.br/1/english/RelBiotechBenefits2010_Ambiental_vf1_Eng.pdf

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Meeting new global demands



Source: David Green, Greenhouse Communications, Virginia. And Economist magazine 2011.

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Where is GM moving?

Who are the new developers?

- Rise of China, India and Brazil (and other emerging nations)
- New developers: public institutions and PP partnerships

Technologically

- First generation: Insect resistance and herbicide tolerance
- Next : nutritional value, stress tolerance, disease resistance
- New crops: emphasis on crops for developing world
- New traits: climate change mitigation and adaptation
- New techniques

New products

- Wheat, rice, potato
- Cassava, cowpea
- Sugar cane, sugar beet
- Many vegetable species

"Approvals of GMOs in the European Union". Report available from EuropaBio.

GM crops under development

Traits

- Tolerance to biotic and abiotic stresses (cold-, drought-, salt-tolerance)
- Insect resistance
- Herbicide tolerance
- Nitrogen use efficiency
- Yield increase
- Fertility control
- Improved grain quality
- Modifications in oil, sugar, starch content
- Protein quality and amino acid composition
- Vitamin content
- Nutritional quality
- Flavor and postharvest quality
- Reduced allergenicity
- Grain processing
- Amylase for ethanol production

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Three interesting GM crops for Europe

GM potato resistant to late blight

- Late blight most important potato diseases (20% losses)
- Resistance genes transferred from South-American wild potato
- Could save pesticide use

Drought-tolerant GM maize

- 1st and 2nd generation drought-tolerant crops under development
- Mitigates environmental impact to maximize yield with reduced water
- Relevant for water poor areas in southern Europe

GM HT sugarbeet

- High potential for European farmers
- Conventional crop has high weed controls costs
- Sugar beet is grown in all the EU countries
- EU farmers would substantially gain from adoption: €194 million

Status: Submitted in EU in 2008, cultivated in NA since 2008

"Approvals of GMOs in the European Union". Report available from EuropaBio.

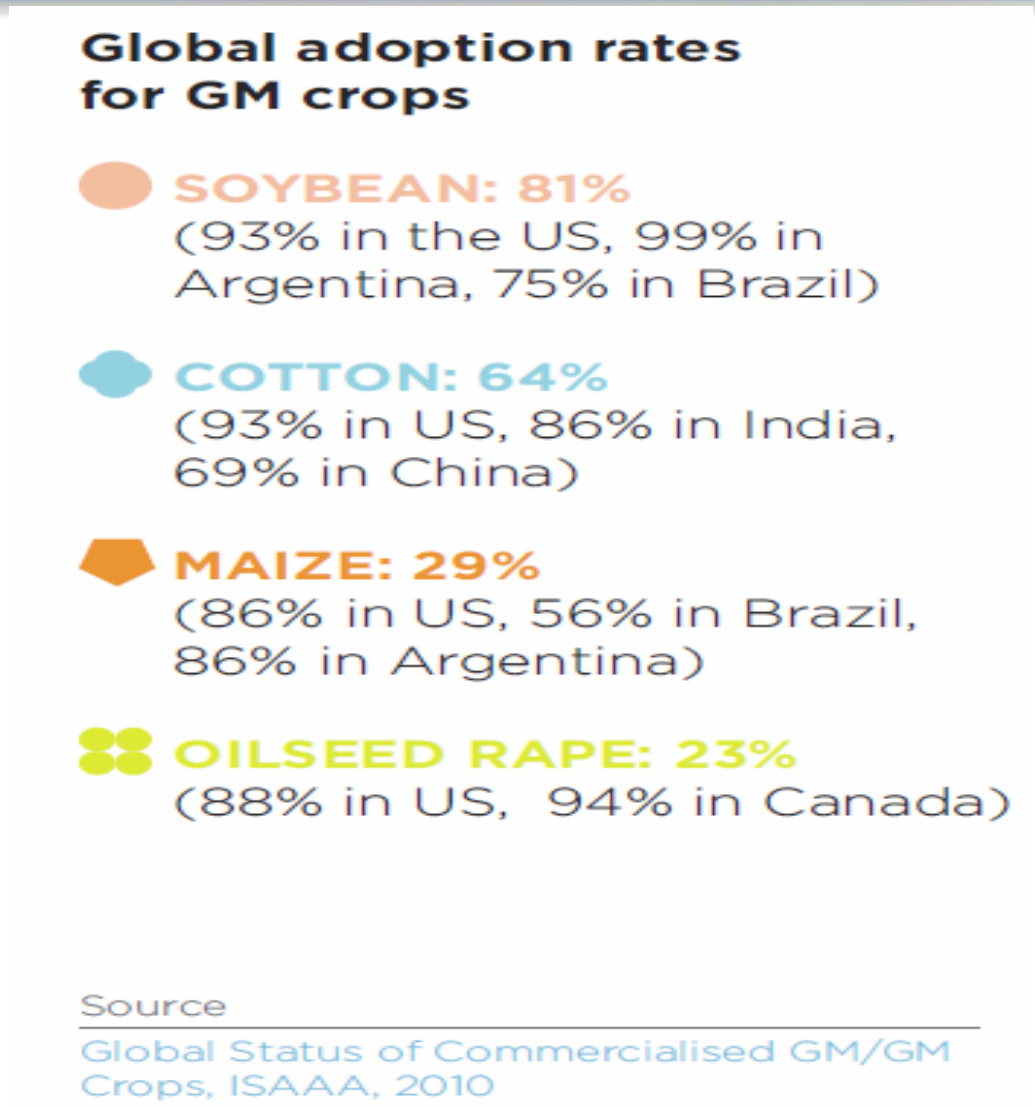
Conclusions

- **Biotechnology is improving world agriculture**
  - 15.4 million farmers globally – more than all EU farmers
  - 10% growth rate - fastest adopted agricultural technology ….accelerating
  - Widely accepted social, economic and environmental benefits
  - Cited as "*one of the tools*" to increase global food, feed, fiber production
- **GM has a positive and unparalleled safety record**
- **More regulatory coordination needed at international level**
- **EU adoption is slower due to heavy EU regulatory burden/consumer fears**
- **Increased global investments in agbiotech, both science & technology**
- **A functional regulatory system should be:**

Science-based and risk-focused	**Transparent**
Clear in criteria for decision-making	**Proportionate**
Predictable in terms of timelines	**Encouraging innovation**

"Approvals of GMOs in the European Union". Report available from EuropaBio.

Global adoption rates 2010

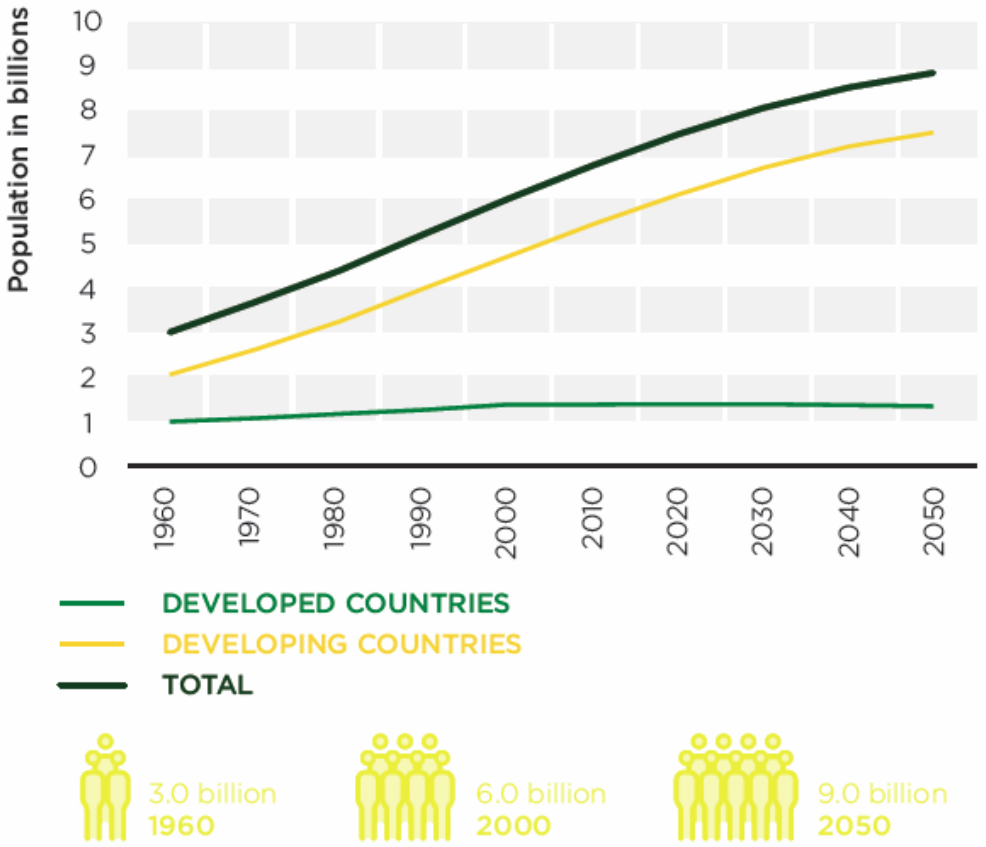


"Approvals of GMOs in the European Union". Report available from EuropaBio.

The global picture:
We face increasing demand for the world's finite resources

Population growth
From 1960 to 2007, the global population grew from 3 billion to over 6.5 billion. Projections for future growth take that number to nearly 9 billion in 2050. The UN Food and Agriculture Organisation (FAO) estimates that **food production must increase by 70%** if we are to feed the world population.

Population growth, actual and projected 1960 - 2050

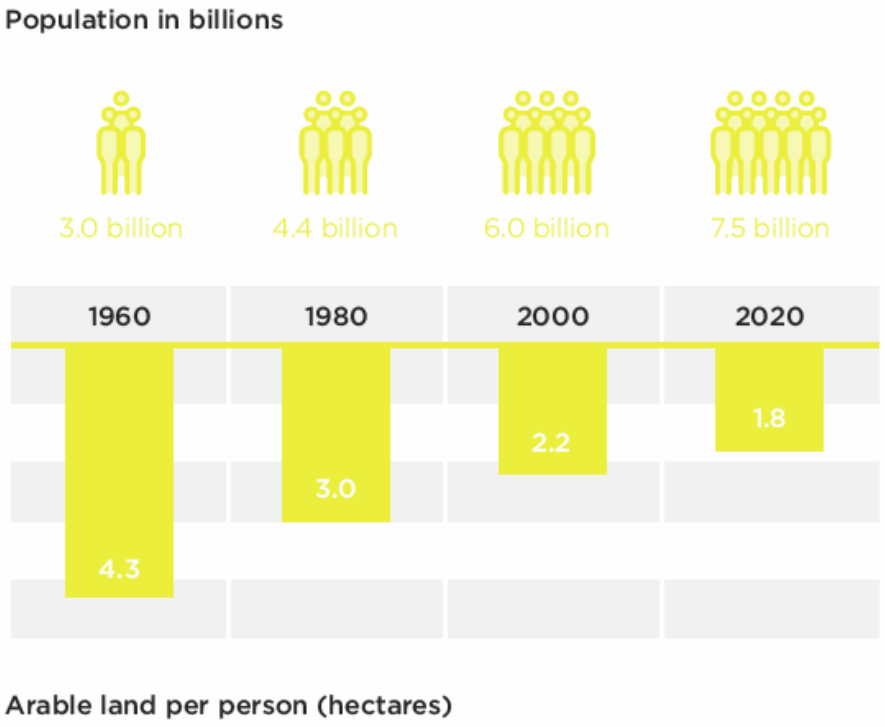


"Approvals of GMOs in the European Union". Report available from EuropaBio.

Arable land
Around the world, the ratio of arable land to population is steadily declining. Between 1960 and 2000, it declined by about 40%, but in developing nations the decline has been fastest. In Africa, for example, the ratio of arable land to population declined by 55% in the same period.

This means more food will need to be produced on less land to provide enough food without harming the environment.

More food must be produced on less land (FAOSTAT)



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