

Zonal applications – Hungarian experiences

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- Not overall analysis of the zonal applications
- Pick out some typical problems:
 - In the procedural / administrative field
 - In the field of technical assessment
- HU zonal work in figures





Procedure - Clock starts



- zRMS evaluation (12 month) starts at finishing completeness check (UK interpretation)
- 120 day cMS accepting process:
at the receipt of the assessment report and the copy of authorisation of zRMS
Uploading of RR on CIRCABC is not enough.
- HU: 120 day starts after zRMS authorisation (English version) and application arrived



Clock stop



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Termőföldtől az asztalig

zRMS procedure can be suspended for max. 6 months

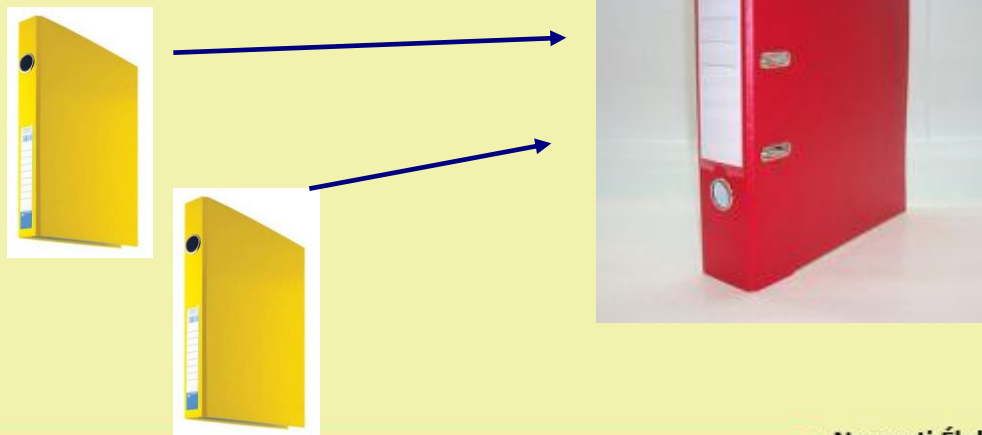
No harmonised approach, but in most countries:

- Clock is stopped as often as necessary until the 6 months are used up.
- Clock stop is started:
 - After completeness check
 - During evaluation
 - While waiting for MRLs
- Clock starts again
 - When the information arrived in the post room provided that the information received is correct and answers the question.



Acting as zRMS – quality of dRR

- dRR is a coherent and standalone document
- Again occurring problem if PPP contains more active substances
a.i. data are used, but PPP evaluation is not elaborated into one dRR



Efficacy issues



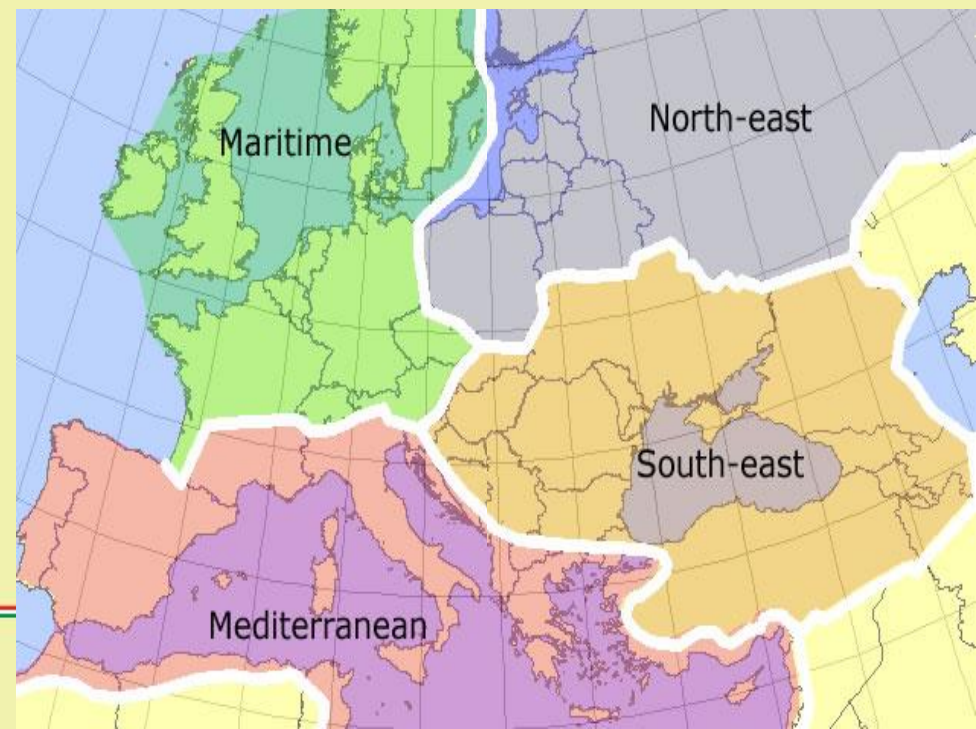
- Central political zone involves 3 climatic zones
- All relevant EPPO zones should be covered
- Lack of evaluation causes problems for cMS

If no evaluation of an EPPO region by zRMS:

cMS can refuse application

or

Carry out evaluation during 120 days



Coherent and well built biodossier



dRR sec. 7



Biol. Ass.
Dossier



Trial
reports

- Crops must be planned in advance by applicant
- EPPO zones should be evaluated separately
- Too much tables – some text evaluation is needed
- Diagrams are useful
- BAD should contain all relevant data (applications)
- dRR should be understandable alone (not copy of some pages from BAD)

Experiences with efficacy



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- Applicant wanted 2 x more crops in cMS than evaluated in zRMS, referring to his similar PPP in cMS – impossible
- Mutual recognition of crops that were evaluated only as minor crops in the reference MS but major crops in cMS – not possible
- Growth regulator from zRMS, with also pesticide effect, but it is not evaluated for the S-E EPPO zone – cMS authorisation only as PGR in HU till trial results arrive
- zRMS refused due to national efficacy GD - we intend to issue authorisation as all other sections are OK, and efficacy is acceptable in S-E EPPO zone

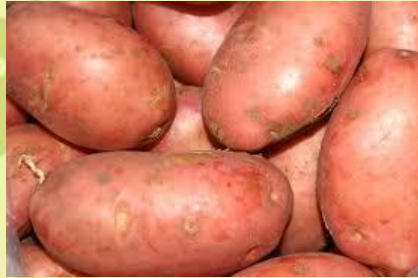


Ecotox, fate evaluation

- In case of failing in a water scenario, some zRMS stops evaluation and does not continue to Step4 refinements - cMS has to evaluate
- Similar case with vole (*Microtus arvalis*) representing small herbivorous species – no refinement in evaluation means passing it to cMS
- Nontarget plants study only in zRMS – same problem as in efficacy, if the agroecological region of cMS was ignored



Example for amendment authorisation existing in both MSs...



- zRMS issues authorisation in potato, applicant wants registration in cMS also in sunflower, not grown in zRMS
- 3 solutions:
 - a) zRMS evaluates sunflower despite it is not existing there
 - b) during 1 year evaluation cMS can cooperate
 - c) cMS accepts potato, and later evaluates sunflower - label extension

Applications under Regulation 1107/2009/EC 2013-14

Status	Number
New authorisation issued - HU zRMS	3
Label extension issued - HU zRMS	1
New PPP evaluation in progress - HU RMS	3
New authorisation issued - HU cMS	15

Applications for re-registration under Directive 91/414 – voluntary work sharing



Status	Number
Zonal voluntary work sharing finished until 2013	4
Zonal voluntary work sharing to be finished in 2014	5
Zonal evaluation in progress – submission in 2013-2014	14



Workload in zonal procedure - reasons



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- 91/414 - „Last minute” submissions (**100 before June 2011**)
- Preparing monographs in 2012-14 (**5**)
- **Administrative tasks** (clones, amendments)
- Same staff for a.s. and PPP evaluations

Workload in the near future

- CLP (2014-2015)
- Renewal of PPPs according Art. 43
- Comparative assessment and substitution



Zonal capacity – HU zRMS:



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- New authorisations: 5-6 / year
- Voluntary work sharing: 5-8 / year





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Thank you for your attention!

