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# Special cases in the authorization procedure

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# Procedures different from normal zonal evaluations



- 1. Emergency use
- 2. Parallel import
- 3. Not PPPs with plant protection effect
- 4. Clone certificates





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# Emergency use



# §

## Emergency use



- Legal basis: Art 53, 1107/2009 EC regulation  
*...in special circumstances a Member State may authorise, for a period **not exceeding 120 days**, the placing on the market of PPPs, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means.*
- Art 79 of Regulation, Decision 1999/468/EC  
Standing Committee can be involved if needed



# Reasons for emergency applications

- No authorised product in the crop against relevant pest
- Lack of effective application method
- Withdrawal of important active substances, PPPs
- Obligation for rotation (fate, resistance)
- Aerial applications – non-expected situations (waterlogged area)
- Lack of PPP in minor crops
- Lack of PPP in eco-production





# Main types of EA

- I: PPP with not approved a.s.
- II: not registered PPP with approved a.s.
- III: authorised PPP with new use  
(often on minor crop)
  - I + II only few/year/ MS  
(10-13 in HU)
  - III more often happens



***Better way to extend original authorisation for minor use***

# Emergency use



- Differences among MSs
- Basically national issue to judge the case
- Strict control by MS authority
- Control of COM and the greens
- Consequence of refusing: illegal use, bigger danger
- Consequence of issuing: increasing need for products by other companies, or concerns



# Redentin - chlorofacinone

- The biggest EA in Hungary
- Historical background – well known by farmers
- Producer (REANAL) has no dossier
- Authorised products are not usable
- Bromadiolone, difenacoum have no authorisation in HU
- Brodifacoum is biocide – caused deer mortality by illegal use
- Extreme vole invasion in 2014 - 20-50% yield loss
- Chlorofacinone is better for environment than all similar substances - no secondary toxicity
- Strict follow-up by authority !
- Area in HU during one year:  
03.2014-02.2015: 211.000 ha





# Neonicotinoids & emergency

after restriction of treated seeds by  
thiametoxam, clothianidin, imidaclopride

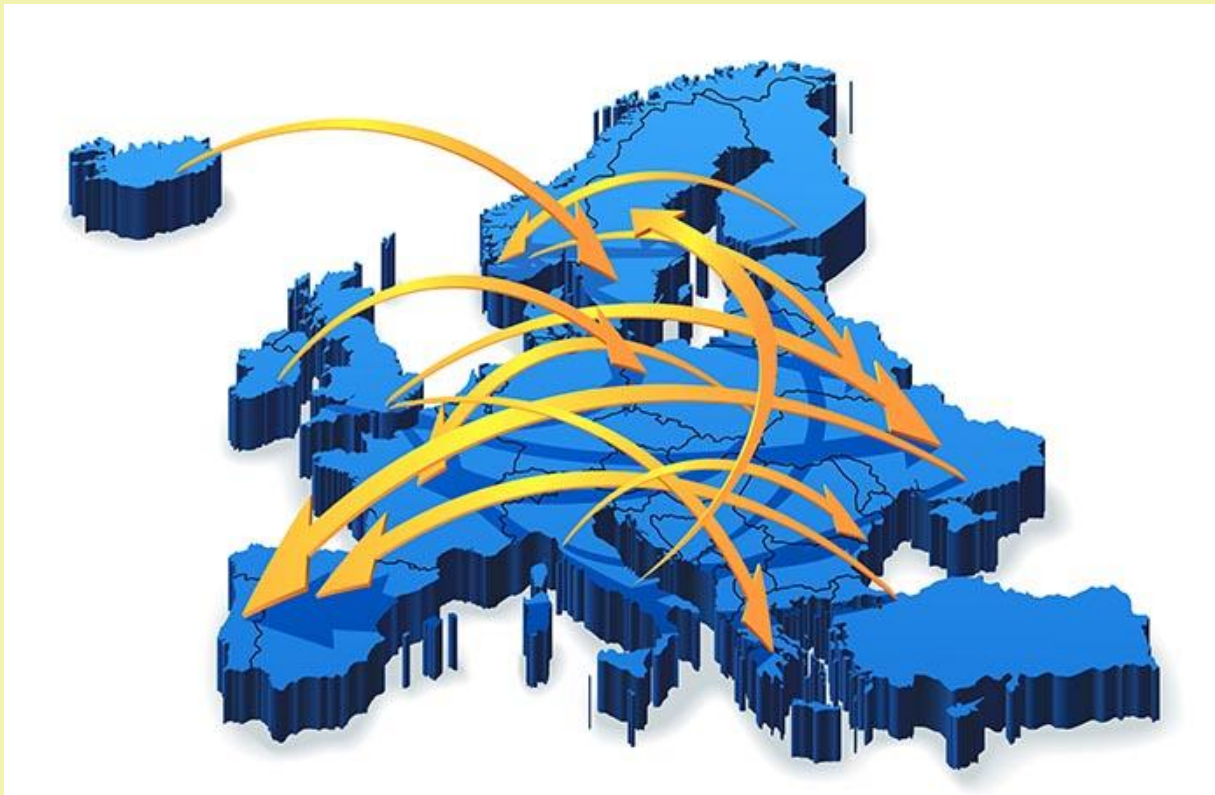
- Legal basis is not clear  
(Art 49 – Art 53 - 485/2013)
- Issued for rape in: Bulgaria, Denmark, Estonia, Finland, Latvia, Romania , United Kingdom
- Hungary: not issued during the 2 year moratorium – decision in the next future
- Dramatic increase of chlorpyrifos amount in HU – 3 x of previous 3 years average ⇒ more problem with bee poisoning





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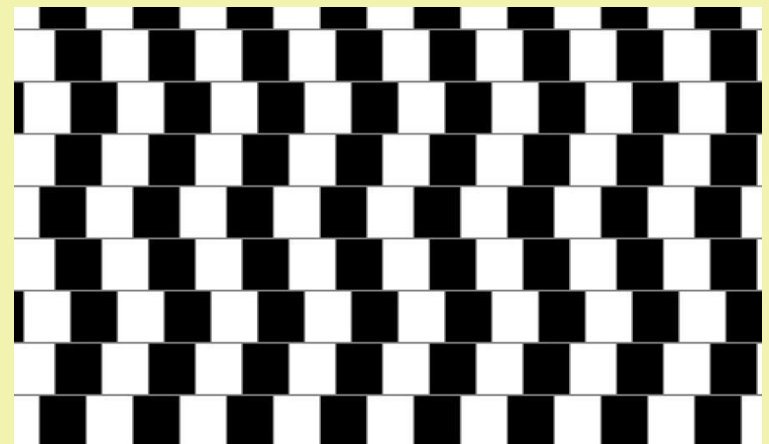
# Parallel trade permits in Hungary



# Characteristics of parallel trade in Hungary



- 170 parallel trade permits (started in 2004)
- Market share in 2014: 1,2 % (in the volume of sales)
- 16-18 companies involved in the parallel trade /2015
- Most frequent countries of origin: RO, PL, DE, SK, ES
- New player in the parallel trade business in HU:  
a generic company submitted  
32 applications in 2015  
(71% of all parallels)



# Statistics

Year	Parallel trade permits	Refused applications
2011	33	3
2012	49	3
2013	39	9
2014	24	1
Until 09/2105	45	2

## Reasons of refusal:

- The composition of the PPP is not identical
- The authorisation of the PPP in the MS of origin is not valid
- Product name (former product name is not allowed)

# Critical issues in parallel trade 1.



## Re-packaging – potential danger of falsification

- Regulation 1107/2009/EC does not prohibit re-packaging of products BUT traceability should be ensured (concerns e.g. repackaging outside HU: in the MS of origin or other MS)
- HU provision: re-packaging is not allowed, import only in original package



## Critical issues in parallel trade 2.



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### Trade name

- Possible names:
  - Own trade name for the parallel product
  - The same name as the reference product  
(Complaints by the representatives of the reference products)
- Not allowed trade names:
  - Name of former authorised (expired) product
  - Name of active substance alone
- Parallel traders should pay attention to the intellectual property rights



# Critical issues in parallel trade 3.



## Labelling

- Approved label is attached to the permit
- Clear display that it is a **parallel trade product** (MS of origin, original product name)
- Original **batch number** and production **date**
- Parallel traders should include the amendments of the reference product on the label



## Traceability and control in HU

- Announcement of the date and volume within 15 days of the import
- Control program started in 2015: priority sampling of parallel trade products together with the reference products (but only few parallels on shelf – direct distribution)



# Critical issues in parallel trade 4.



## Court case - Parallel trade of parallel traded products

Till 2014 it was not allowed

C-108/13 - Judgment of the Court (6/11/2014)- Mac GmbH v MOA (FR)

Parallel trade permit on a parallel traded product can be granted or refused case by case. Application may be examined by MS under the rules of the Treaty.

## How to handle the new situation in HU?

HU is the MS of origin: we are not in the position to grant information about composition.

HU is the target MS :  
only in original package, if there is reliable composition info

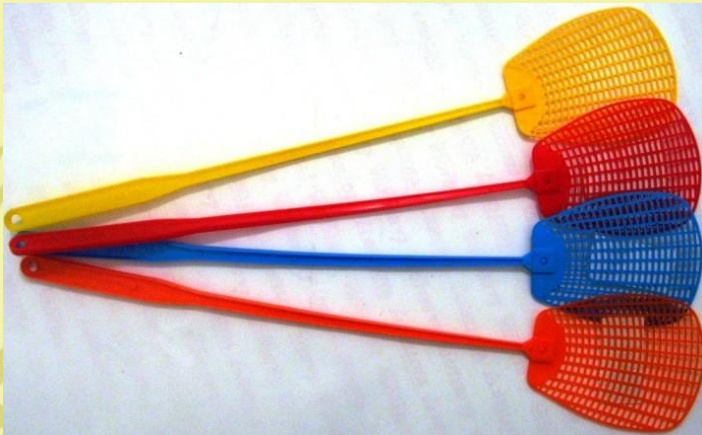






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# Not PPPs with plant protection effect



# PPP and not PPP

## Plant protection products (PPP)

Herbicides, fungicides, zoocides, plant growth regulators

+ later on: safeners, synergists, co-formulants, adjuvants  
in R. 1107/2009/EC till COM regulation : national issue as not PPP  
*In many countries not to be registered !*

## Not PPPs:

Products used in plant protection but not to be considered as PPP  
– not under the scope of R. 1107/2009/EC



# Products used in plant protection but not to be considered as PPP

HU: regulated in decree 89/2004 FVM about PPP authorisation

- Safeners, synergists, co-formulants, adjuvants  
They will go under R. 1107/2009/EC after COM regulation  
Cleaners, stickers, additives etc



- Plant protection tools (e.g. traps)



- Macro organisms



**Simple and cheap procedure (compared to PPPs)**

# Safeners, Synergists, Co-formulants, Adjuvants, Cleaners, Stickers, Additives etc.

- Data requirement similar to PPP but much lighter
- Less data needed and non GLP accepted
  - Identity
  - Phys-chem properties
  - Toxicology
  - Ecotoxicology
  - Efficacy
- In case of well-known substances literature data are accepted



# Plant protection tools (e.g. traps)

- Traps without pheromones or with pheromones but not used for mass trapping are not PPPs
- Tools containing repellents against wild animals, moles
- Simplified data requirement
  - description of tool and substance,
  - description of application
  - efficacy



# Macro organisms



Despite of plant protection purpose,  
not considered as PPP in the R.1107/2009/EC

Data requirements:

- Identity of the formulation containing macro-organisms
- Biological properties
- Biological activity, mode of action, efficacy
- Effects on human health,  
non-target organisms and the environment



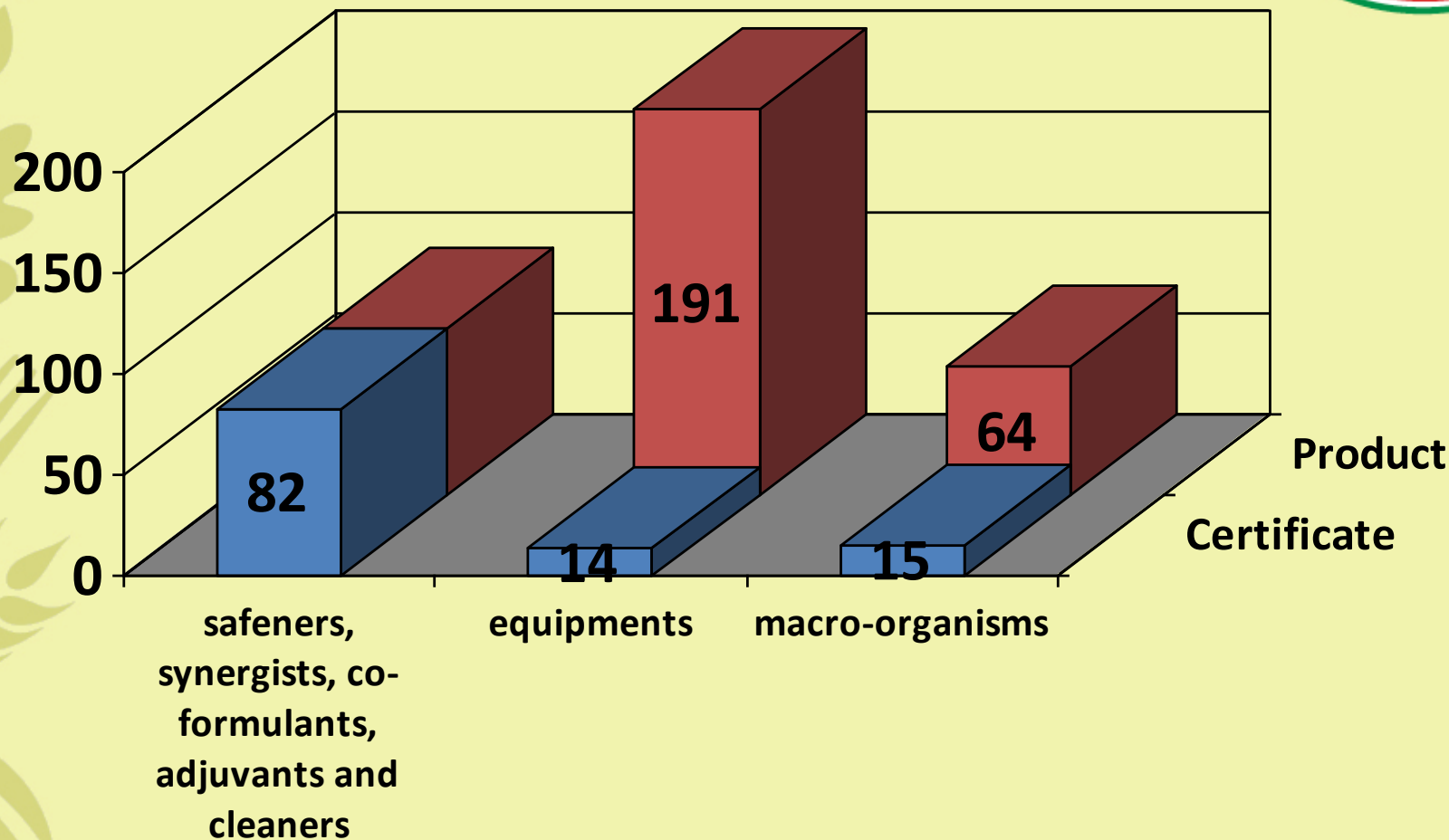
In case of newly introduced organism the opinion of  
environmental authority is essential

(bad example of *Harmonia axyridis* - harlequin ladybird)

# Number of products and certificates



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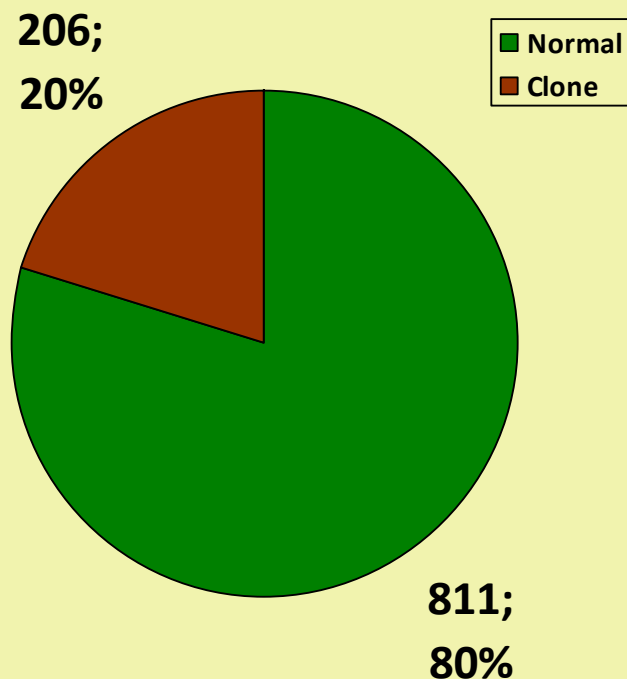
# Clone certificates





# 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 in HU



Number of certificates in HU  
PPP+ notPPP (without parallel)

# Clone registrations (2nd trade names)

- Number of PPP names can not be limited legally (but at yield enhancers we limited to max. 3 clone names)
- Label must be the same as on reference (except for name and owner)  
other name = other use is not allowed
- Obligation in HU:  
For information of users, obligation for marking the reference name with 30% of the new one

# Clone name 60pt

Reference name 18pt



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**Thank you for your attention!**

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