

Mutual recognition in zonal system

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Background of mutual recognition (MR)

- **Article 10 of Directive 91/414**
- **Intention: Authorizations should be copied between MSs**
- **Take account of different agro-ecological conditions and dietary patterns**
- **MSs should inform COM about refusals of MR**

Practice of mutual recognition (MR)

- Harmonized data requirements
- Harmonized risk assessments
- Different risk management
- Requirements of further information on local conditions



RESULT

- Few „pure” MR
- Practice of „pseudo MR” (assessment is accepted, but further data involved)
- COM is not informed
- Zonal work-sharing is being formed at Step2

Real problems

- High evaluation requirements for member states
- Decreasing capacity for evaluations
- Parallel assessments in 27 MS
- No human source for real assessments
- Share of work must be enhanced !



COM is not satisfied with practice of MR

⇒ **NEW REGULATION on REGISTRATION**

COM creates a 3 zonal mutual recognition system (3ZMRS) in the new regulation



PRODUCT AUTHORIZATION

3 zonal mutual recognition (3ZMR)



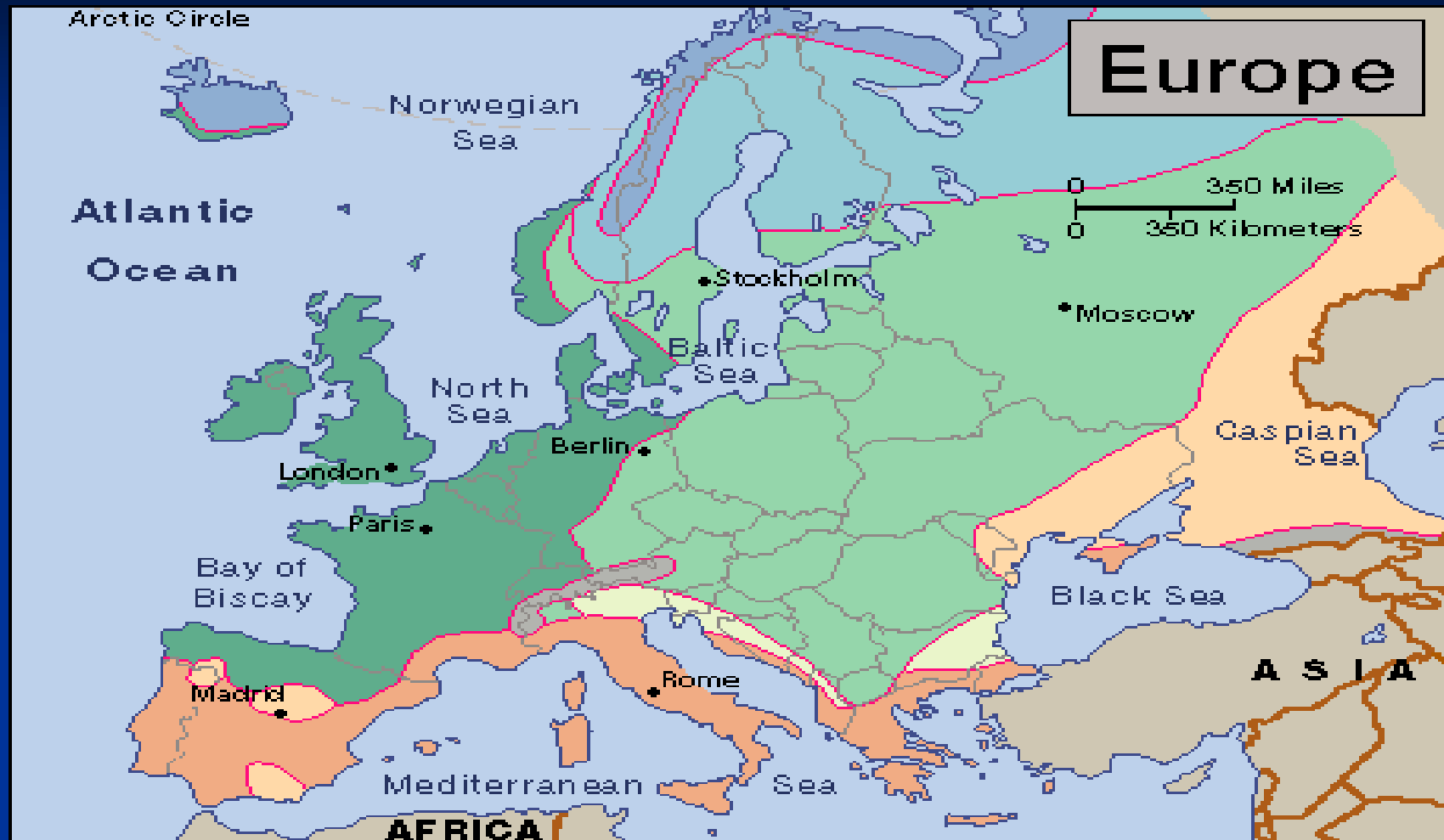
- Reference member state registrates
- Other MSs in zone recognise within 120 days
- Refusal only in extraordinary cases (report to COM)
- Extra zonal recognition on voluntary base

A map of Europe and surrounding regions, including parts of North Africa, the Middle East, and Greenland. A thick black line is drawn across the map, dividing it into three distinct zones. The zones are defined by the line's path: Zone 1 covers the British Isles and the Atlantic Ocean; Zone 2 covers Central Europe, including Germany, France, and Poland; Zone 3 covers Eastern Europe, including Russia, Ukraine, and the Balkans. The map is labeled with various countries and cities in Dutch, and the title '3 zonal system for mutual recognition of authorizations' is prominently displayed at the top.

EPPO zones (PP 1/241) comparable climats



Climatic zones of Europe according to rainfall

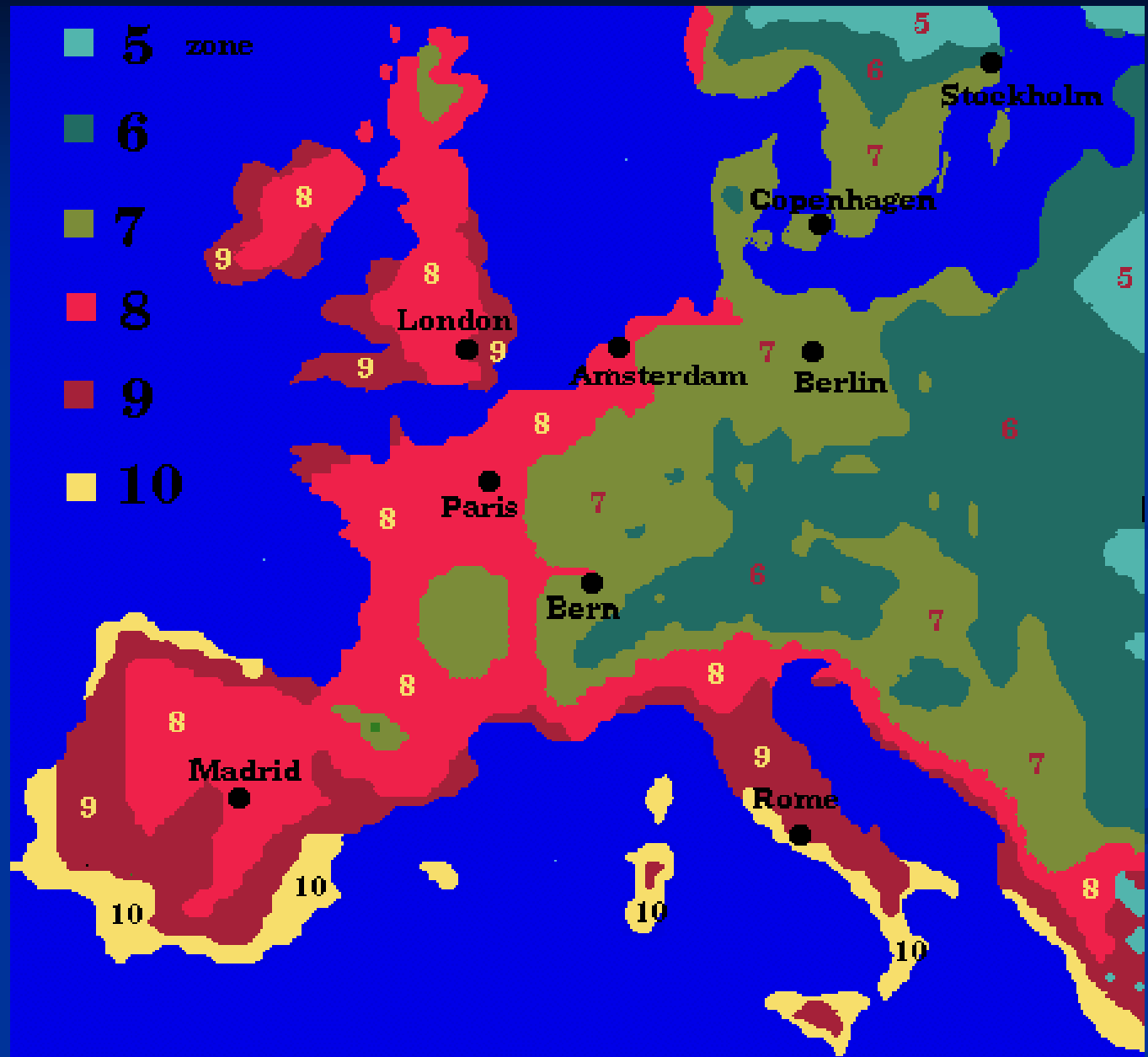


- Semiarid
- Subtropical dry summer
- Humid subtropical
- Humid oceanic

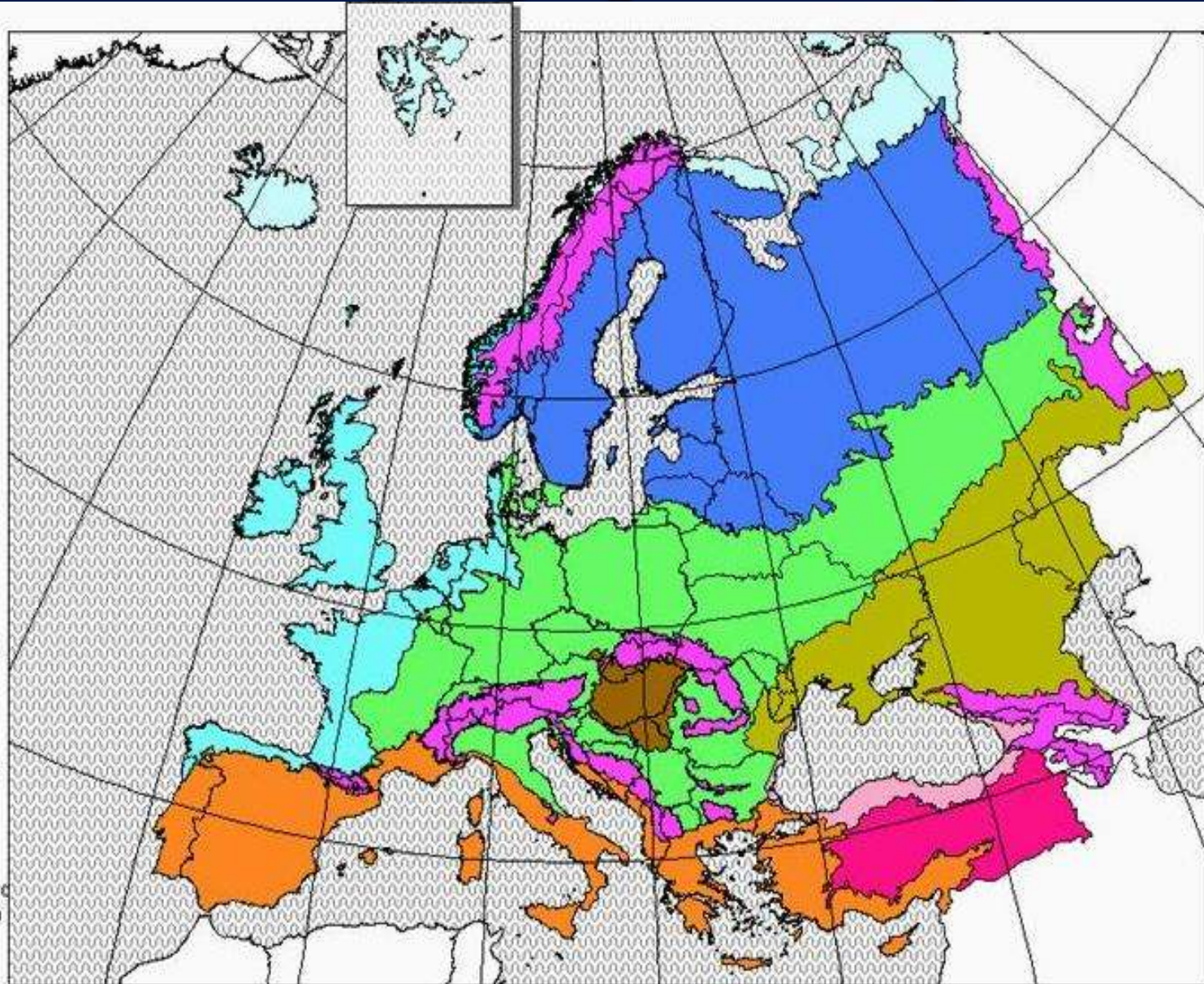
- Humid continental
- Subarctic
- Tundra
- Highland

USDA zones according to winter hardiness

Zone 5 (-26 °C)
Zone 6 (-21 °C)
Zone 7 (-15 °C)
Zone 8 (-9 °C)
Zone 9 (-4 °C)
Zone 10 (+2 °C)

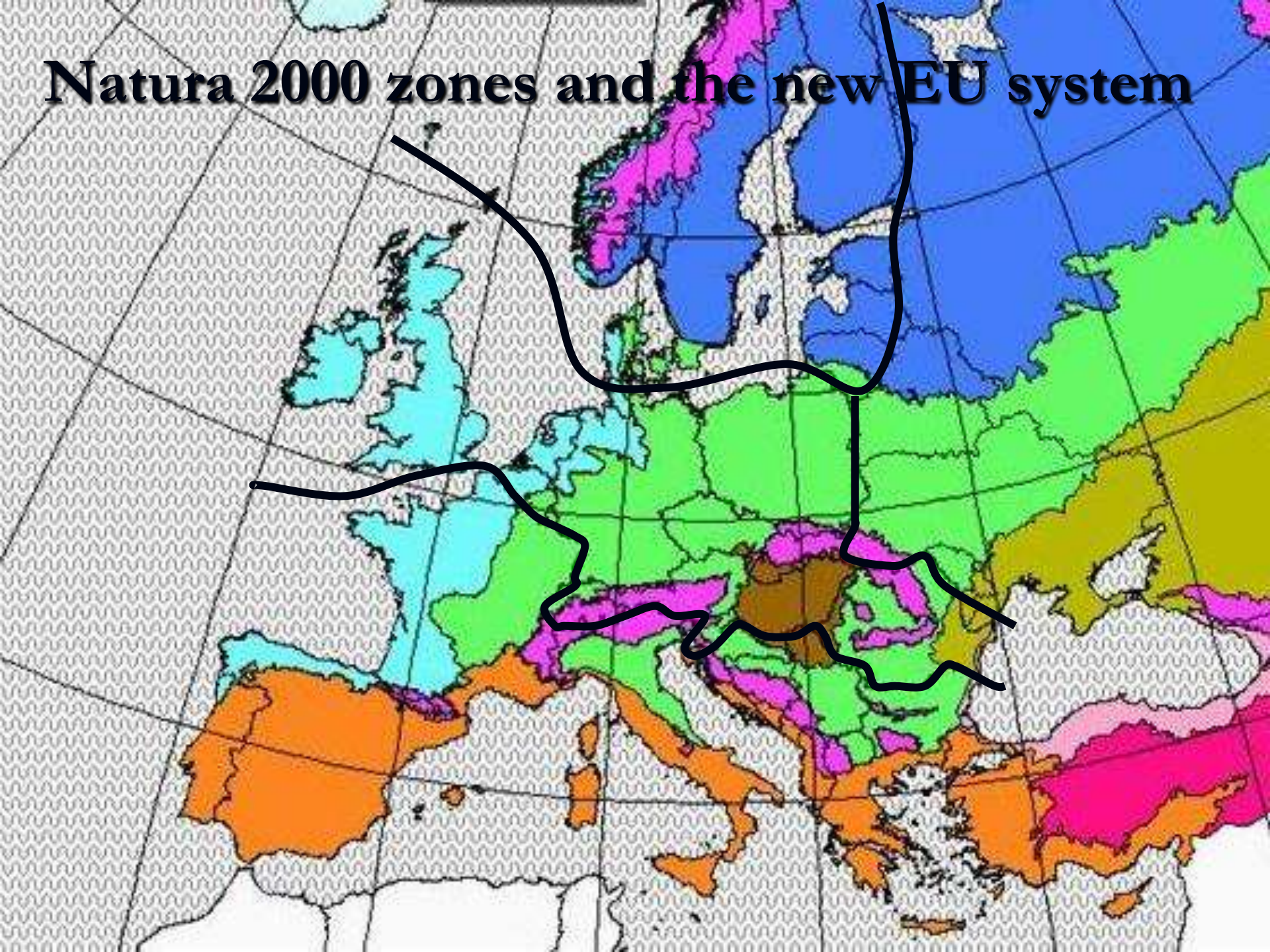


Natura 2000 biogeographical regions



The Biogeographical map developed under Council Directive 92/43/CEE (NATURA 2000) formed the basis for this Pan-European extension. 5 Biogeographical regions were added (Arctic, Pannonian, Steppic, Black Sea and Anatolian). (the EU-map is not changed)

Natura 2000 zones and the new EU system



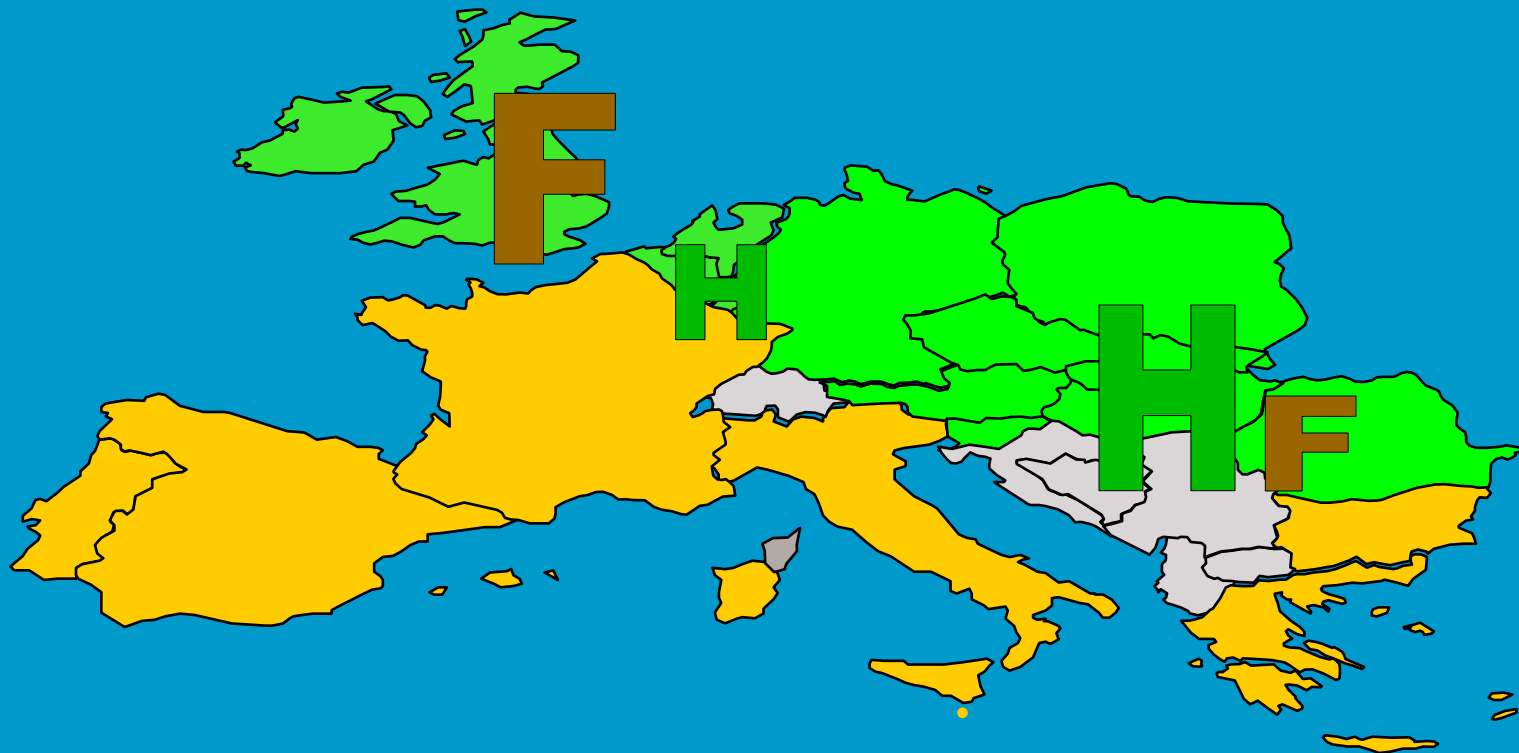
DIFFERENCES

within one zone that cannot be ignored...

- Temperature, winter hardiness
- Rainfall
- Infection pressure
- Sensitivity and variety spectrum of crops
- Sensitivity of pests
- Agronomical requirements
- User's knowledge and habit
- Environmental characteristics

Differences in application between W-Eu & C-Eu at some cases

- **Herbicides:** 50-100% higher dose in C-Eu
- **Fungicides:** 50-100% higher dose in W-Eu
- **Zoocides:** 50-100% differences variably



Correction of the 3ZMRS was proposed by

- EPPO, PAN, ECPA
- Some member states
(BE, DK, NL, FR, PT, HU)
at the final discussions only HU)
- European Parliament
(C. Regions and ENVI, EP plenar)
- EP refusal of 3ZMR on 23.10.2007.

Triialogue lead to compromise

on 18th Dec2008

- **Am 110 refused**
(additional tests)
- **Am 118 accepted**
(local circumstances
of MSs)



EP+COM
+Council
trialogue

3 ZMR final compromise

- §36(1) MSs can comment to reference MS
- Am 110 (additional tests) refused by PRES
- Am 118 accepted (local circumstances of MS)
§36(3) & 31(3) authorization can differ in dose, last application, and number of applications
- Am11 (Rec27): Authorization can be modified according to special circumstances
- Am 112 , Art 36(3) Recognition can be refused in case of nonacceptable risk



PROCESS OF PPP REGISTRATION

- Designation of Reference MS (Who can do it?)
- Evaluation of dossier by RefMS within 12 months (+ 6 months data supplement)
- Equivalency : RMS (or RefMS) 60 days
- Mutual Recognition – applicant requires for other MSs inside the ZONE and for greenhouse, seed dressing and storage for 3 ZONES
- Accepting MS authorizes (or refuses) within 120 days taking into account local circumstances

PROCESS OF PPP REGISTRATION 2

- Derogations: 36§(3) és 31§(3-4)
- Authorization may be refused in case of unacceptable risk
- Validity : max. Annex I + 1 year \Rightarrow
constant re-registration in case of more a.i.
- Extra zonal recognition on voluntary base at neighbouring MS, but no domino !



Possibility for derogations

31§(3) Authorizations shall include :

- a) Dose (kg/ha, l/ha)*
- b) Preharvest interval (PHI)*
- c) Max. applications per year*

31§(4) Authorizations may include :

- a) Restrictions for trade and use,
- b) Obligation for information of neighbours
- c) Proper use according to,
- d) User's category
- e) Approved label
- f) Interval between applications
- g) Period between the last application and consumption ;
- h) Re-entry interval ;
- i) Packaging size and material .

Contradiction to be solved

- Requiring additional tests are not allowed
- But local circumstances can take into account
- It is the interest of manufacturers to negotiate with MSs in advance



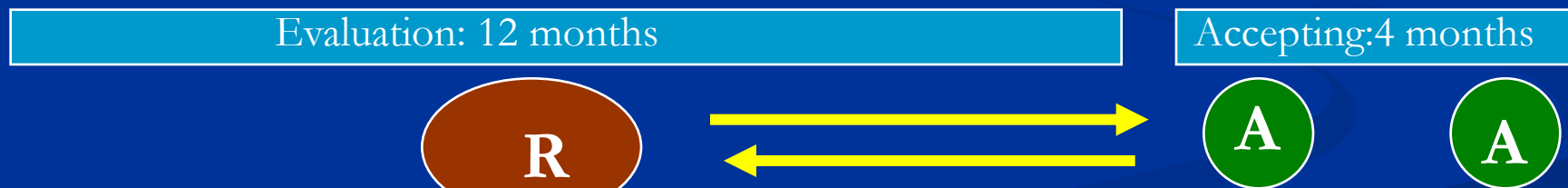
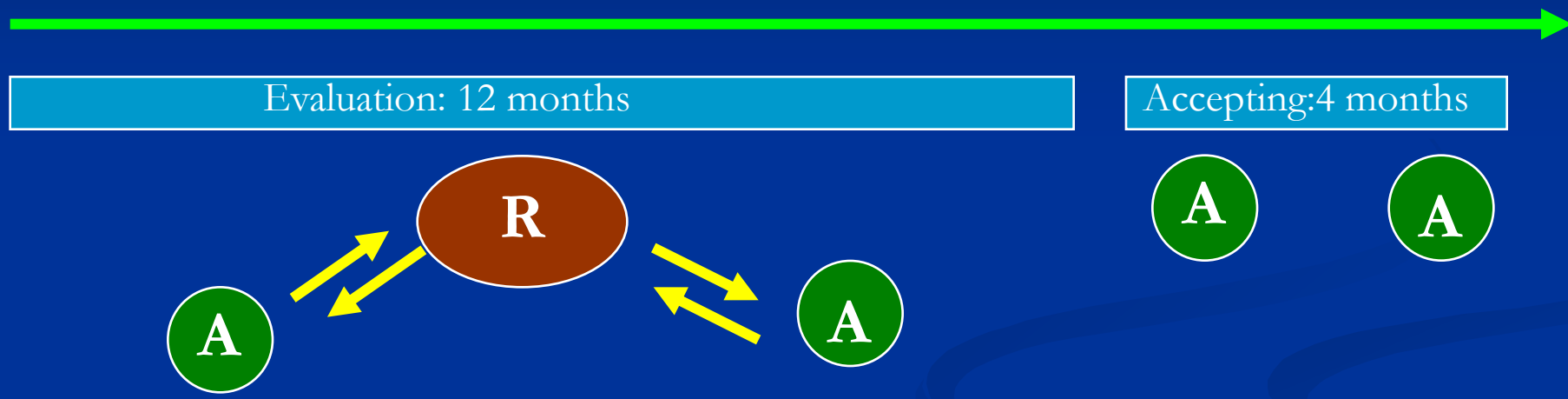
Possible options for the 3ZMR

by EU Post Annex I WG

- Op1: MS ignores 3ZMR and continues full evaluations (\Rightarrow infraction proceedings)
- Op2: MS accepts bulk of RefMS assessments, but maintains national requirements (\Rightarrow keeps protection level, moderate harmonization)
- Op3: Complete acceptance (\Rightarrow good harmonization, but lowering of protection level, \Rightarrow rejections in some MSs)
- Op4: Complete harmonization with zonal assessment models (\Rightarrow investments for new models and guidances, extensive cooperation between MSs \Rightarrow a lot of work)

Op2

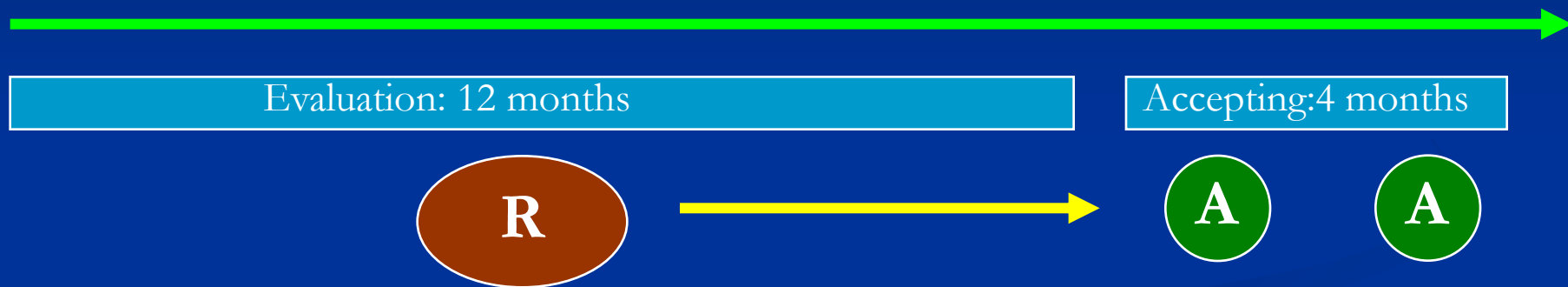
- Op2a: RefMS must cooperate with AMS during evaluation
4 months is not enough to evaluate local circumstances



- Op2b: AMS evaluates during accepting period, or asks additional tests (not allowed and not prohibited ??? No time)

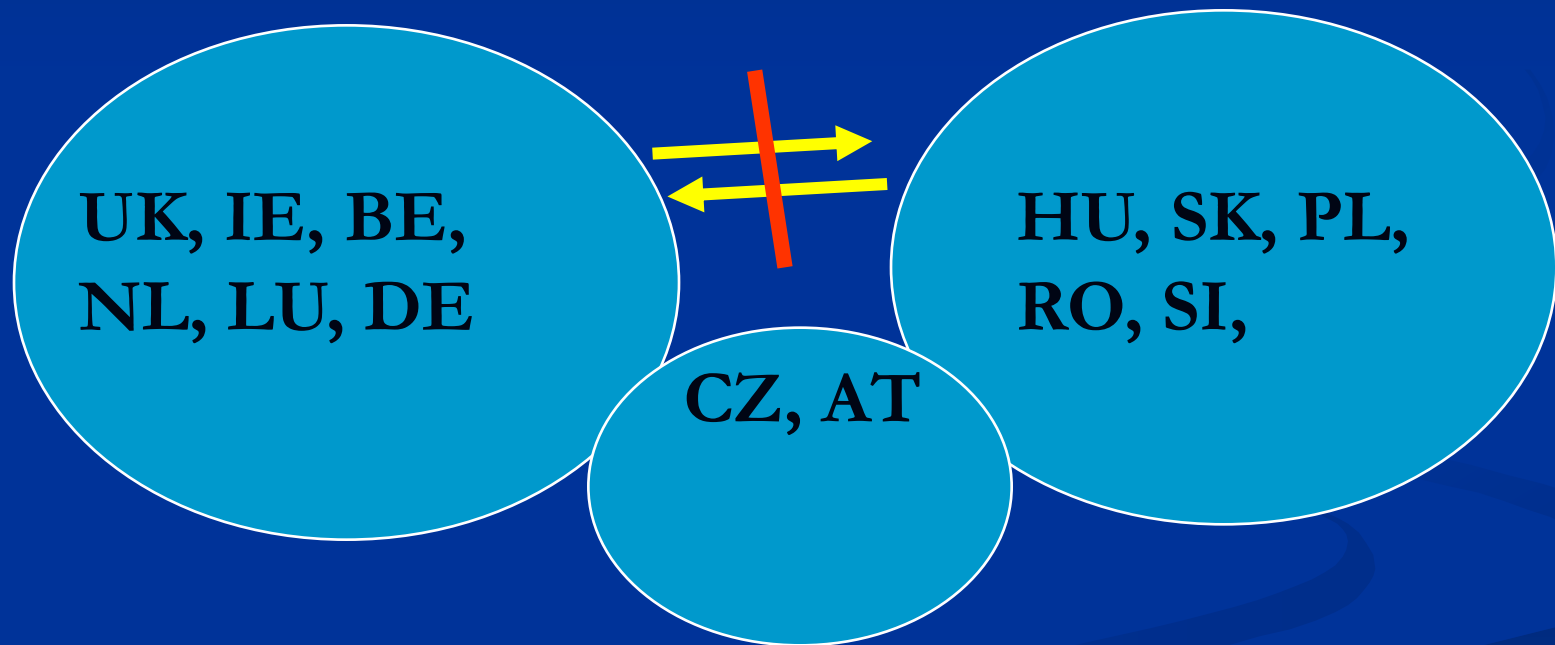
Op3

- Op3a: RefMS evaluates for AMS, and AMS accepts



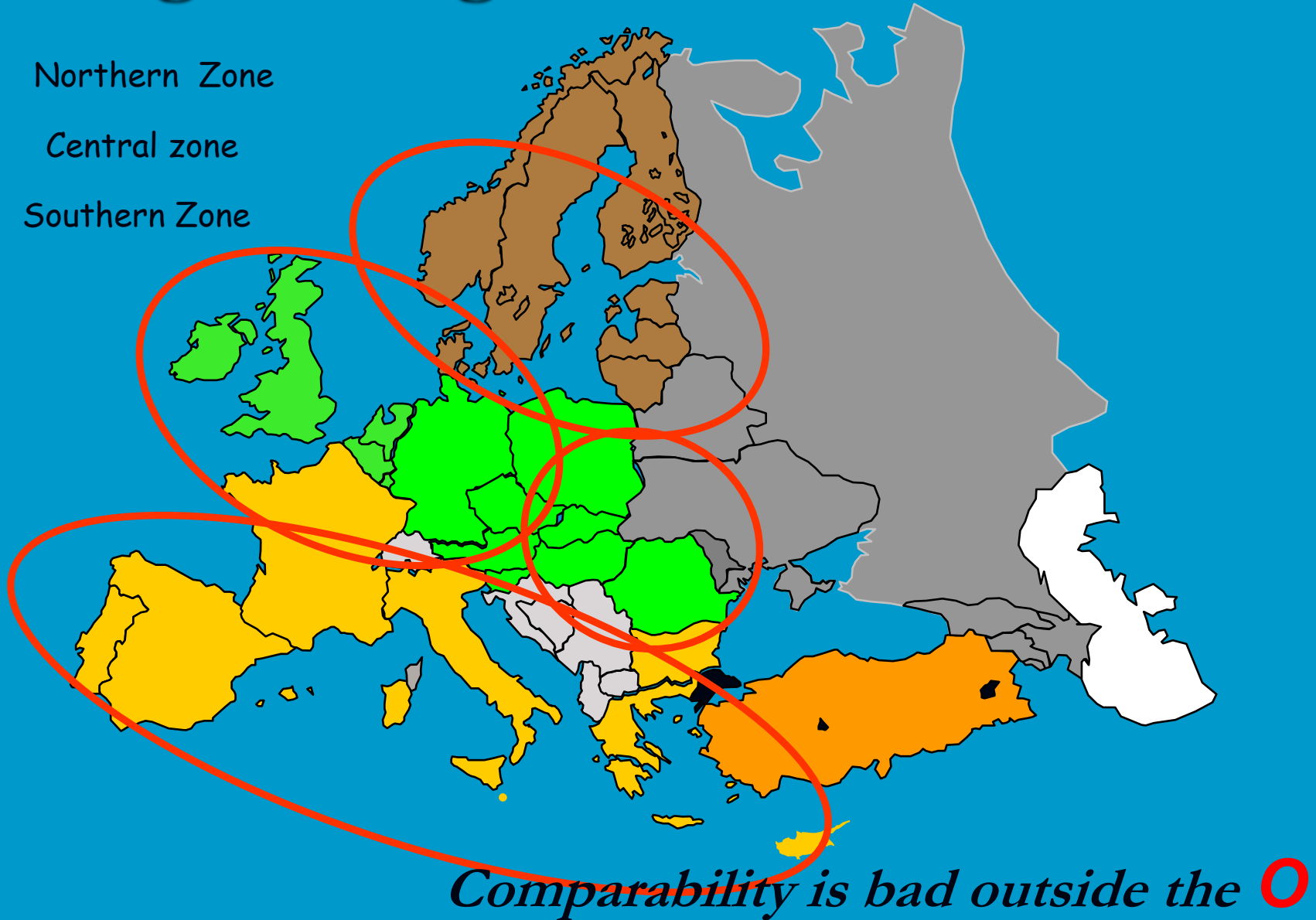
- Op3b: RefMS does not evaluate for AMS, and AMS rejects authorization

Predictable difficulties in acceptance because of agroecological differences



Probable noncomparability in agroecological circumstances

- Northern Zone
- Central zone
- Southern Zone



Conclusions

- Capacity of most MSs is low,
⇒ work-sharing is inevitable
- Interpretation of 3ZMR is not unambiguous
⇒ EU workshop would be important
- Bulk of evaluations will be accepted, but some MSs will need specific assessment for efficacy and fate.
- Cooperation is needed among RefMS and AMSs
- Work of authorities could decrease, but also increase because of new tasks (comp.assessment, re-reg after each inclusion etc.)

