EUROPEAN COMMISSION

Directorate-General for Health & Consumers

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Views of the European Commission on the new Regulation on placing plant protection products on the market

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Important objectives of the proposal

- To protect human and animal health and the environment
- To safeguard the competitiveness of agriculture
- To improve the functioning of the common market within the EU
- To speed up decision making

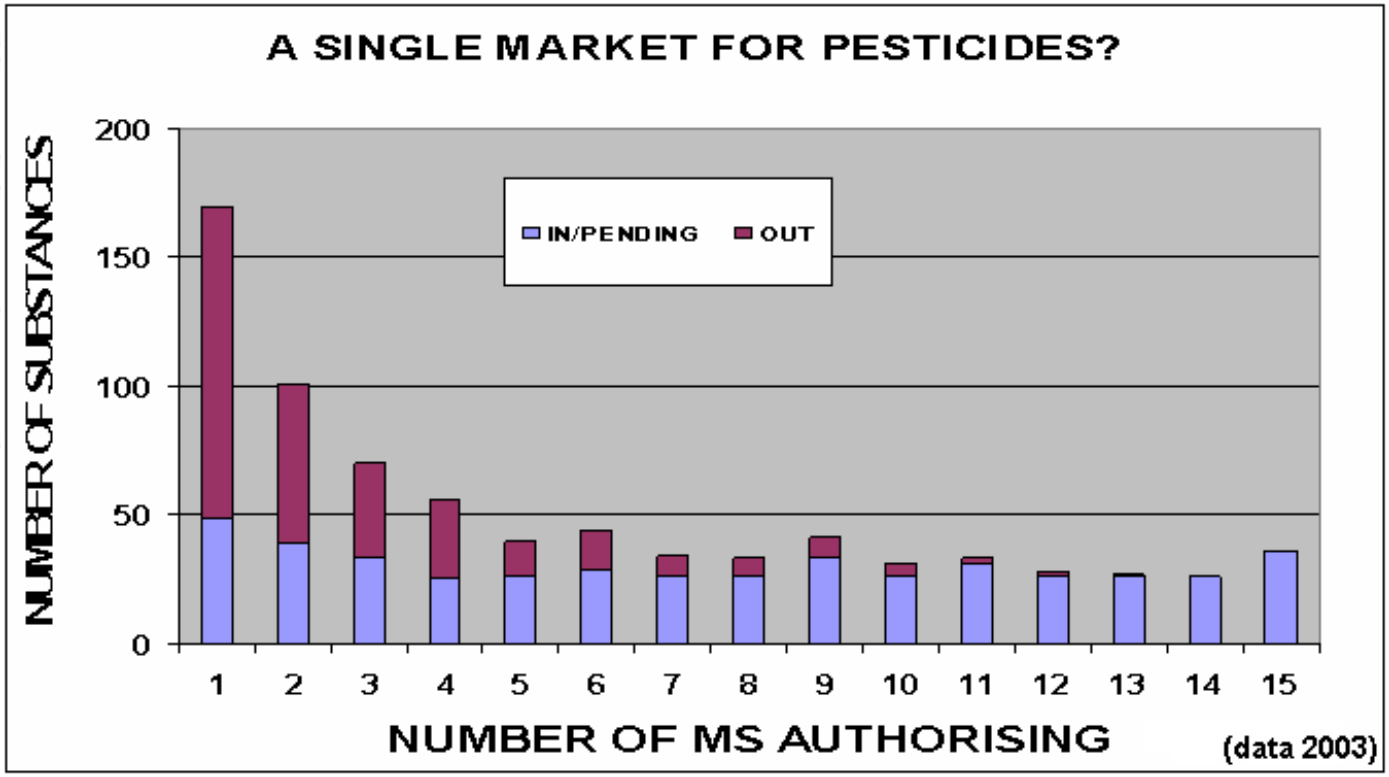
Commission proposal

Key issues

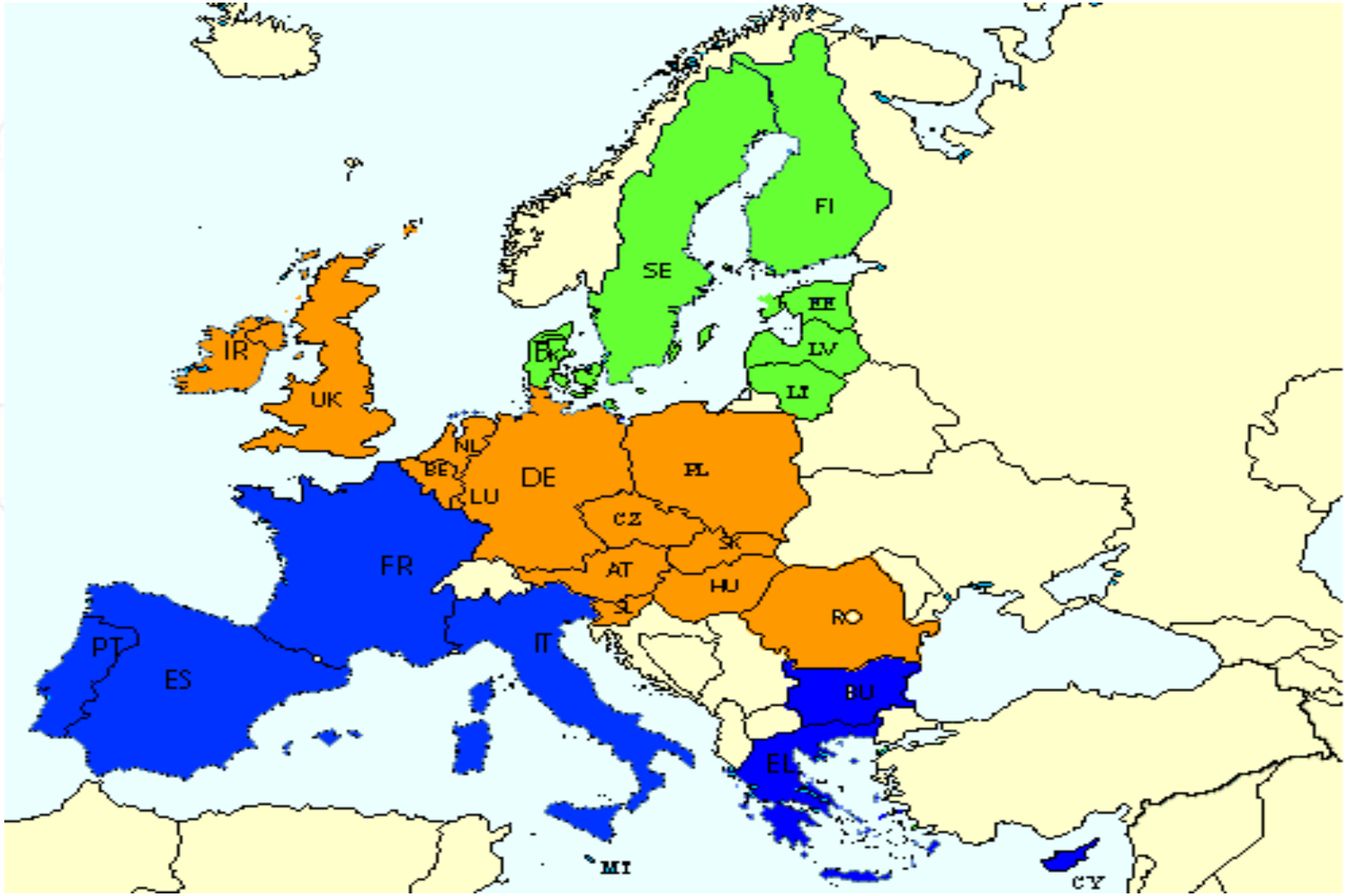
- Zonal system and obligatory mutual recognition
- Criteria for approval
- Comparative assessment and substitution principle
- Clear deadlines for the evaluation
- Data protection
- Information of neighbours
- Minor uses
- Provisional authorisations
- Scope (safeners & synergists, co-formulants)
- IPM
- Monitoring and controls
- Human testing
- Low risk/basic substances
- Information about storage and use

Zonal Mutual Recognition 1/4

- Primary objective: Harmonise availability of PPP



Zonal Mutual Recognition 2/4



Zonal Mutual Recognition 3/4

- Art 40 (also: 41, 36)
- 3 zones in general (one zone for greenhouse, post-harvest, storage rooms and seed treatment)
- Initial evaluation shall take into account the whole zone
- All Member States of a zone can participate in evaluation
- Different time periods for initial (12+6 months) and recognised authorisation (120 days)

Zonal Mutual Recognition 4/4

- Obligatory Mutual Recognition within a zone
- Voluntary Mutual Recognition between zones, for candidates for substitution, for provisional authorisations, for derogations under art. 4(7)
- Mutual recognition no longer needs consent of authorisation holder in case of a prevailing public interest
- 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

Criteria for approval (1/2)

- Primary objective: Create a high level of protection of health and environment and increase transparency in decision making
- Annex II.3
- CMR cat. 1A&1B, POP, PBT, vPvB, endocrine disruption
- CMR as defined in Regulation (EC) 1272/2008 – GHS)
- POP, PBT, vPvB as defined in Regulation (EC) 1907/2006 - REACH
- Exemption for CR cat. 1A&1B and ED if only negligible exposure to humans
- Negligible exposure:
  - Conditions of use exclude contact with humans (i.e. in closed systems)
  - Residues do not exceed 0.01 mg/kg (default value in art. 18(1) of Regulation (EC) 396/2005)

Criteria for approval (2/2)

- Endocrine Disruptors:
  - COM to present specific scientific criteria within 4 years
  - Transitional regime: C+R cat. 2 shall and R cat. 2 + toxic to endocrine organs may be considered as endocrine disruptors
- Art. 4(7)
- Derogation in order to control a serious danger to plant health
- Endocrine disruptors and CR cat. 1B can be approved for 5 years
- MS to report on possible phasing out
- Burden of proof on notifier

Substitution and Comparative Assessment (1/2)

- Primary objective: Minimise the possible negative impact on health and environment without compromising the protection of plant
- Art. 50, Annex II.4, Annex IV
- Candidates for substitution identified at EU level
- Comparative Assessment at MS level
- Criteria: low ADI/ARfD/AOEL, PB/PT/BT, non-manageable concerns (critical effect + exposure pattern), high in non-active isomers, falls under point 3.6.3-3.6.5 together with negligible exposure
- Approval period: 7 years

Substitution and Comparative Assessment (2/2)

- Conditions:
  - significant difference in risk
  - no significant economic or practical disadvantages
  - sufficient chemical diversity to minimise occurrence of resistance
  - sufficient experience
  - minor uses are taken into account

- Transition:
  - One authorisation without comparative assessment of 5 years in order to gain experience
  - Compliance deadline 3 years after assessment

Key timelines in the new Regulation

- Primary objective: Streamline and speed up decision making

Regular timing	
Dossier submission	Day 0
Assessment by RMS	12 months
EFSA peer review	7.5 months, including 2 months commenting period,
Commission to present draft decision	6 months
Additional time	
Notifier to submit additional data to RMS	+ 6 months
Expert meetings	+ 1 month
Notifier to submit additional data to EFSA	+ 3 months
RMS to evaluate additional data	+ 2 months

Data protection

- Primary objective: Simplify and clarify the existing rules on data protection
- Initial period of 10 years
- 13 years for low risk products
- Additional data protection for minor uses (3 months per additional minor use, maximum 3 years)
- Total period not longer than 15 years
- Improved protection of animals
- 2.5 years of data protection for additional data at review/renewal

Any Other Thoughts...

- Regulation = directly applicable in MS
- The dual system approval/authorisation is not touched
- Legislative framework, many technical issues to be tackled during the implementation phase (31 tasks for implementation given to COM)
- Zonal system and comparative assessment must be seen as complementary concerning MS workload
- Adoption in Council likely in October 2009, application 18 months after publication

Directorate-General for Health & Consumers

Thank you for your attention!

For more information...

... please consult our new website:

http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm

... and find the final version of the document in the Council's Public Register:

http://register.consilium.europa.eu/pdf/en/09/st03/st03608.en09.pdf