OPEN QUESTIONS in the new system (1107/2009 EC)

Gábor Tőkés

Central Agricultural Office

Directorate for Plant Protection and Soil Conservation

Budapest, Hungary

PRODUCT AUTHORIZATION
3 zonal mutual recognition (3ZMR)

- Reference member state evaluates & registrates (1 year)
- Other MSs in zone recognise within 120 days
- In case of refusal report to COM
- Extra zonal recognition on voluntary base

Parallel import
(Art 52)

Re-packaging is allowed but the product have to remain equivalent.

- Re-packing may be a source of fake products
- Prohibition of re-packing ?
- Inhibition of re-packing with administrative breaks?
- Using original name?

Back to back registration (2nd name)

No prescription in 1107

LEGAL BASIS CAN BE:

- Art 45 : amendment of an authorisation at the request of the authorisation holder
- Art 33: Application for authorisation or amendment of an authorisation
- Art 33 (2c) where relevant, a copy of any authorisations already granted for that plant protection product in a Member State;
- Art 34 (1) Applicants shall be exempted from supplying the test and study reports where… the applicants demonstrate that they have been granted access (LoA) or any data protection period has expired.

Seed dressing (Art 49)

No registration case

- Import is possible if registered in 1 MS but
- Treating of seed is not allowed – registration is necessary
- The new situation causes problems for the seed treating companies.
- France allows treating

Recognition of 91/414 (old) authorizations

- Text and original intention is not clear
- COM and more MSs: obligatory
- DE: legally not possible
- HU, SK, SE: only voluntary
- Fulfilling Art 29 ?
- 120 day or more? (can 91/414 be followed = no strickt deadline?)
- Only in cases when Step2 has been done?

Amendment of authorizations
(Art 45)

No detailed rules in 1107

Principle (GD 2010/13170):

- Administrative changes (name, owner, address)– national
  (Deadline?)
- If evaluation needed – zonal
  Deadline: 1 year, or 6 months for smaller evaluations, + 120 days for MR

Amendment of ‘old’ authorizations

A) 91/414 authorizations by UP (Annex VI)

B) very old authorizations, without Step 2

- Extensions to new use (crop, mode etc)
  A) normally zonal (needs part of dRR !)
  B) national?
- Decreasing of dose (risk envelope covers the amendment!)
  only efficacy evaluation is needed
  Zonal? National?

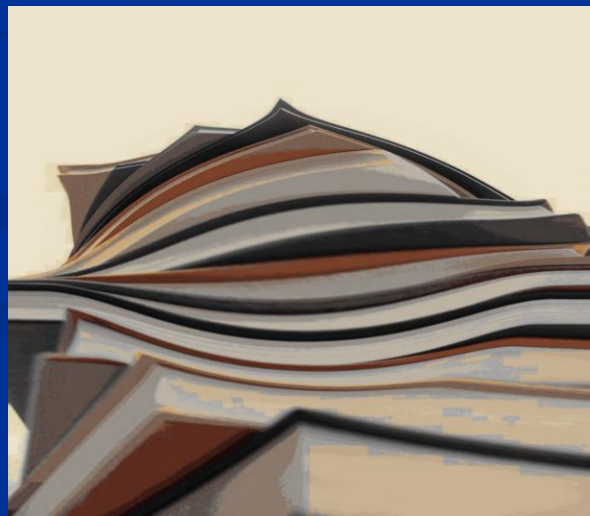
If an old authorization can not be recognised as an 1107 authorization (see DE) , why should it be amended according to 1107?

Amendment of ‘old’ authorizations

- Change of user category for small pack – only 1 MS is interested
  new tox evaluation is needed
  Zonal? National?
- Extensions to minor uses
  Residue and efficacy is most important – new evaluation is needed
  Zonal? National?

Step2 re-registration

- Post Annex I group agreed that basis will be 91/414 if a.i was taken to Annex I according to old rules (1st inlusion, voluntary withdrawn actives, AIR 1)
- Zonal process based on work-sharing



Residue trials

2 zones: N & S

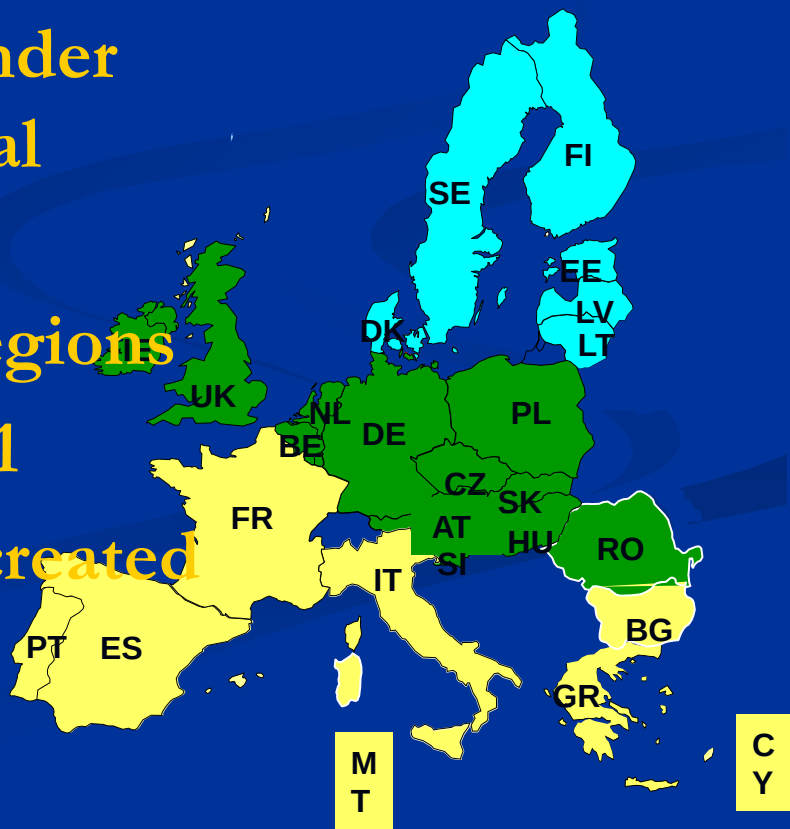
Lundehn document:
Appropriate number of
trials from the relevant zone

HU belongs to N zone, but has S crops without N trials. Acception of S trials?

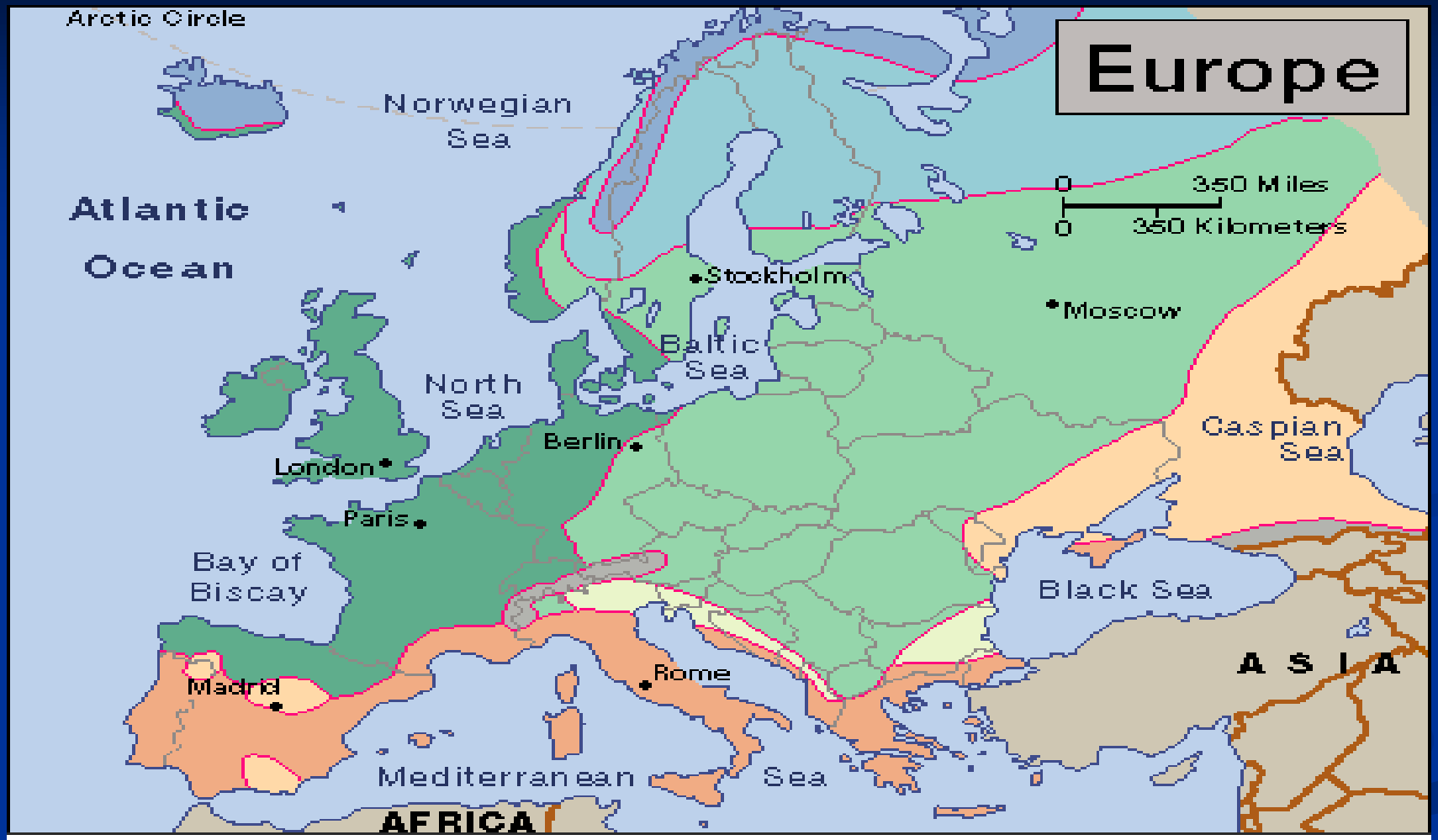
RO and SI belongs to S residue zone and Central political zone. They have also S trials!

Efficacy

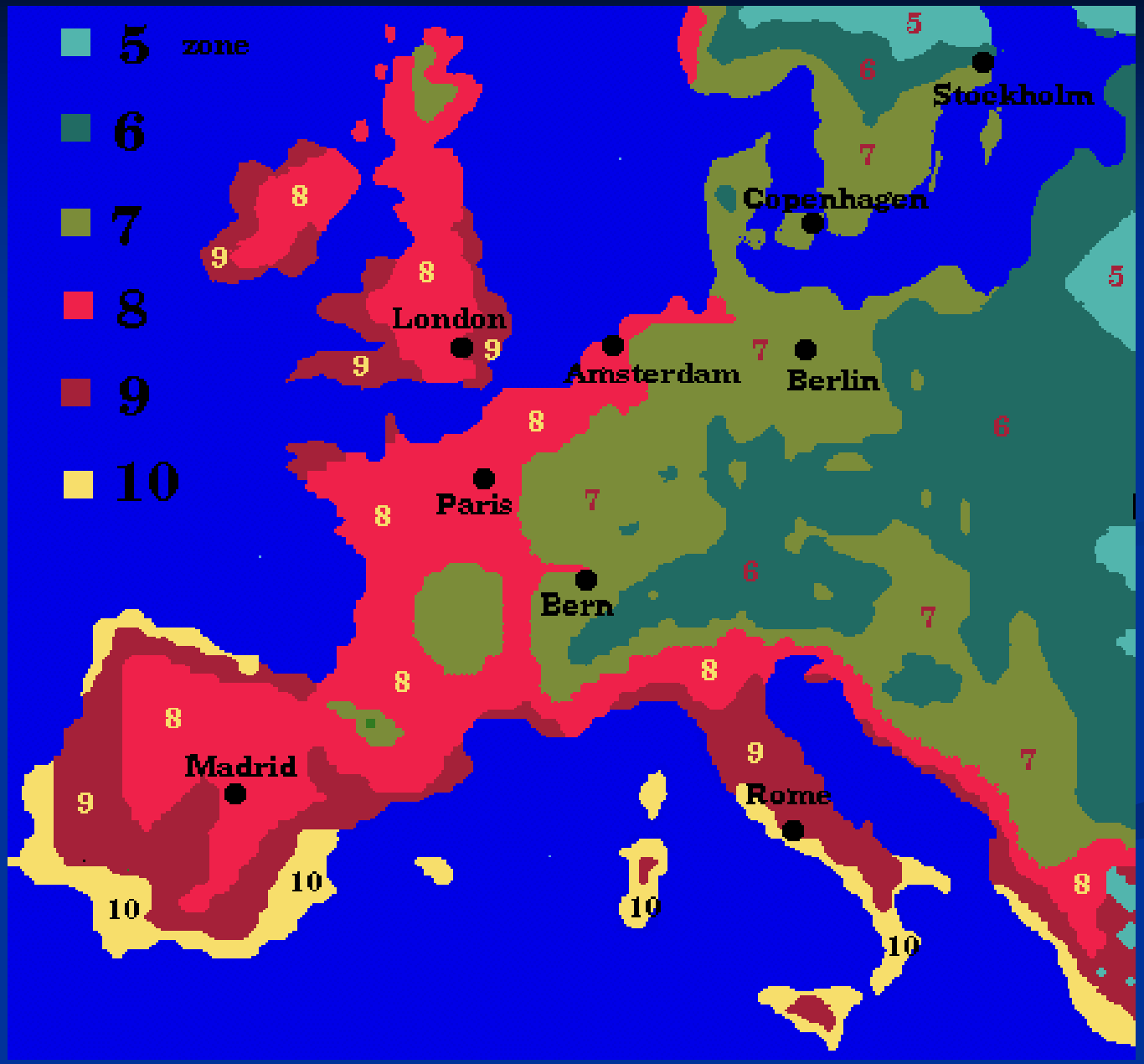
- Art 41(1): The MS to which an application is submitted shall, … as appropriate with regard to the circumstances in its territory, authorise the PPP concerned under the same conditions as the Zonal Reference Member State.
- 1 zone = more agroecological regions
- Practical approach: EPPO 1/241
- New EPPO guidance is being created



Climatic zones of Europe according to rainfall

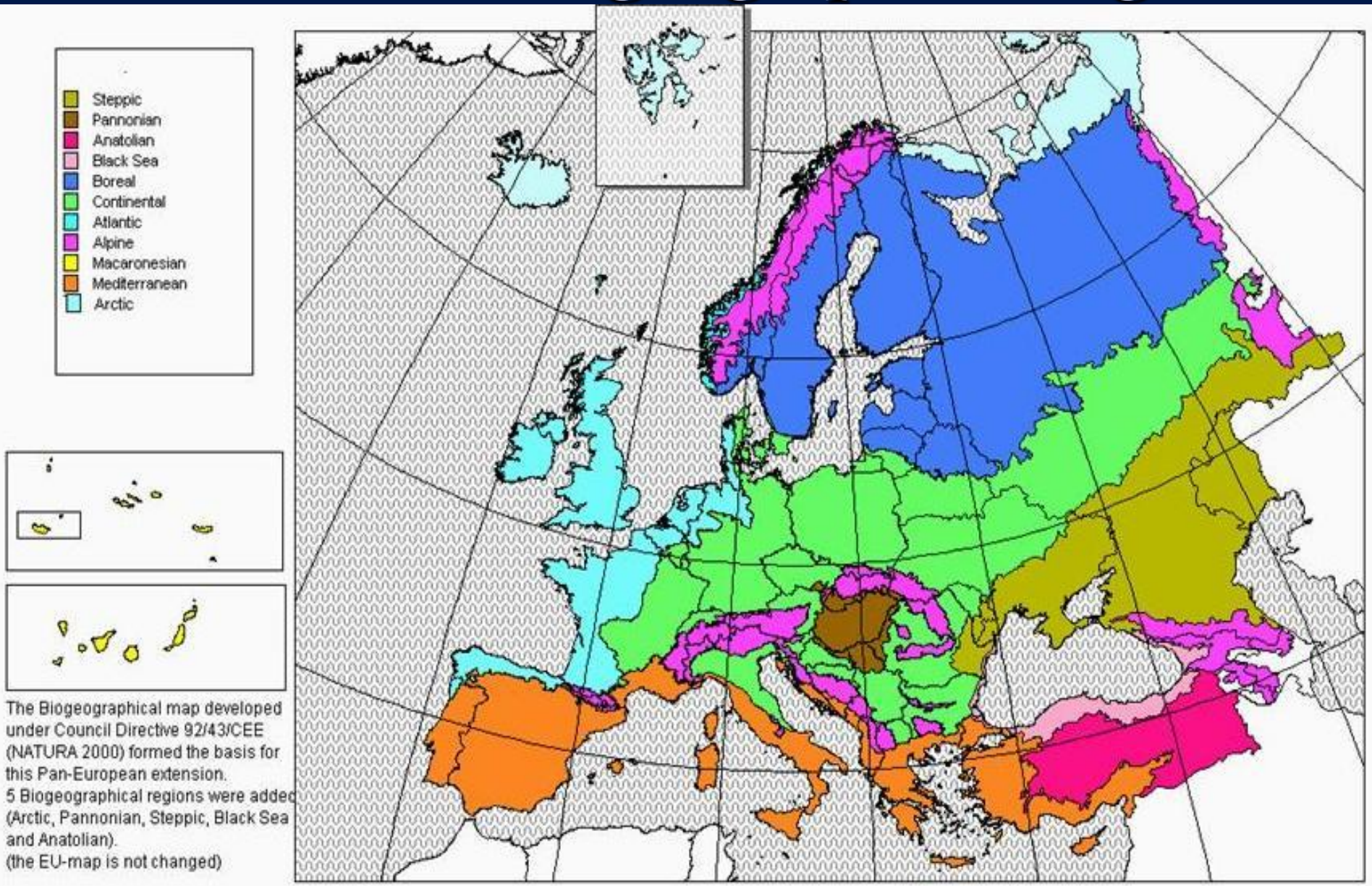


USDA zones according to winter hardiness



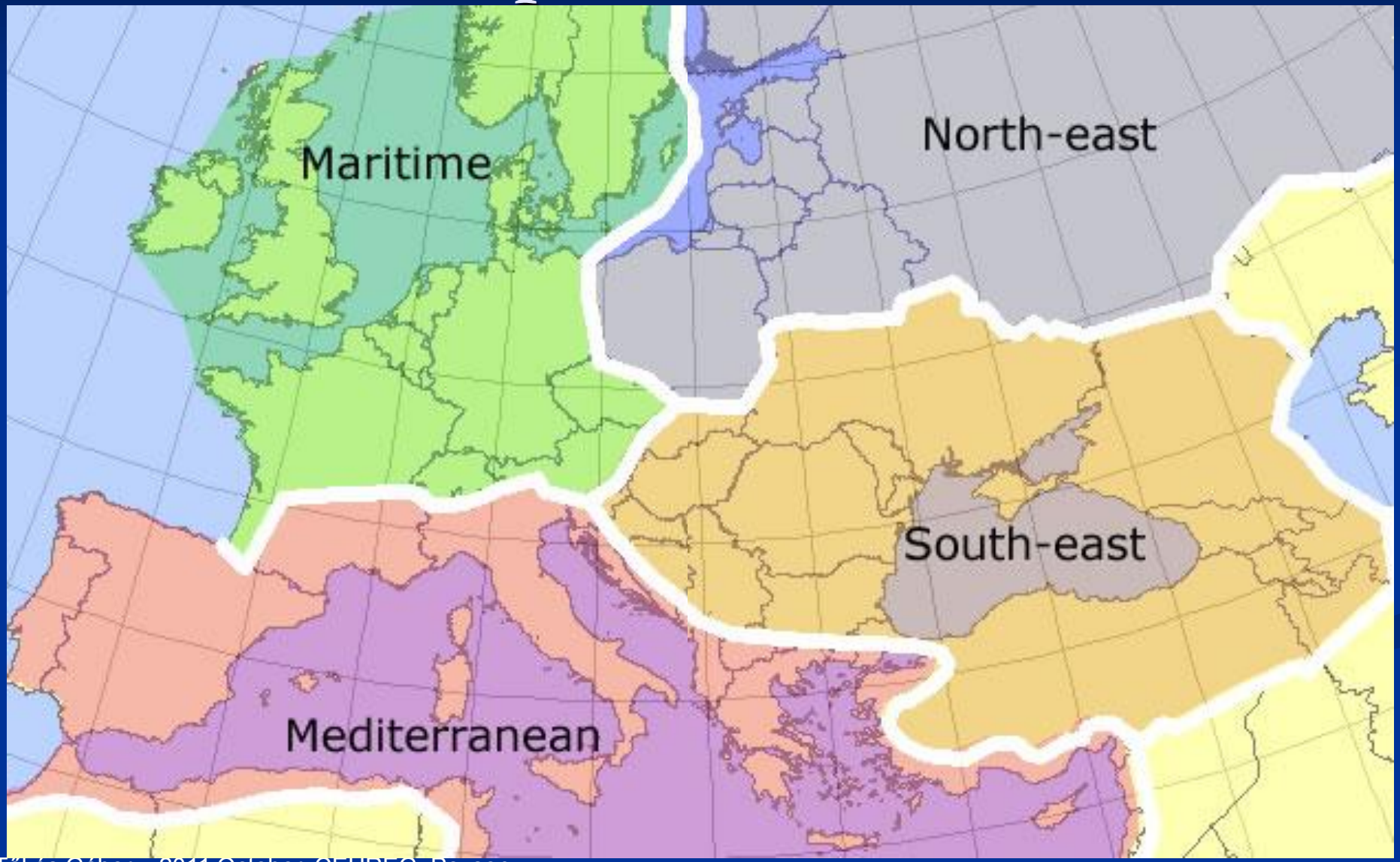
Zone 5 (-26 °C)
Zone 6 (-21 °C)
Zone 7 (-15 °C)
Zone 8 (-9 °C)
Zone 9 (-4 °C)
Zone 10 (+2 °C)

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)

EPPO zones (PP 1/241) comparable climats



Trial numbers

- Efficacy should be proved to the relevant EPPO zone of the zRMS or AMS
- Trials should be representative for the area of potential use
- Trial number: 10 trials (6-15) as mean proposed in a region within 2 years

Duration and number of proposed efficacy trials in the S-E EPPO zone

Cases of active substance, plant protection	*trials*		*Related to*
	Minimum duration	*Total number*	
1. Plant protection product containing **active substances not authorised** in Hungary in case of **major crops and major pests**	**2 year**	**6 – 14**	each crop
2. Plant protection product containing **active substances not authorised** in Hungary in case of **minor crops or pests of minor importance**	**1-2 year**	**3 – 6**	each crop
3. Extension of the authorisation of (new or authorised) plant protection product containing **active substances authorised** in Hungary to other **major crop or major pests**	**1-2 year**	**4 –14**	each crop or each crop group
4. Extension of the authorisation of (new or authorised) plant protection product containing **active substances authorised** in Hungary to other **minor crop or minor pests**	**1-2 year**	**3 – 6**	each crop or each crop group
5. **Authorised active substance in new plant protection product**, in case of authorised crops	**1 year**	**2 – 6**	each crop group
6. Extension of the authorisation of new preparation or authorised plant protection product to other crops or pests **under protected unit**	**1-2 year**	**4 – 8**	Each crop or each crop group
7. **Change of pest management techniques** for authorised plant protection product (e.g. reduction of application rate, change of application, tank mixture)	**1-2 year**	**4 – 8**	each crop
8. **Changing of preparation**, changing of additives	**1 year**	**2 – 6**	each crop group, or cultivation sector *
9. Additives used in authorised pest management techniques	**1 year**	**1 – 3**	Type of PPP (H,F,Z,R) and cultivation sector *
10. Products, pheromones, as well as parasitoids and predatory organisms of plant protection effect **not qualified as plant protection products,** equipment used for plant protection	**1-2 year**	**2 – 6**	All crops/pest

5.6. Proposed number of phytotoxicity tests and yield measurements (N = number of direct efficacy trials)

	Herbicide (H)	**Fungicide (F)**	**Zoocide (Z)**	**Regulator and other (R)**	**Seed dressing**
1. Phytotoxicity and yield measurement in separate study	**2 – 4**	Only in case of problem	Only in case of problem	Only in case of problem	Only in case of problem
2. Phytotoxicity in efficacy trial	**N**	**N**	**N**	**N**	**N**
3. Phytotoxicity under protected unit	**N**	**N**	**N**	**N**	**N**
4. Yield measurement in efficacy trial	**2-4**	**2-4**	**2-4**	**N**	**2-4**

**Cultivation sector: Category 8 – field crops, vegetables, fruit, grapes, category 9 – field and horticultural crops.*

Result of detailed efficacy trials

- Prove of intended use, or
- Differences within 1 zone

- Differing labels in the MSs, but only within risk envelope (worst case is covered)!
  e.g. 2.0 l/ha in DE but 2.5-3.0 l/ha in HU and 1.5 l/ha in NL

STAFF

- Art 75 (3) Member States **shall ensure** that competent authorities have a **sufficient number** of suitably qualified and **experienced staff** so that the obligations laid down in this Regulation shall be carried out efficiently and effectively
- **Lack of staff can be the biggest obstackle against proper working of the new system**
- **Pile of 'old' aplication+ New tasks + shorter deadlines !**

New tasks

- Zonal evaluations
- Accepting registrations (120 day)
- a.s. renewals: AIR 2 and AIR 3
- Comparative assessment
- Modifications on zonal level
- Step2 on zonal level (work-sharing)

PROPOSED MINIMUM NUMBER OF STAFF

Evaluation **(Identity, Physchem, Anal, Residue, Tox, Ecotox, Fate, Biol)**	18
Step2 coordination	2
Zonal coordination	2
Reg. Document compiling (H,F,Z,R)	4
Administrative changes	1
Emergency and trial reg.	1
Administration	1
Juristic matters	1
Σ	30

Proposal – staff

Reg.fee is enough to maintain the necessary staff, if turned just to this purpose - no need for state investment!

COM should warn MS Ministries to fulfill Art 75 (3) with 30 people as minimum and 40-50 as optimum

Common aim: well working system