



EuropaBio[®]

The European Association for Bioindustries

Facts not fiction

Budapest, 17 April 2015



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Facts not Fiction

1. GMO-free agriculture in Europe?
2. Safety concerns?
3. The EU's approval process for GMOs
4. Nationalisation
5. EuropaBio's position

Three sectors:

Industrial biotechnology / White : Industrial processes

Healthcare biotechnology / Red : Pharmaceutical products

Plant biotechnology / Green : Agriculture/ seeds

- 55 corporate members (Healthcare + Industrial + Agbiotech)
- 15 associate members and Bioregions
- 17 national biotech associations = +1800 biotech SMEs

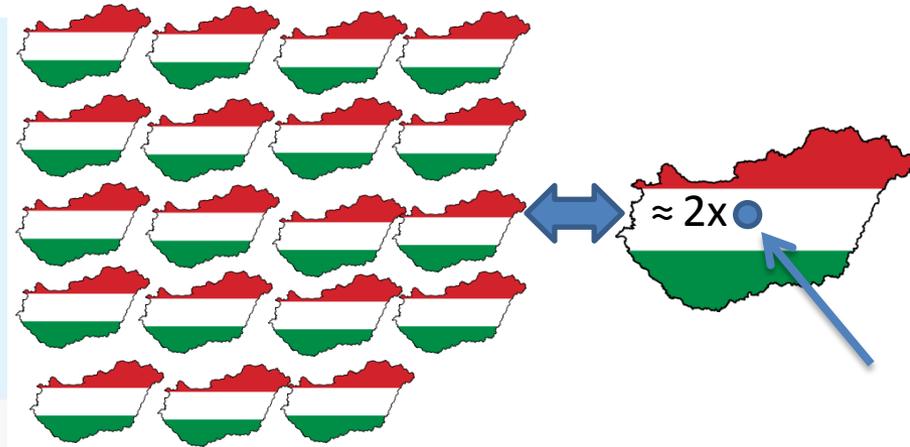
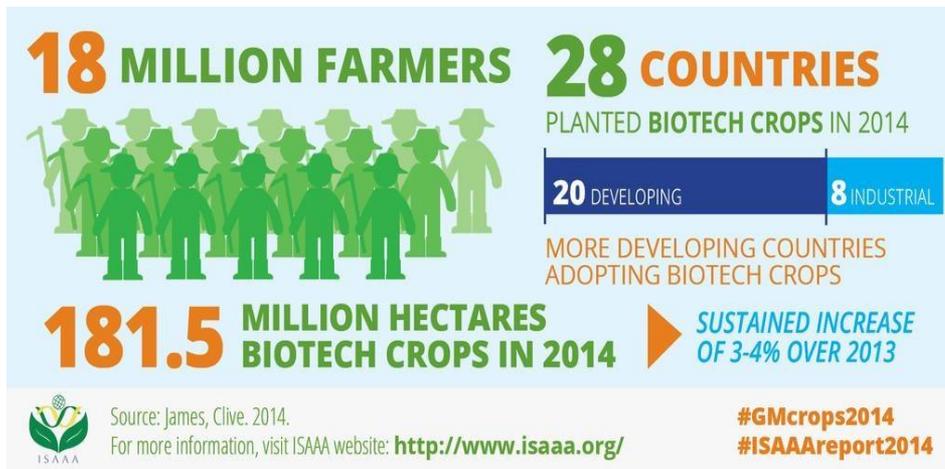
9 Green biotech member companies



1. GMO-free Agriculture in Europe?

EU Agriculture consumes huge amounts of imported GMOs

- Ca. 35 m tons of soya beans and soya meal per year = as heavy as all EU citizens
- EU livestock farming depends on GM soy imports



GM farming globally bigger than EU farming

- More farmers than all EU farmers
- Global GM cultivation = ca. 15 % of global, and larger than the EU arable land
- 19 X Hungary landmass (EU GM cultivation \approx twice the size of Budapest)

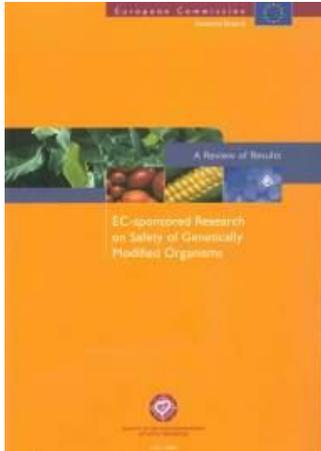
1. GMO-free Agriculture in Europe?

ALL EU Member States import (GM) soya beans

(sources: Oil World, FAOstat)

- **More than 60kg per EU citizen per year on average**
- **Selected Member States regularly voting against the science:**
Hungary 60 kg/capita; Poland almost 52 kg/capita, Greece over 45 kg/capita, Slovenia 300 kg/capita, Cyprus 81 kg/capita
- **Selected Member states regularly voting in favour of science:**
The Netherlands 470 kg/capita, Spain 112 kg/capita, Portugal 86 kg/capita
- **Selected Member States with unstable voting / abstentions:**
Germany 79 kg/capita, France 59 kg/capita, Denmark over 285 kg/capita, Belgium/Luxemburg 128 kg/capita

2. Safety Concerns about GMOs?



EU Commission: “EU Commission-sponsored Research on Safety of GMOs” (1985-2000): “*The use of more precise technology and the greater regulatory scrutiny probably makes GMOs even safer than conventional plants and foods.*”

European Academies of Science (EASAC) : “Planting the future (...), 2013”: “*The scientific literature shows no compelling evidence to associate such crops (...) with risks to the environment or with safety hazards for food and animal feed greater than might be expected from conventionally bred varieties of the same crop.*”



EU Commission: “A decade of EU-funded GMO research” (2001-2010). 50 EU projects, more than 400 independent research groups, EU research grants of some EUR 300 million. “*Biotechnology, and in particular GMOs, are not per se more risky than conventional plant breeding technologies*”

3. The EU's approval process for GMOs

ON PAPER

- EU legislation: strict but workable pre market approval system, based on safety
- Based on democratically agreed EU law with full European Parliament and Member State participation
- Same democratically agreed procedure (“comitology”) as all other EU product approval systems
- Science is clear (GMOs at least as safe as conventional crops)

Submission application



EFSA Risk Assessment



Commission Proposal



Member State voting



Authorisation



Post-release Monitoring

3. The EU's approval process for GMOs

IN PRACTICE

- **Imports: System currently dysfunctional**
 - Approvals interrupted since November 2013
 - Undue delays are the rule
 - Trade disruptions imminent
 - Uncertainty affects conventional supplies
 - 47 GM products approved for food/ feed/ import
 - 59 are pending in the system, of these, the 18 post EFSA dossiers have been pending 6.5 years on average
- **Cultivation: System constantly dysfunctional**
 - Member State approval votes illegally prevented
 - scientifically untenable and legally questionable/ illegal national bans
 - cultivation largely prevented
 - 1 GM product currently approved for cultivation (insect resistant maize MON 810)

Submission application



EFSA Risk Assessment



Commission Proposal



Member State voting



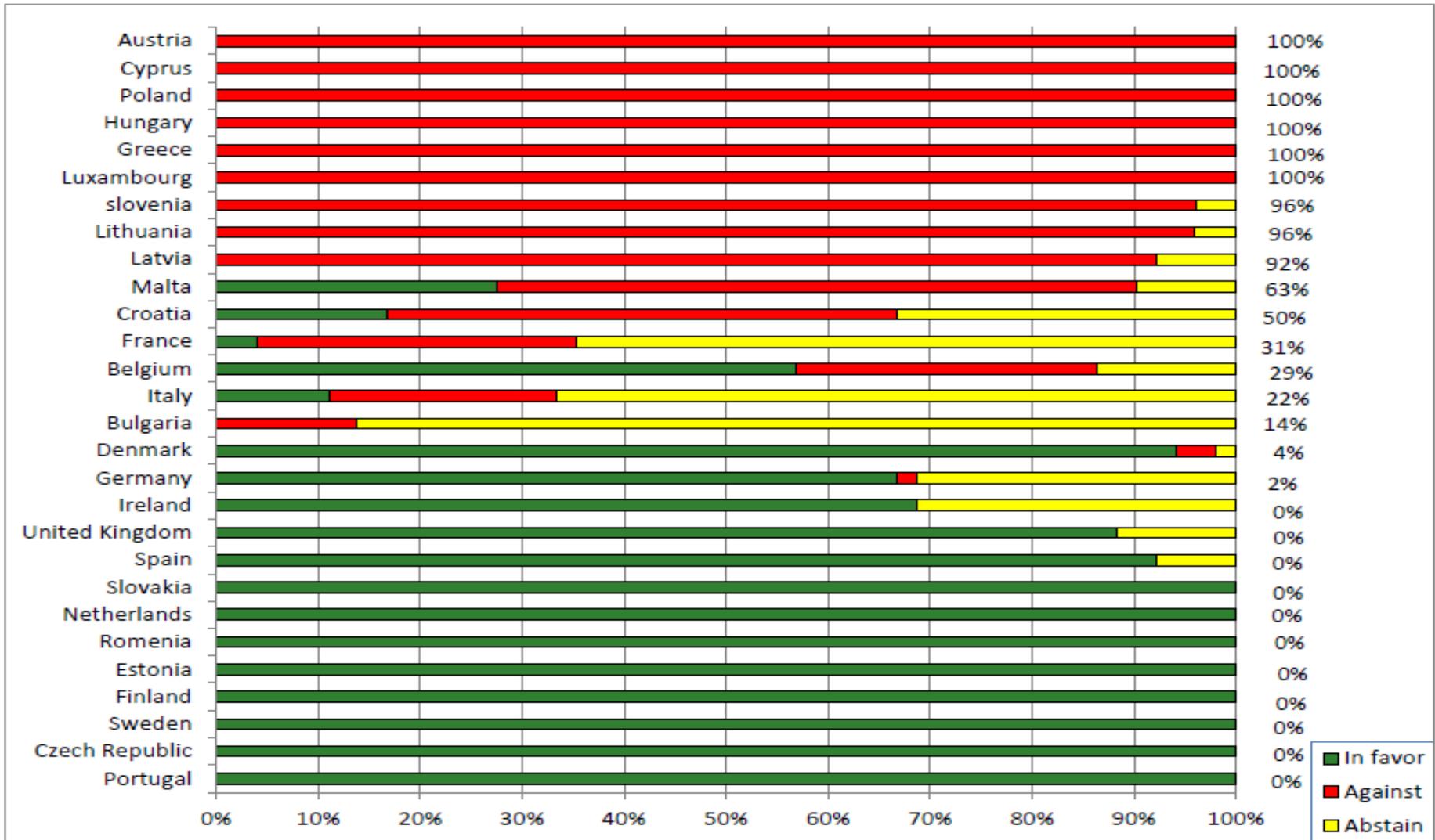
Authorisation



Post-release Monitoring

3. The EU's approval process for GMOs

Countries voting against the evidence (2004-14)



4. Nationalisation

Non-Cultivation Legislation

- Allows Member States to “opt out” of cultivation of EU approved products
- Entered into force early April 2015
- **Does NOT change the authorisation system at EU level**
- **No sign yet of any de-blockage** of the illegally stopped authorisation system.
- The adopted grounds for national “opt outs” are legally questionable as confirmed by the legal assessments from all EU institutions:
 - *EP Legal service: “the practical application of the proposal seems to be rather narrow in view of the limited possibilities for Member states to take restrictive measures”*
 - *Council Legal service: “..there would be strong doubts about the compatibility with the Treaties or with the GATT of any measures the Member States might adopt”*
 - *Commission Legal Service: “it cannot be concluded in abstracto and in a prioristic manner that there are strong doubts that **any** measures to be adopted by the Member States on the basis of the proposal would be compatible with the Treaty and the GATT.” (emphasis added)*

5. EuropaBio position

a) Non-Cultivation

- EuropaBio Press Release June 2014: André Goig, Chair of EuropaBio:
“dangerous precedent and sends a negative signal for innovative industries considering whether or not to operate in Europe”
- EuropaBio Press Release December 2014:
“Non Cultivation Agreement on Genetically Modified Crops Undermines Innovation and the Single Market”
- EuropaBio Press Release January 2015: Jeff Rowe, Chair of EuropaBio Agri-Food Council:
“This is a stop sign for innovation in Europe”
- EuropaBio Press Release March 2015: Beat Spath:
“It enables Member States to formally reject safe EU approved products, based on arbitrary and non-scientific reasons.”
- EuropaBio Online Statement 2010:
“These measures will disable rather than enable those that wish to grow safe, beneficial and rigorously scientifically tested GM crops within the EU. (...) Creates a precedent that would imply that other sectors, and other nations, could use non-scientific reasons.”

5. EuropaBio position

a) Non-Cultivation (continued)

- Takes away even more legal certainty for farmers and applicants
- Regarding geographical scoping of applications before their authorisation:
 - this was legally possible before, but now explicit procedure
 - EuropaBio cannot speak for on individual product applications
 - But: we have always said that our member companies are open to dialogue with individual Member States, on a product-specific basis, **If it helps to unblock the system.**

b) Possible nationalisation of imports

Press Release April 2015: “*EU food and feed chain partners reject EU Commission move to undermine the Internal Market for Agri-food products*”

Any questions?



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