# EXPERIENCES AND DIFFICULTIES IN THE NEW AUTHORISATION SYSTEM

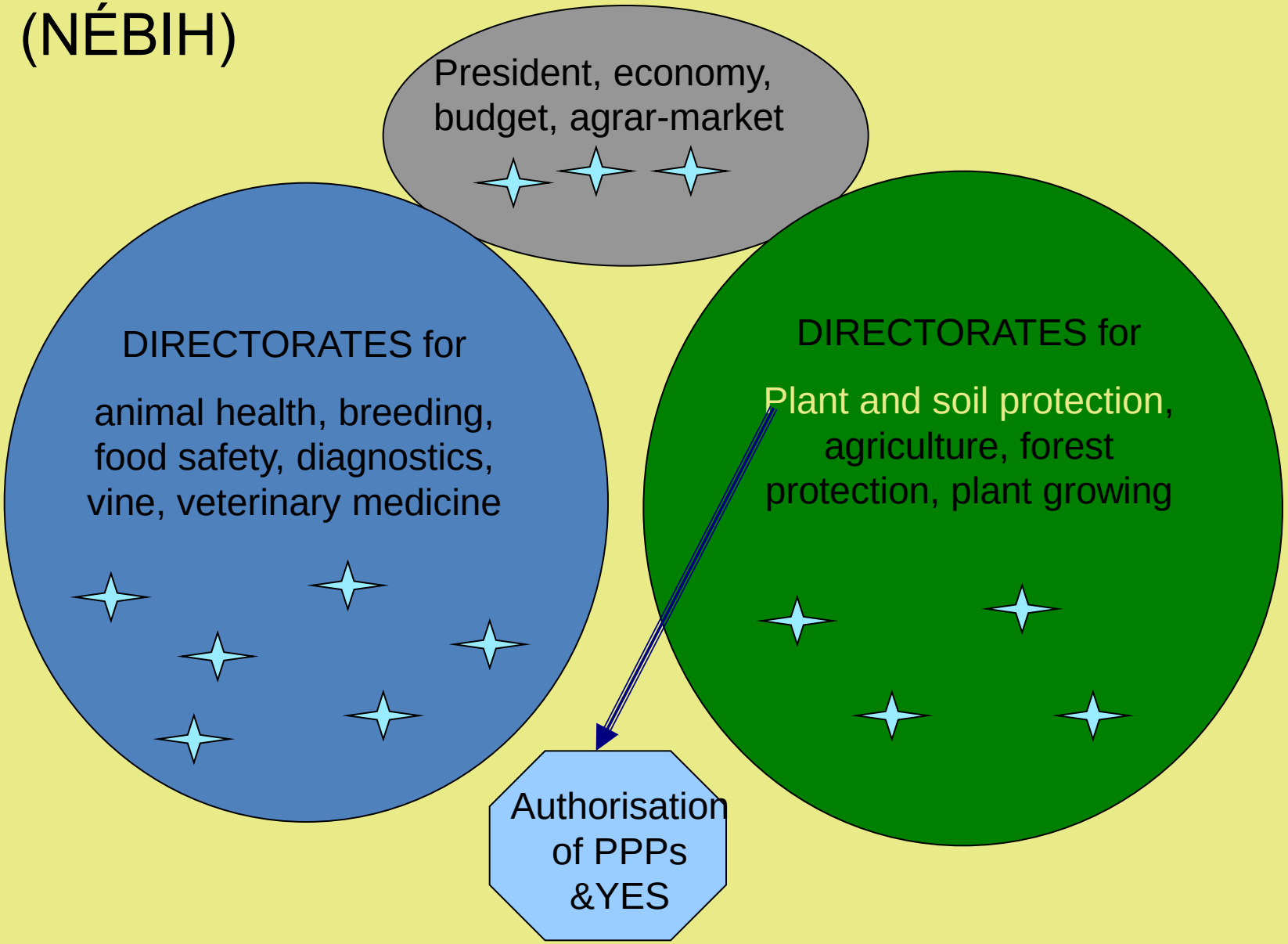
**Gábor Tőkés**

**National Food Chain Safety Office**

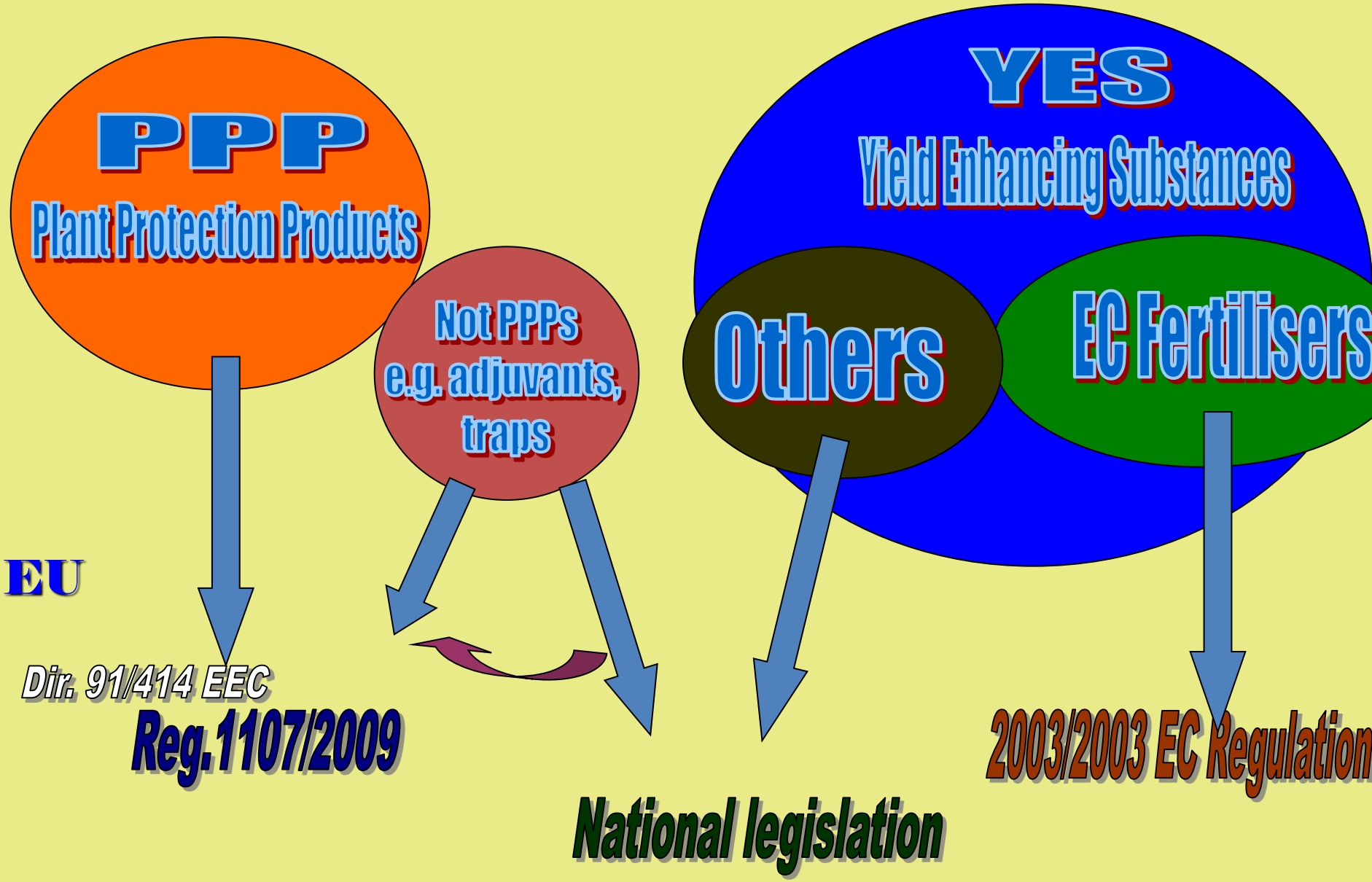
Directorate of Plant Protection ,
Soil Conservation and Agri-environment

**Agricultural institutes were merged into the**

# National Food Chain Safety Office (NÉBIH)



# Products used in agriculture:



# Products subject to authorisation

## ***Plant protection products (PPP)***

**Herbicides, Fungicides, Zoocides, Plant growth regulators**

**+ later on: Safeners,Synergists,Co-formulants,Adjuvants in 1107**
**(till COM reguléation : light Annex III on national level)**

***NOT PPPs***

***e.g.* Traps with stickers or pheromones, leaf sprayers etc.**

*In many countries not to be registered !*

## ***Yield enhancing substances (YES)***

1.Fertilizers, 2.Organic fertilizers, 3.Mineral fertilizers,
4.Composts, 5.Earthworm humus,
6.Soil improving substances, 7.Soil-conditioners,
8.Microbiological products (living)
9.Growing media
10. Plant-streghteners

*In many countries YESs are not to be registered !*

# Each product is to be registered in Hungary

With the exception of

Water, untreated manure, and EC fertilisers

**Number of registered products in HU : 827**

**(Date 2012.Sept1. - PPP+ notPPP, without YES)**

# Yearly workload of registration in the old system (2011, 2012)

| | New authorisation | Significant modification |
|---|---|---|
| PPP (+ notPPP) | 80 | 60 |
| YES | 60 (160 products) | 30 |
| Experimental | 100 (600 products) | - |
| Administrative change | 100 | - |
| Parallel import | 30-40 | - |

# Workload in the new system

| | |
|---|---|
| Zonal evaluation and new authorisation issued (HU=zRMS) | 1 |
| Submission and evaluation in 2012 (HU=zRMS) | 5 |
| Submission and evaluation in 2013 (HU=zRMS) | 5 |
| Submission for accepting (HU=cMS) | 50 |
| Zonal amendments | 7 |
| Mutual recognition (Art 40) | 5 |
| Step 2 Zonal evaluation/voluntary worksharing - submission in2012 | 10 |

# Step2 re-registration

## 91/414 can be followed

Starting point 2004 (EU accession) :
92 active and 190 PPP to be transferred to the EU system

•**1st class step2** - Zonal evaluation/voluntary worksharing English reg.report, cMS can change endpoints, GAP and risk management. Flexible but often no dRR

•**2nd class step2** – national evaluation according to Annex VI - Hungarian report

•**3rd class step2** - fast evaluation , short report

•**4th class 'step2'** – in case of old authorizations with obviously wrong classification – new CL based on MSDS, checked by experts

# Experiences with zonal evaluations

- **PPP1** 2 a.s. = 2 manufacturers → 2 different dossier
  -
  dRR must be unified by applicant !

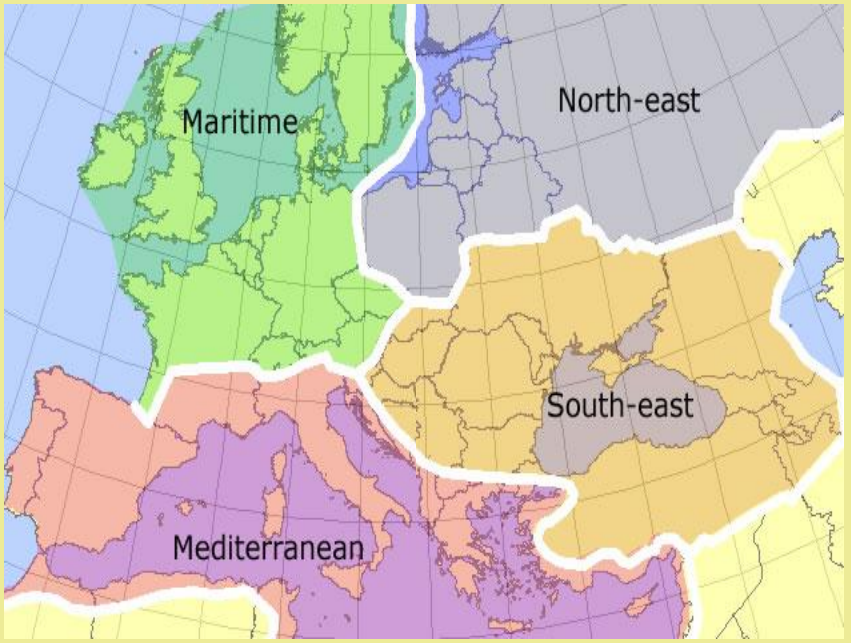
- **PPP2** New a.s. – still not in positive list
  endpoints of dRR differs from EFSA conclusion !
  - waiting for applicant's modifications

- **PPP3** Reg.report hidden in CADDY, not coherent, fragmented - difficult to find

- 1 year deadline can be kept

# Authorisation as cMS (Art 36)

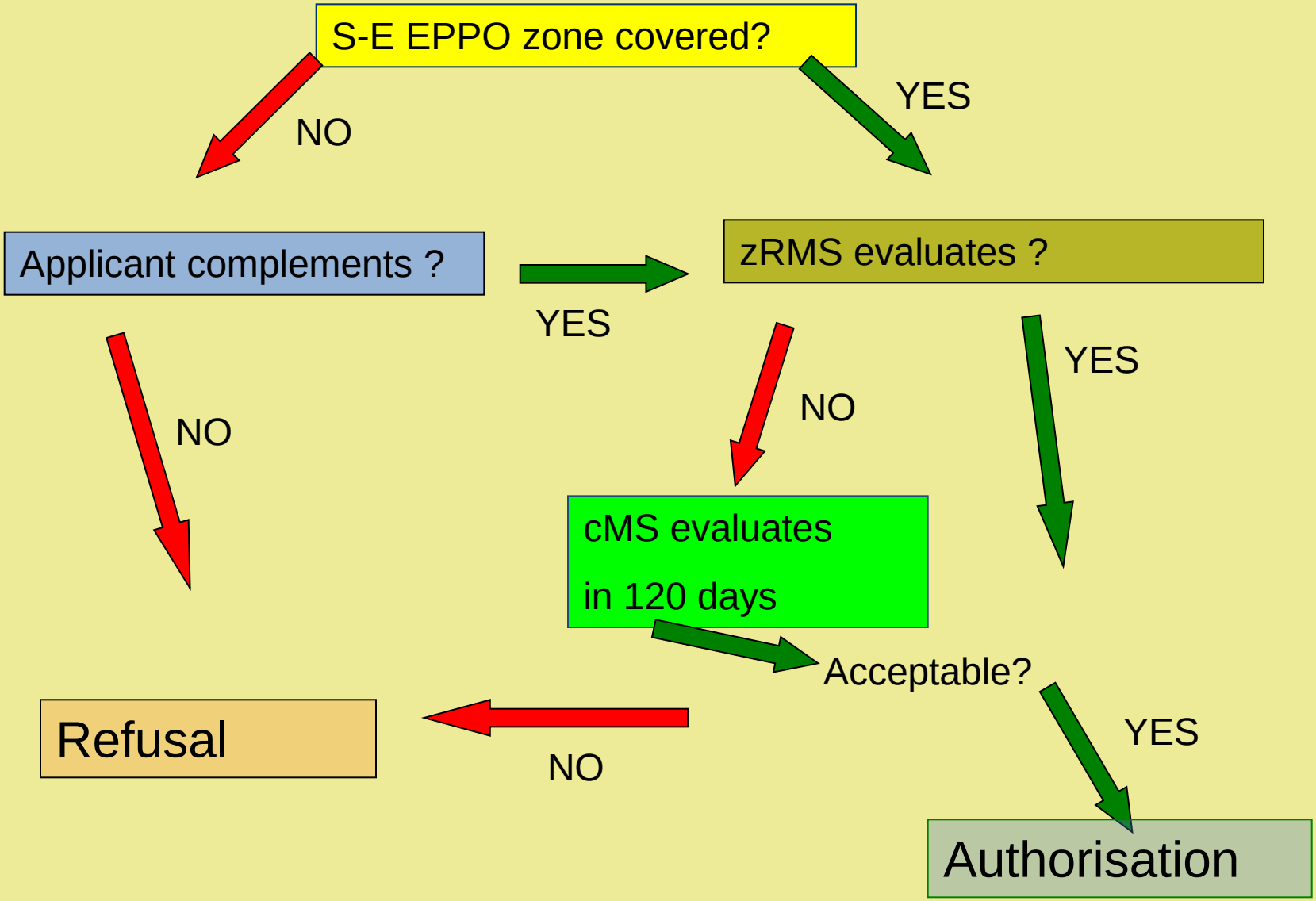
- Still no finished case
- HU has no specific requirement
  but we stick to
  1. Relevant fate scenarios
  2. Efficacy evaluation for
     S-E EPPO zone (PP1/241)



# Procedure as cMS

- After getting application , Biol dept. checks if S-E EPPO zone covered with efficacy trials
- If not, applicant is asked to carry out trials
- Same with fate scenarios

# Procedure for efficacy



# Refusal based on efficacy ?

- Art 36(3) - Not possible, only on health and environmental reasons
- Art 41(1) – perhaps - this was the intention but sanction is not in the text
- Art 29 – Yes, efficacy is essential for authorisation
- EPPO and EU efficacy guidances (being prepared) – PPP should be tested in the relevant EPPO zones

Conclusion of Central Zone: Everybody should be cautious with this topic

Policy of HU: without relevant efficacy evaluation authorisation can not be granted

# Difference in GAP on the label

## Is it possible ?


- Yes, ‘same use’ means crop but not GAP
- 2 main reason:
  - optimal dose differs inside political zone
    (going to East higher herbicide and lower fungicide)
  - MS practice to give range or only max. dose
    (e.g. 2 l/ha or 1-2 l/ha)

*(EPPO efficacy workshop 2012 October 2-4, Wien)*

GAP difference must be inside the risk envelope !!!

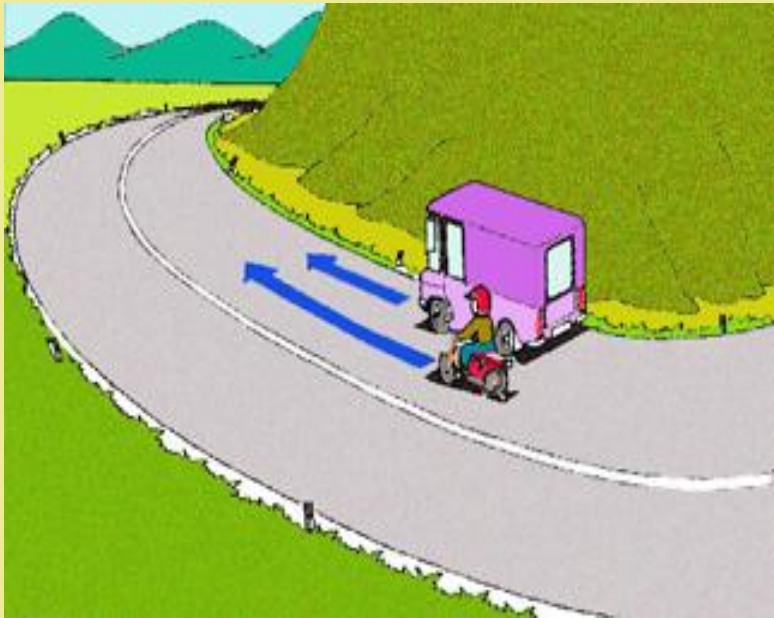
(no higher dose, more treatment or shorter waiting period etc)

# Clock starts…

- For 12 month zRMS evaluation at finishing completness check (UK interpretation)
- For 120 day cMS accepting process:
  when evaluation and copy of authorisation of zRM arrived to cMS.
  Uploading of RR is not enough.
- HU: 120 day start must be applied – this is start of process (otherwise payment would be necessary before zRMS evaluation )

# Mutual recognition of 1107 products (Art 40)

- New tendency: Misuse of Art 40 for avoiding zonal system (Art 33) !
- Applicant goes only to 1 MS, then asks MR in others - no zonal evaluation
- Intention was to authorise more years after zonal evaluation
- What should be evaluated ?
- Risk of more refusals ?



# Mutual recognition of generic products

- Art 34 allows use of existing (original) documents, if generic PPP is „similar”
- Requirement for generic is not clear
- Similarity depends on opinion of zRMS
- cMS can have other opinion

**Are they similar?**

# Mutual recognition of generic products
# Case study

- Generic applied for authorisation of a fungicide before June 14. 2011 in a zRMS
- zRMS refused authorisation according to 91/414
- Generic applied again after June 14. 2011
- zRMS issued generic authorisation at the end of 2011 based on an old dossier of the original company (PPP was similar, but all component except a.s. was different)
- Generic applied for MR in CZ, SK and HU immediately referring to Art 40 & 34
- CZ, SK, and HU refused giving authorisation – partly because Step 1 was not still done and access to some study was not clear
- In middle of 2012 zRMS carried out Step 1 and proved its equvivalency together with data access
- Generic is waiting for decision of CZ, SK, HU

# Mutual recognition of 91/414 products

- Not original intention of 1107
- Legally doubtful – PPPs did not go through the zonal process
- DE still does not recognise
- HU allows it from Oct 2012 because of practical reasons
- Conditions in HU:
  English reg.report + efficacy in the S-E EPPO zone
  (+ relevant fate scenarios + copy of authorisation paper)
  **Applicant should declare he will not stick to the 120 day deadline**

# Amendment of old authorisations

- Administrative changes (name, 2nd name, owner, address, prolongation ) – we do nationally
- Improving the quality of old authorisations – 3rd and 4th class of Step2 - we do it nationally because step2 is under 91/414
- User category modification – national issue, can not be interpreted in other MSs – despite some evaluation is needed
- Significant amendments (extension of use)
  if still no step2 – national (?)
  after step2 - zonal

# Minor use

- Legally zonal, but practically zonal process is against the intention of 1107.
- If company has no dRR, who will write it? (DNA?  Growers? )
- DE developed MU dRR template
- Who wants to comment some hundred ha of Asparagus in Hungary?

# CLP regulation classification

- 1272/2008 manufacturer's responsibility
- 1107/2009 authority's responsibility
- COM statement 25.04.2012: PPP suppliers can not decide alone without accepting or amending by DNA
- On the label only 1 type of classification (either ATP or CLP but not both)
- We incorporate both classification into authorisation papers step by step


# Parallel import

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

- Re-packing is an important source of fake products (we have some evidence)
  1 t original + 9 t illegal = 10 t legal product?
- Prohibition of re-packing in not proposed in GD, as not mentioned in 1107

- Some MSs prohibit re-packing
- Inhibition of re-packing with administrative obstackles?
- By using original name we do not allow re-packing
- Bad packing is not allowed at parallel import

# Commenting and capacity

- Our experts commented only few times
- Commenting would need extra capacity
- Zonal process and English evaluations need more work
- In 2012 we had staff reduction , not increase
- COM should urge governments to keep Art 75

# Conclusions

- Aim of 1107 was to simplify and fasten authorisation
- Result seems to be opposite
- Good opportunitites for harmonisation and work-sharing
- Extra tasks for DNA-s and manufacturers
- Find solutions to solve problems by the easyest way

# The most important : to survive


Thank you for attention