TWO YEARS OF 1107

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Main aims of zonal autorization

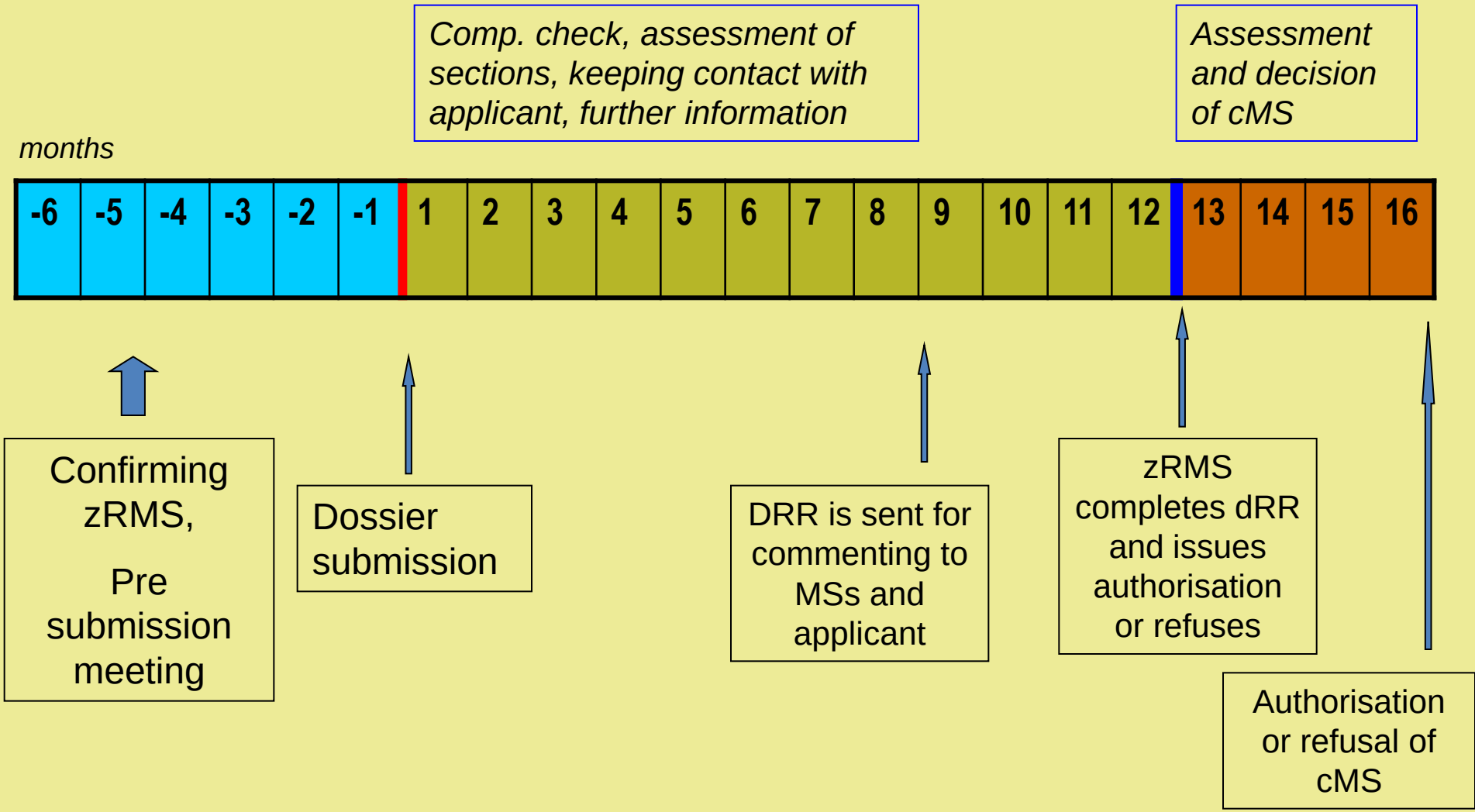
- To avoid duplication of work and to reduce workload
- To enhance the procedures and to reduce the administrative burdens
- To provide for more harmonised availability of plant protection products to users.

HOW ARE THESE AIMS FULFILLED ???

Changes in evaluation

91/414 EEC:	1107/2009 EC
•time 18-24 months, •national language, •different formats •Reg.report often not applied •MR is often not possible 	•time 12 months, •reg.report in English •mistakes are observed and commented by other MSs •Evaluation for more MSs, or full zone •DRR is made by applicant **Evaluation is more difficult, but applicant's dRR helps much** 

The draft system



Applications under Regulation 1107/2009/EC
HU zRMS

Status	Number
New authorisation issued	1
New PPP evaluation in progress	5
Amendment – label extension	1
Notifications – intended submission in 2013-14	7
Applications withdrawn	2

Applications under Regulation 1107/2009/EC
HU = cMS

Status	Number
New authorisations issued (2013)	5
Evaluation in progress – submissions in 2011-13	78*
Notifications for authorisations	60-70
Zonal amendments (formulation change, label extension)	7
Application for mutual recognitions	19

*73 Central Zone + 5 Interzonal

Re-registrations

Status	Number
Zonal voluntary work sharing finished	4
Zonal evaluation in progress - submission in 2012-2013	7
Intended submission for voluntary work sharing for 2013-2014	12
National re-registrations finished in 2012-2013	23
National evaluation in progress	9
Intended national evaluations for 2014	20

Applications for re-registration under Regulation 1107/2009/EC – HU zRMS

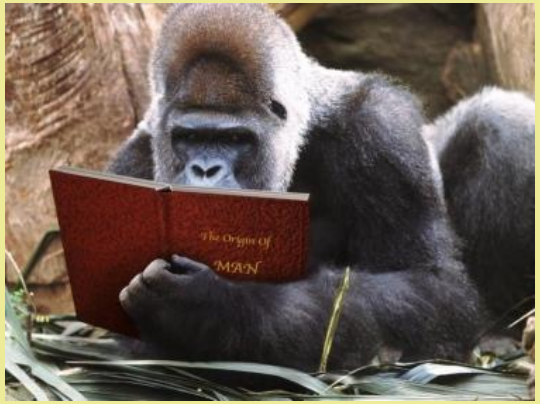
Intended application for 2014	1

Applications for active substance approval/re-approval

Status	Number
DAR completed in 2012-2013	2
DAR ongoing in 2013	1
Intended application for renewal (HU-RMS) in 2014-2016	5
Intended application for renewal (HU-coRMS) in 2014-2015	5

Experiences with dRRs (HU=zRMS)

- **PPP1** 2 a.s. = 2 manufacturers 2 different dossier - dRR must be unified by applicant !
- **PPP2** New a.s. – still not in positive list endpoints of dRR differs from EFSA conclusion ! - waiting for applicant's modifications
- **PPP3** Reg.report hidden in CADDY, not coherent, fragmented - difficult to find
- **PPP4** S-E EPPO zone is not covered – applicant wants evaluation only for other MSs and only minor use for HU



- **PPP5** Application for crop extension of an old authorisation where no old dRR exists – re-evaluation of the whole ?

- 1 year deadline can be kept
- Clock stop max 6 months – can be devided for more parts(e.g 2 x 3 months ?)
- Extension of 91/414 authorisation – DRR only for new crop?
- Application only for 1 MS – procedure is the same, but what should DRR cover (1 MS or whole zone?)

Experiences as cMS (Art 36-37)

- 120 days must be kept
- Use can be different, but within risk envelop
- Clock stop is possible? (e.g. in case of lack of national label)
- Sensitive areas: Fate and efficacy should be covered
- Applicants generally fulfil fate & efficacy for cMS
- Lack of evaluation relevant for cMS:
  - fate scenarios were not evaluated for HU by zRMS1
  - fate scenarios were evaluated according to national model and not according to FOCUS by zRMS2
  - efficacy is often not evaluated for S-E EPPO zone by zRMS from other EPPO zone

Authorisation of refused PPP in cMS?

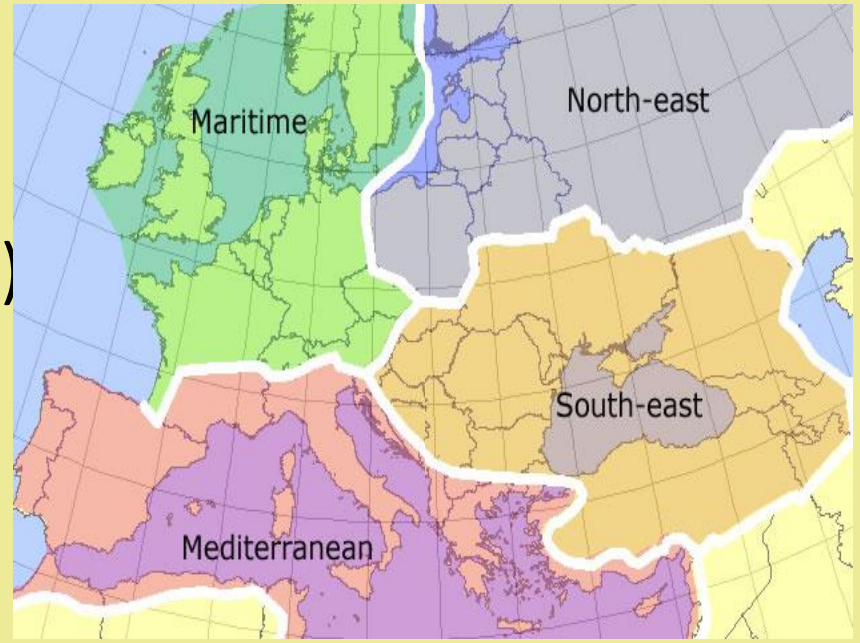
- zRMS refusal because of **unacceptable risk** in the zone – **cMS can not authorise**, but theoretically can reevaluate as new zRMS (not practical)
- zRMS refusal because of **conditions specific** to its territory, **cMS can give authorisation,** if reevaluated the specific area

- Example: zRMS refuses because of failing national fate assessment or missing relevant efficacy data, cMS can judge data are satisfactory for it, and can give registration, despite the original copy of authorisation does not exixst.

Conditions for authorisation as cMS (Art 36) or MR (Art 40)

- National requirements – tendency to decrease them
- Important factors, differing within a zone:

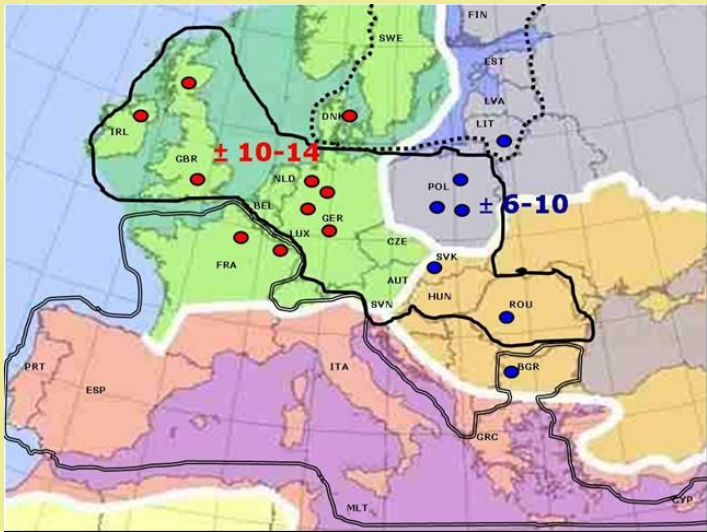
- Relevant fate scenarios for cMS
- Efficacy evaluation for S-E EPPO zone (PP1/241)



Trial number and location

- Efficacy should be proved to the relevant EPPO zone of the zRMS or cMS
- Trials should be representative for the area of potential use *(not all from the same county)*
- Trial number : (EPPO 1/226)

  6 - 15 trial / ~~MS~~ ~~Eu zone~~ EPPO zone
- EPPO **Case studies** for pesticides: **20-30 trials for the central zone**
- **Trials from different political zone can be regarded**



Case study for yellow rust in wheat

Guidance of HU on trial number

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.*

Suspension of authorisation

(e.g. neonicotinoids)

- Not regulated in 1107 – thus generally not possible
- In case of temporary restrictions - withdrawal
- Can be used only in MSs where national legislation allows (e.g. DE)

Seed dressing with non-authorised product (Art 49)

- Import and **sowing is poss**ible if registered in 1 MS but
- **Treating of seed is not allowed** – registration is necessary
- In reality the main risk is at sowing and not at treatment !
- The new situation causes problems for the seed treating companies. *(e.g.neonicotinoid restrictions!)*
- France allows treating
- It is good to put sowing prescriptions in the authorisation certificate. (good experience in HU)

National or zonal process ?

- In general:
  - modifications that need evaluations are **zonal** (need DRR)
  - administrative modifications, clone and parallel registrations are **national**

  BUT:
  - 91/414 authorisations not gone through Step2 can be modified nationally
  - Step2 of authorisations (even published after June2011) where a.s was evaluated according to pre June 2011 process, are evaluated according to 91/414 (national or voluntary zonal work-sharing)

Emergency use (Art. 53)

- Only if no alternative for a problem

I: PPP with not approved a.s.

II: not registered PPP with aproved a.s.

III: authorised PPP with new use
(often on minor crop)

- I + II only few/year/ MS
- III more often happens

Better way to extend original authorisation for minor use

Minor use

- Interpretation of Art 51
- Legally zonal, but practically zonal process is against the intention of 1107.
- Who writes dRR?
  PoAI: If company applies, he should do, if association applies, authority should write
- DE developed minor use dRR template
- Comment is not necessary
  (Who wants to comment some hundred ha of Asparagus in Hungary?)
- HU has program for official MU extensions, but zonal process can be applied only step by step if conditions exist.

Parallel import

- Advantage for users: **decreasing prices**
  Concern for users: **danger of fake products**

- **Re-packaging** is allowed but the product have to remain equivalent.
- Re-packing is an important source of fake products

- Prohibition of re-packing is not proposed in GD, as not mentioned in 1107

- Some MSs prohibit re-packing
- Inhibition of re-packing with administrative obstackles?
- Bad packing is not allowed at parallel import
- **HU does not allow re-packing since January 2013**

Parallel import 2.

- **Expiry date**: Generally the date of reference product.
  In case of ‘marketing withdrawal’ of ref. PPP, parallel can stay.
  Prolongation is not automatic, must be applied !!
  Otherwise parallel would live forever, even without real import.
  By Step2 of ref. product (re-reg = new registration number) parallel must be renewed.
- Parallel import must come from MS issuing the composition
  Sometimes import comes from other MS – how to prove?

- **Parallel import of parallel import** – possible ?
GD does not support, but legally doubtful

- Court case with a PPP – original in FR, parallel in UK, and a company wants to import back it to FR as parallel of parallel.(How is it profitable ??)

Clone registrations (2nd trade names)

- Allowance of selling a product on different names
- Not directly regulated in the 1107
- Marketing vs. consumers – **virtual choice increase**
- Dramatic increase in number of applications since 2012 inHU
- Number of names can not be limited legally
- New in HU: For information of users, obligation for marking the reference name with 30% of the new one

Clone name 60pt

Reference name 18pt

Authorisation of generic products

If generic wants to use „reference" dossier:

- Data protection must be over
- Reference product must have evaluation according to Annex VI + English reg.report (generally this is not the case in Eastern MSs !)
- Generic must submit minimum dRR part A and part C
- Problem if no original Step2, or not UP
- Ongoing discussion in EU about the requirements
- GD is planned for 'minimal' dRR

Refusal of zRMS role

is it possible ?

- Legally not, practically yes
- No capacity even for the present tasks
- New step2 can make the system collapse

FEES

Article 74 (2)

Member States shall ensure that the fees or charges referred to in paragraph 1:

(a) are established in a transparent manner; and

(b) correspond to the actual total cost of the work involved except if it is in public interest to lower the fees or charges.

Fees should be fully turned to authorisation tasks (staff) , but this is not the case everywhere.

Fees are paied by manufacturers, states should not turn it to other purposes (transparency !)

Conclusions

- More complication than simplification
- Good opportunitites for harmonisation and work-sharing
- Extra tasks for DNA-s and manufacturers
- Find practical solutions to solve problems
- Huge pile of tasks emerge in the near future
- System is in danger without solving staff problems