# Evolution of EU Regulatory Framework of GM Crops/Food

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# Why the EU Matters

FT
FINANCIAL TIMES

Sometimes voluntarily, sometimes through gritted teeth and sometimes without even knowing, countries around the world are importing the EU's rules..... As much as some loathe it, it is a trend that business leaders and policymakers from Tokyo to Washington feel they cannot afford to ignore.

*Financial Times*

*July 9, 2007*

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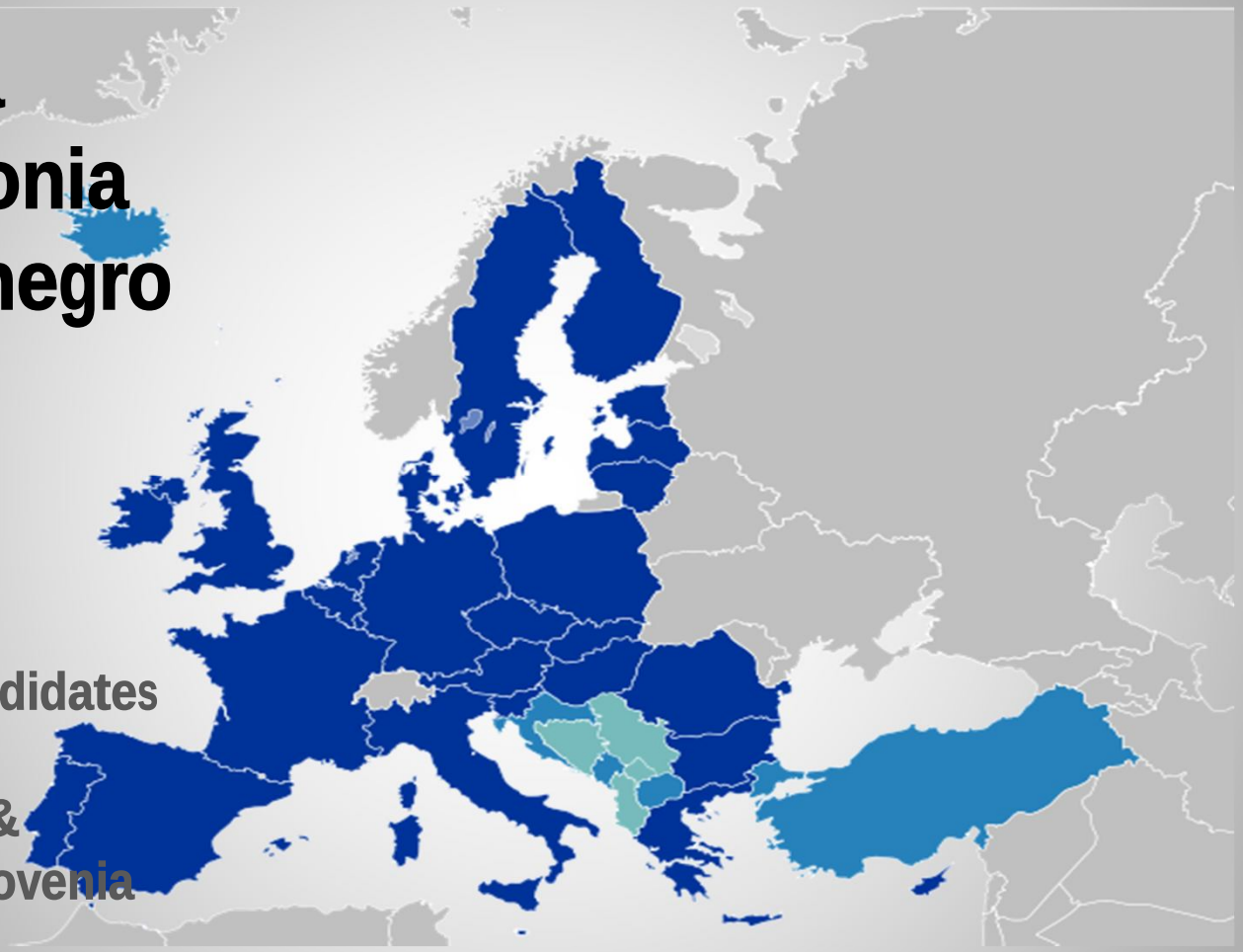
# EU 28 + five candidate countries

- **Albania**
- **Macedonia**
- **Montenegro**
- **Serbia**
- **Turkey**



- **Potential candidates**
  - **Kosovo**
  - **Bosnia& Herzogovenia**

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# EU Institutions and Agencies

## Key EU Institutions In Brussels

European Parliament
European Commission
Council of Ministers

## EU Institutions Outside Brussels

European Courts of Justice & First Instance
European Central Bank

## EU Agencies across EU (a selection)

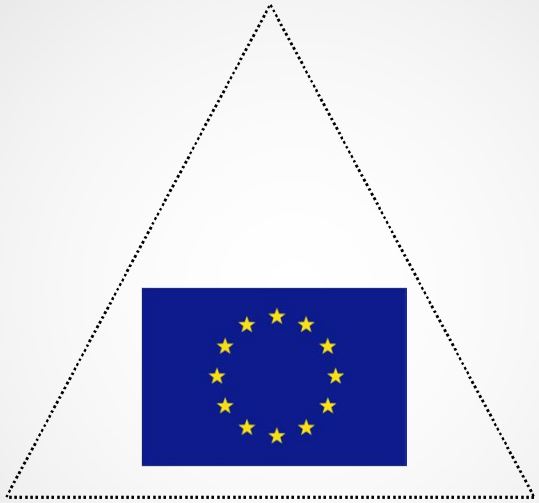
European Medicines Agency (UK)
European Environment Agency (Denmark)
European Trade Marks Office (Spain)
European Food Safety Authority (Italy)
European Aviation Safety Agency (Germany)
European Chemicals Agency (Finland)

# European Union Institutions

## European Commission

- European general interest
- Proposal maker
- Independent
- Small administration

Culture of consultation



## European Parliament

- Direct mandate
- Decision-maker

« (Co-decision) »
1992

## Council of Ministers

- 28 Governments
- Decision-maker

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# EU Biotechnology Framework for GM Crops & Food

- **Protect human and animal health & the environment**
  - safety assessment of the highest possible standards at EU level before any GMO is placed on the market.
- **Harmonized procedures**
  - Covering risk assessment and authorization of GMOs that are efficient, time-limited and transparent.
- **Labeling of GMOs placed on the market**
  - to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice.
- **Traceability of GMOs placed on the market**

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# Legislation

- **Directive 2001/18/EC**
  - the deliberate release of GMOs into the environment
- **Regulation 1829/2003**
  - genetically modified food and feed
- **Directive EU) 2015/412**
  - amending Directive 2001/18/EC allowing Member States to restrict or prohibit the cultivation of GMOs in their territory
- **Regulation (EC) 1830/2003**
  - Traceability & labeling of genetically modified organisms and the traceability of food and feed products produced from GMOss
- **Directive 2009/41/EC**
  - on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs

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# EU biotech approval process

## Two-stage process

1. Risk assessment – technical and scientific evaluation by European Food Safety Authority (EFSA)
2. Risk management
    I. Council of 28 member states vote on the EFSA scientific evaluation (Opinions)
    II. Final approval decisions taken by the European Commission

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# EU Authorization Procedure

Biotech company submits application to Competent Authority (CA) of a Member State

**14 days** — CA sends receipt to applicant **- and without delay forwards dossier to EFSA**

**without delay** — EFSA forwards to other Member States, European Commission, Publishes dossier abstract on web

**6 months (always longer)** — EFSA develops Opinion
EFSA may ask Member States for safety and/or environmental assessments
EFSA forwards Opinion to Member States, the Commission and applicant and publishes it for public comment (30 days deadline)

**3 months** — Commission sends proposal for a decision to Standing Committee (member state technical experts)

**3 months** — Standing Committee votes by Qualified Majority

If no decision - proposal returns to Commission

**without delay** by Permanent Representatives informs the European Parliament — Commission re-submits to Appeal Committee - made up & chaired by the Commission – and

**No time limit** **MAY** decide on final approval — If no decision at Appeal Committee the Commission

Technology providers

Company in-country reps

Scientific Community

Industry – feed, ag, pork, poultry etc

Other stakeholders

(National politicians)

(Retailers)

(Media)

(Consumers)

(NGOs)

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# 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)




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# The EU's approval process for GMOs

**IN PRACTICE**

- **Imports: System currently dysfunctional**
  - Approvals interrupted since November 2013
  - Undue delays are the rule
  - 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: revised legislation**
  - 19 Member States opted out of allowing cultivation
  - cultivation largely prevented
  - One GM product currently approved for cultivation (insect resistant maize MON 810)




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# Voting Pattern Appeal Committee: for Canola event November 14, 2014

| For | Against | Abstained | Absent |
|---|---|---|---|
| United Kingdom | France | Italy | Spain |
| Romania | Poland | Germany | |
| The Netherlands | Greece | Sweden | |
| Belgium | Bulgaria | Denmark | |
| Czech Republic | Croatia | | |
| Portugal | Hungary | | |
| Finland | Austria | | |
| Ireland | Lithuania | | |
| Slovakia | Cyprus | | |
| Estonia | Latvia | | |
| | Luxembourg | | |
| | Slovenia | | |
| | Malta | | |
| Totals:149 million (10) | 153 million (13) | 157 million (4) | 46 million (1) |

Qualified Majority: at least 16 countries representing 65 % (circa 328 million) of the total EU population (circa 505 million)

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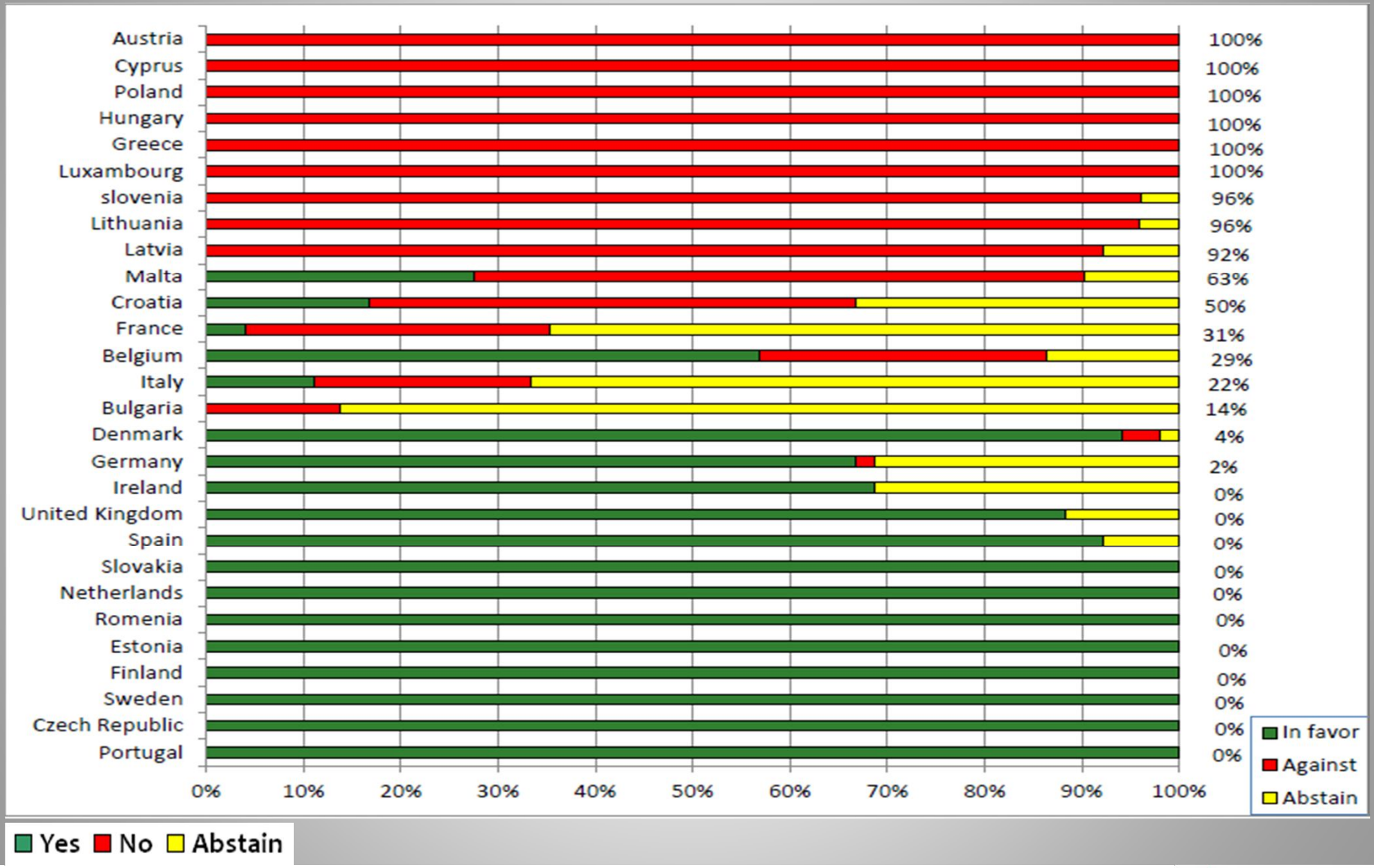
# The EU's approval process for GMOs

*Countries voting against the evidence (2004-14)*

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# Status of GM crops and food approvals

- Commission proposed (April) to allow member states to restrict or ban the use of imported GMOs in their country.

- Based on wrong premise:
  - Excerpt of Pres. Juncker's policy guidelines (summer 2014): *"Commission is **legally forced** to authorise new organisms for import and processing even though a **clear majority** of Member States is against (…)"*
  - Excerpt from the EC Communication on the GMO proposal (22 April 2015): *"While voting positions have broadly stabilised over time, there is typically **more Member States supporting** the draft decision than opposing to it"*
- No impact assessment, no consultation
- Widespread opposition
- Co-Decision procedure between the Parliament and Council of Ministers
- Parliament vote October 26 likely to reject
- Council of Ministers will consider Parliament vote
- European Commission reiterates "There Is No Plan B"

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# Further Information

These main pieces of legislation are supplemented by a number of implementing rules or by recommendations and guidelines on more specific aspects:

http://ec.europa.eu/food/plant/gmo/new/legislation/index_en.htm

# Thank You

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