

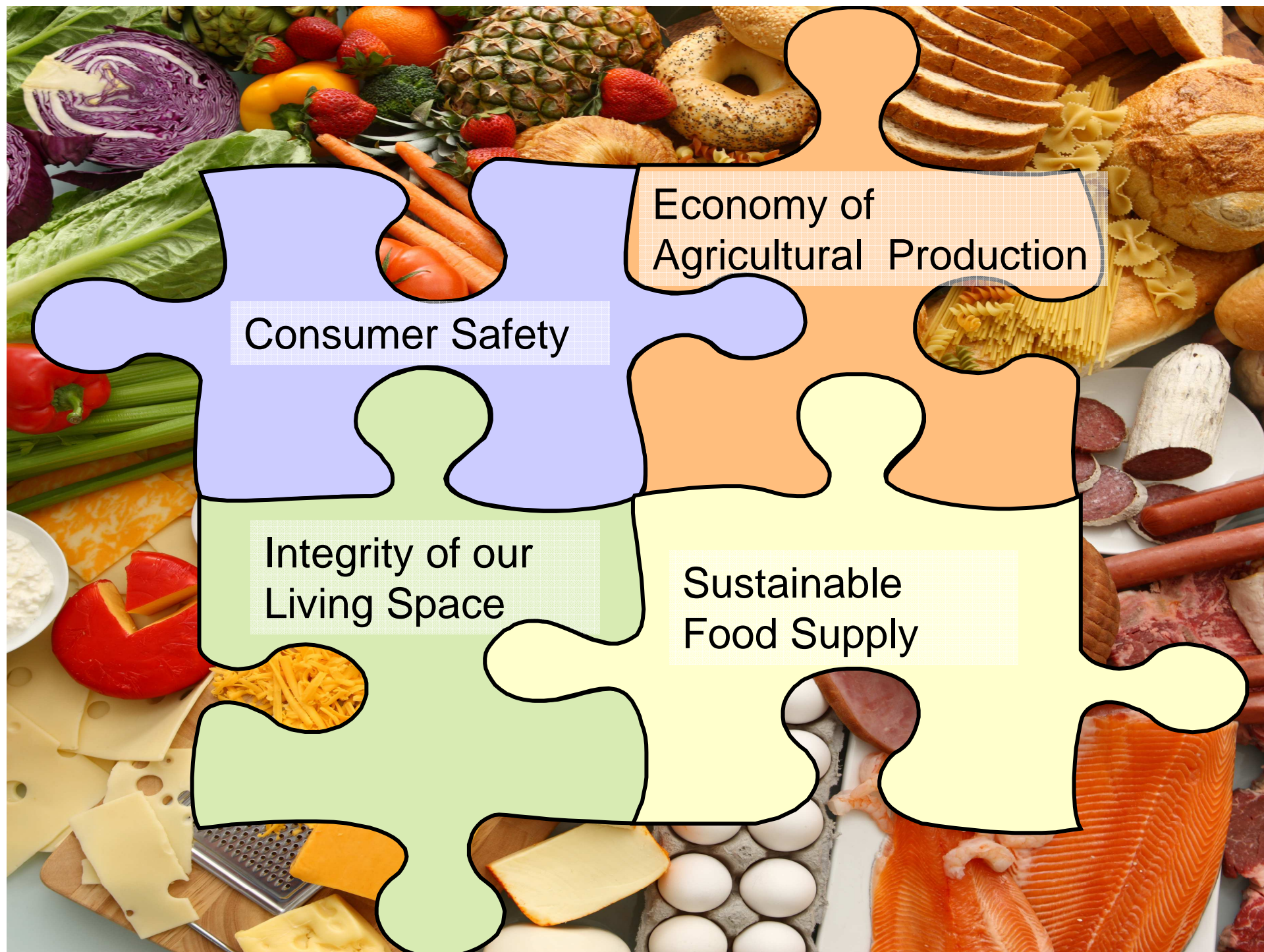


# Mutual recognition, an opportunity for plant protection within the southern zone

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***Mutual recognition as a tool for harmonisation and simplification with the new regulatory provisions***

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Economy of  
Agricultural Production

Consumer Safety

Integrity of our  
Living Space

Sustainable  
Food Supply





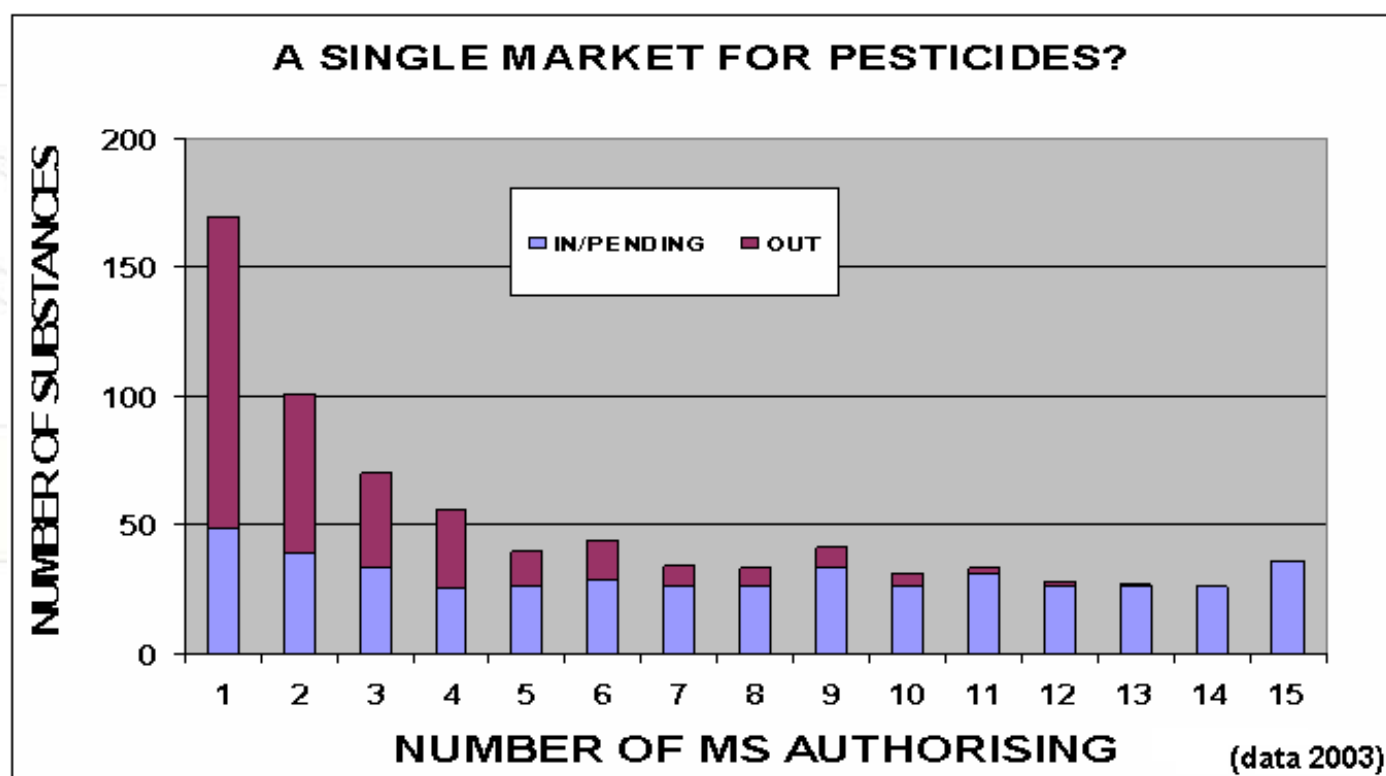




## Limited availability of plant protection products can lead to:

- Problems in resistance management
- Distorted market for farm production
- De facto monopoly of certain products
- Illegal use
- Counterfeit

## The baseline in EU15 in 2003



## Mutual recognition under Directive 91/414/EEC

- Mutual recognition is not a new instrument
- Article 10 of Directive 91/414/EEC
- Obligatory mutual recognition for products which contain active substances included in Annex I to Directive 91/414
- Agricultural, plant health and climatic conditions comparable
- Commission as arbiter

## The problems

- Only recently, the number of active substances on Annex I grew quickly
- No new procedure was put in place because of high workload
- Lack of transparency
- Lack of confidence
- National risk assessments and risk mitigation measures

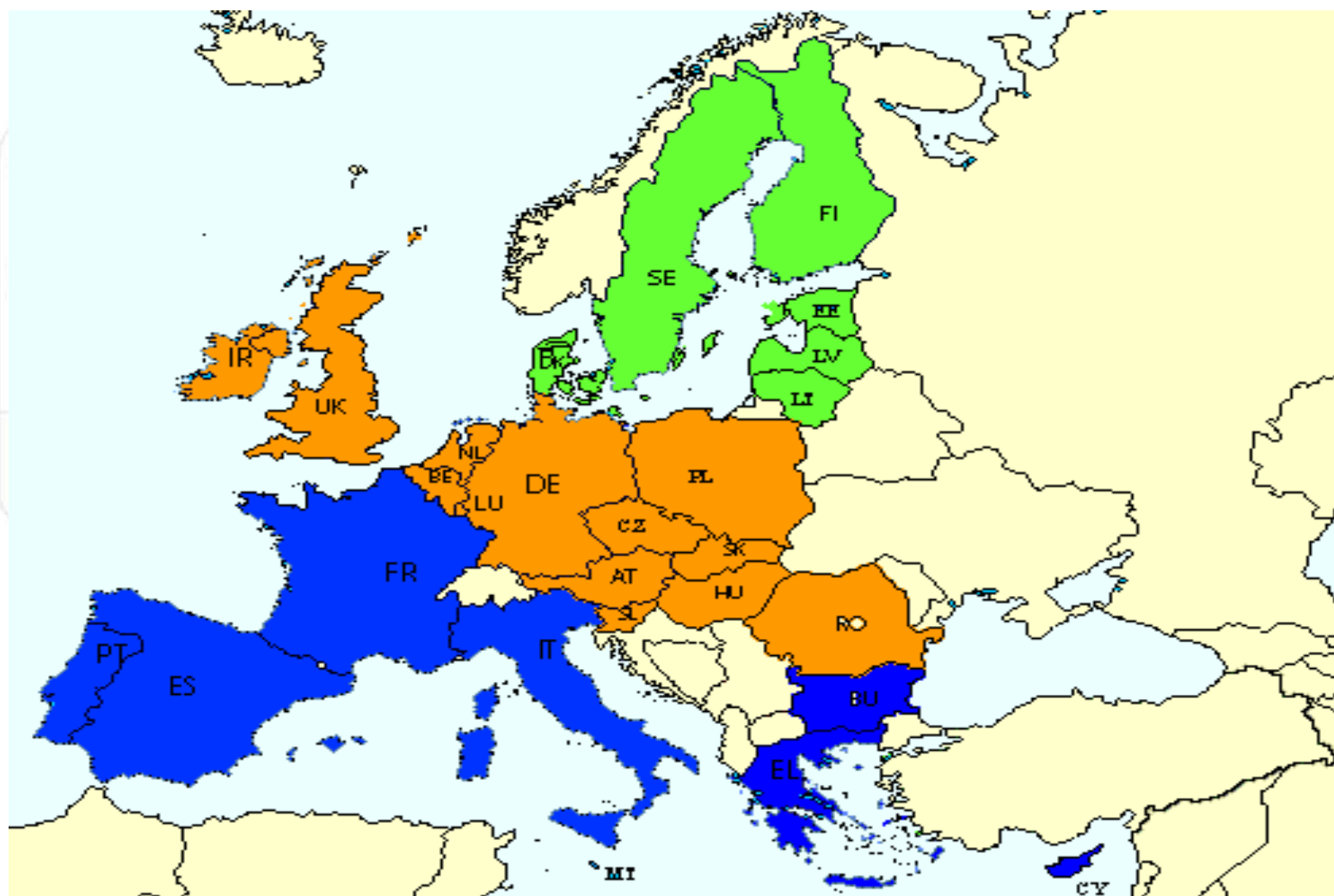


## Mutual recognition under Reg. (EC) N° 1907/2009

- Article 40 (also: 41, 42, 36)
- Each Member State allocated to one zone
- Application for the recognition for
  - the same product,
  - the same use
  - under comparable agricultural practices
- Different time periods for authorisation (12+6 months) and recognition (120 days)



## The «zonal approach»



## The rule

- Obligatory Mutual Recognition within a zone
- Voluntary Mutual Recognition between zones, for candidates for substitution, for provisional authorisations, for derogations under art. 4(7)
- Consent of authorisation holder not indispensable (in case of a prevailing public interest)

## The exemptions

- Adapting risk mitigation measures is possible in order to address the specific situation in a MS
- Possibility to refuse mutual recognition in case of a serious risk for health or the environment
- For some homogenous uses (greenhouse, post-harvest, storage rooms and seed treatment), all EU is considered one single zone
- Mutual recognition does not apply to provisional authorisations, candidates of substitution and authorisations under article 4(7)



## The benefits

- To speed up decision making
- To avoid duplication of work
- To increase the availability of a particular product throughout the Member States
- To reduce the administrative burden for industry and authorities.
- To safeguard the competitiveness of agriculture
- To protect human and animal health and the environment
- To provide for a more common market for plant protection products

## The precondition

- Basis: Zonal Evaluation (Art. 33-39)
- Only one application per zone
- Application must cover all intended uses of the zone
- Evaluation takes into account the whole zone
- Member States to cooperate in terms of:
  - worksharing
  - information exchange
  - stepwise further harmonisation

## A formula for success?

- Mutual recognition is a counterbalance to the criteria for approval and the substitution principle
- Mutual recognition is no longer a unilateral decision, but is embedded into a multilateral worksharing environment
  - > Member States will be more committed
  - > Clear structures need to be established
- Regulation 1107/2009 creates only a regulatory framework for mutual recognition
  - > Harmonised procedures have to be agreed during the twelve months to come
  - > Consultation ongoing (e.g. workshops, expert meetings)



An aerial photograph of a vast vineyard with rows of grapevines stretching across a hillside. In the foreground, a small village with several buildings, including a church with a clock tower, is visible. The text is overlaid on the image.

**Thank you for your attention!**

**...and in any case: the  
Commission will have  
to review the system of  
mutual recognition by  
14 December 2014**

**For more information...**

**... please consult our website:**

**[http://ec.europa.eu/food/plant/protection/evaluation/index\\_en.htm](http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm)**