



# EU Legal framework for Pesticides and Residues

**2018 MRL Harmonization Workshop  
May 30-31, 2018, San Francisco, USA**

**Klaus Berend  
Head of Unit Pesticides and Biocides  
DG Health and Food Safety  
European Commission**

# The regulatory lifecycle of a Plant Protection Product



Horizontal legislation, esp. Regulation (EC) No 178/2002 General Food Law

# Separation risk assessment / risk management

## 1. Application

Industry → Data dossier

## 2. Risk Assessment

1 Member State → Draft Assessment Report  
European Food Safety Authority (EFSA) + all Member States → Expert meetings, Peer review of the DAR  
EFSA → "Conclusion on the peer review"

## 3. Risk management

Commission + all Member States → (Restricted) approval / Non-approval





European  
Commission

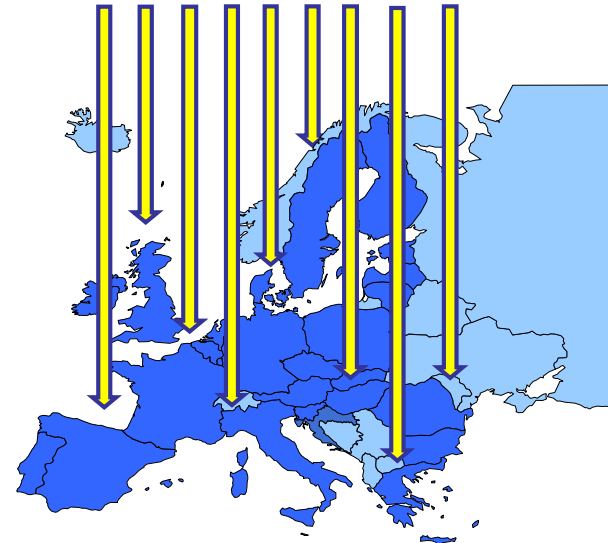
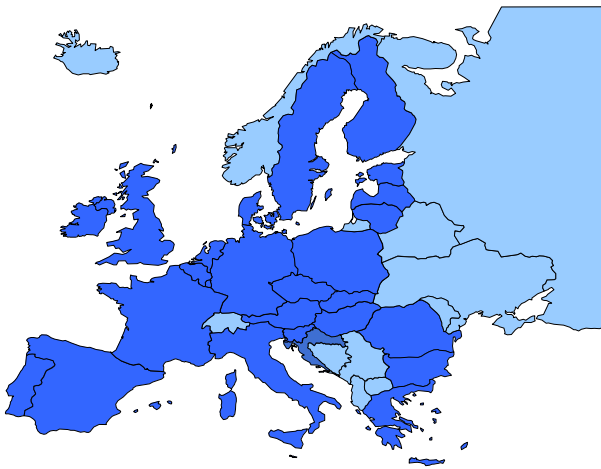
# "Approval"

# vs. "Authorisation"



## Active substance

## Formulated Product



# Active Substances = Approval at EU level

- Application for approval
  - **Data requirements**
- Evaluation shared between 28 Member States: for each substance => one Rapporteur MS
  - **Uniform principles of evaluation**
- Peer review by the **European Food Safety Authority**
- Approval => List of approved substances
  - <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>
- Total length of the procedure = 2,5 to 3 years
- First approval for 10 years – renewal for up to 15 years

# Criteria for approval of substances

- *Plant protection products containing the substance must:*
  - a) be sufficiently effective;
  - b) have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health,
  - c) have no unacceptable effects on plants or plant Products
  - d) shall not cause unnecessary suffering to vertebrates to be controlled
  - e) shall have no unacceptable effects on the environment (biotic and abiotic)

**Exclusion from approval for substances of high concern** (health or environment): **CMR Cat 1A or 1B, POP, PBT, vPvB, endocrine disruptor**

- **Limited derogation possibilities** from these criteria are provided:
  - ✓ Serious danger to plant health
  - ✓ negligible human exposure

# Plant Protection products = Authorisation at national level

- In assessing applications, Member States evaluate the active substance- and the product-dossier
- In granting authorisations, MS set out the requirements for placing on the market, e.g.:
  - classification
  - conditions of use
  - labelling
- Member States enforce compliance with the authorisation
- Commission monitors and controls Member States activities



European  
Commission

# EU zonal system



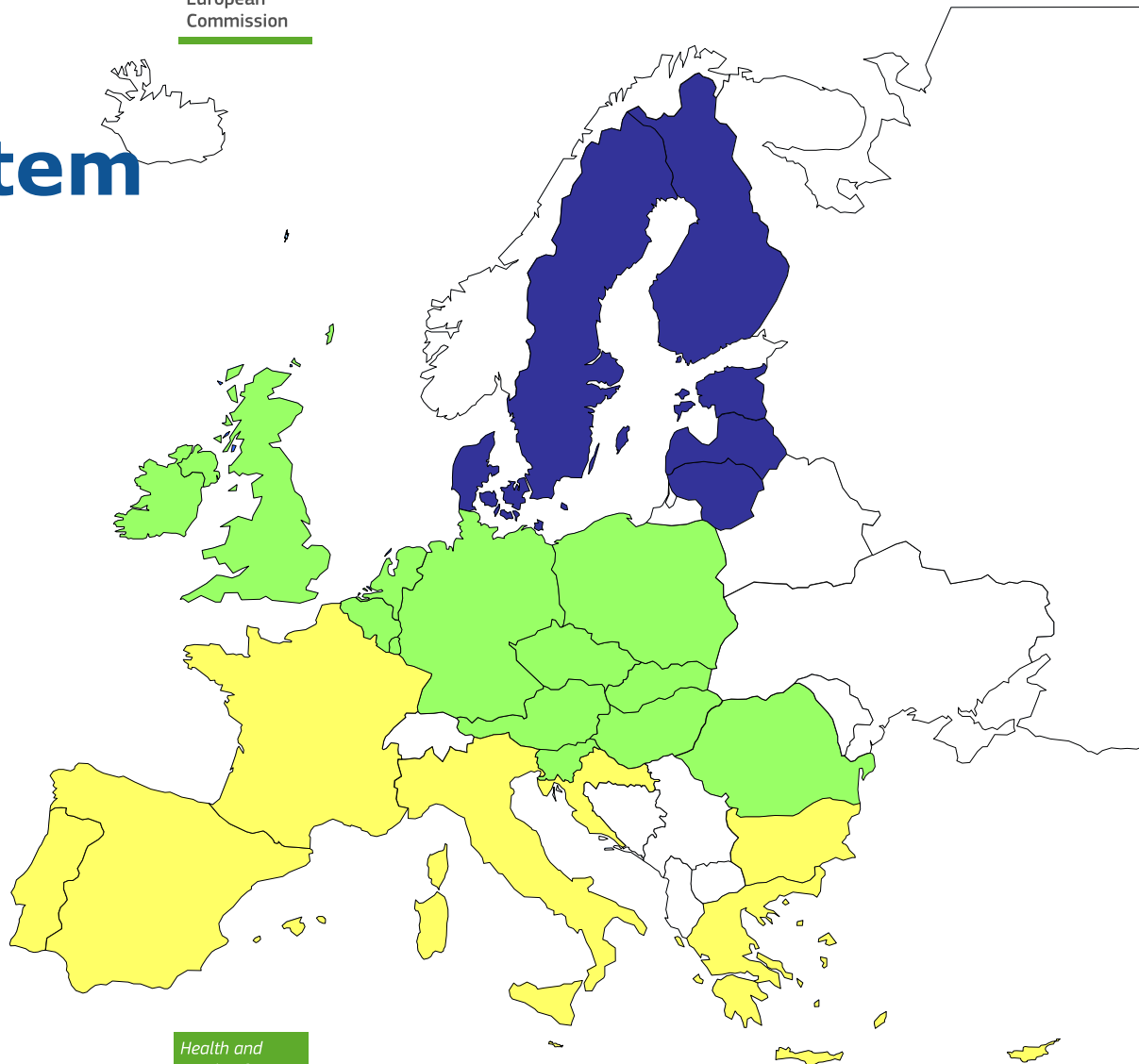
**North**



**Center**



**South**





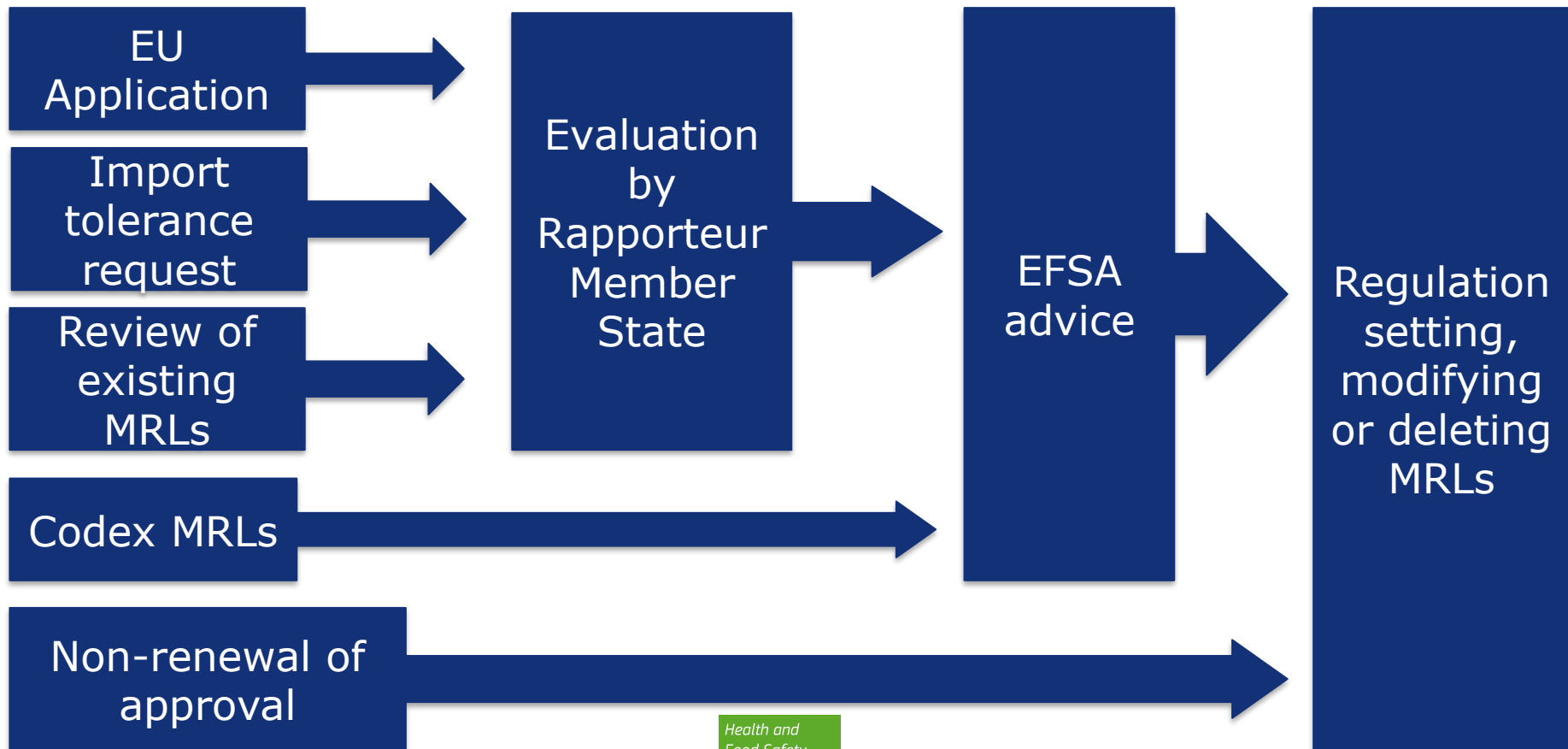
# "Zonal" Evaluation and recognition of authorisations

- One evaluation per zone
  - even if applications in several Member States of the zone
  - carried out by one "zonal rapporteur" Member State
  - including a zonal peer review
- Obligatory recognition of authorisations within the zone, based on the zonal evaluation
- For greenhouse, seed treatment and post-harvest: One evaluation for whole EU
- Total length of the procedure = 16 to 22 months
- Duration of the authorisation = Duration of approval of substance + one year



European  
Commission

# Regulation (EC) No 396/2005 – setting EU MRLs

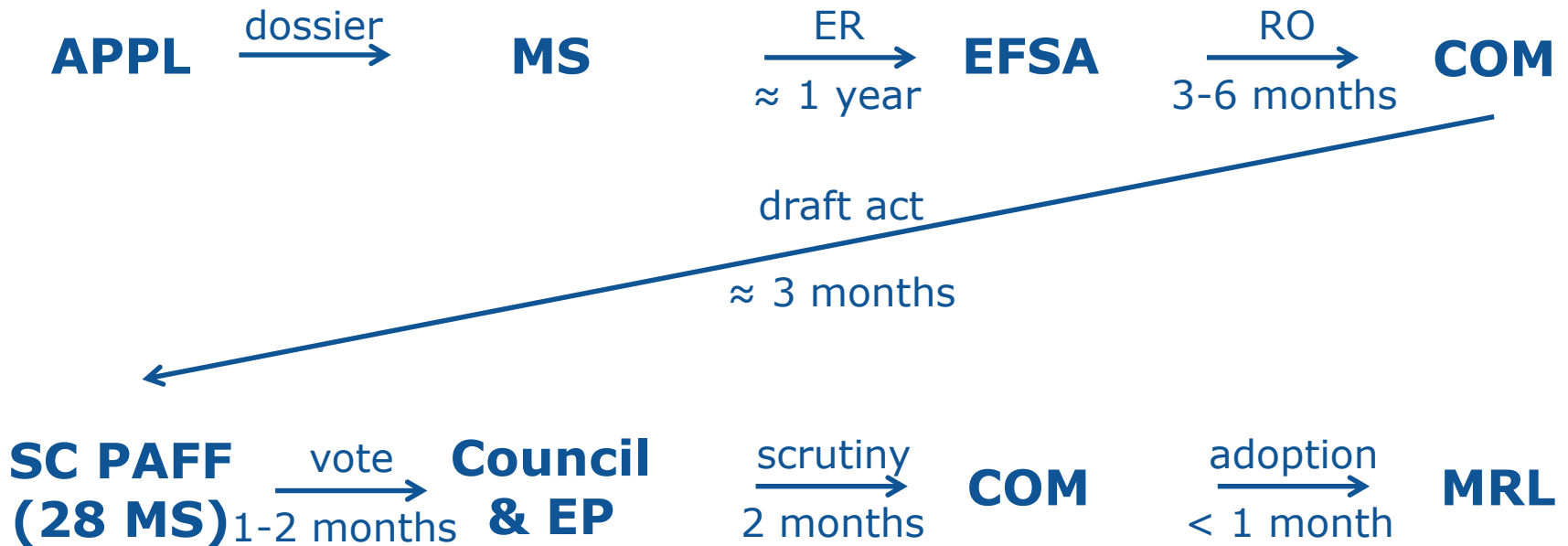




European  
Commission

# From application to MRL setting

(MRL applications based on EU uses and import tolerance requests)



# Review of existing MRLs

- *Regulation (EC) No. 396/2005: entry into force in 2008*
- *MRLs were based on EU Directives and national MRLs*
- *Need to review all MRLs at EU level*
- *Delete obsolete MRLs, align to "old" CXLs if those are safe*
- *Notification to WTO/SPS Committee (draft act)*
- *Better: early input=>see G/SPS/GEN/1494 Rev.1*
- *Around 230 out of 350 substances reviewed so far*

## MRL setting after the renewal process

- *In case of **renewal** (also when restricted) case by case decision on whether to change MRLs*
- *In case of **non-renewal**, MRLs for the substance will **in general be lowered to the limit of quantification***
- *However, the following will be considered*
  - Existing **safe import tolerances** and **CXLs** can be **maintained** in certain circumstances (substance does not fall under the health-based cut-off criteria)
  - The **grace periods** that were granted for marketing an use of products need to be respected

# Application of EU MRL measures- transitional measures

- ***Time between publication and application***
  - Acts with MRL increases only: 20 days
  - Acts with MRL decreases: 20 days + **6 months** (**deferred application date** to enable economic operators to prepare)
- ***Transitional period for products lawfully produced before application of new MRLs if no concerns on consumer protection: generally 6 months***



European  
Commission

# Impact of cut-off criteria on MRLs

Non-compliance with cut-off criteria

Non-renewal decision

Derogation

No renewal process – expired approval

Neither approved nor non-approved

Deletion of existing MRLs, including Import Tolerances

Default MRL applies

New IT request undergo risk assessment

**WORK IN PROGRESS**

# Thank you for your attention !!

- **Guidance document on MRL setting procedure (SANTE/2015/10595 Rev. 4 – June 2016)**  
**Detailed technical and procedural guidance**

**[http://ec.europa.eu/food/plant/pesticides/max\\_residue\\_levels/guidelines/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm)**

- **SPS Note to non-EU countries about Art. 12:**

**[https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_mrl\\_guidelines\\_mrl-review\\_en.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-review_en.pdf)**

- **Legal texts: <http://eur-ex.europa.eu/homepage.html>**

- **EU Pesticides database:**

**<http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public>**

- **Refit evaluation:**

**[http://ec.europa.eu/food/plant/pesticides/refit\\_en](http://ec.europa.eu/food/plant/pesticides/refit_en)**