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Termőföldtől az asztalig

Background & Difficulties In decision making of active substances

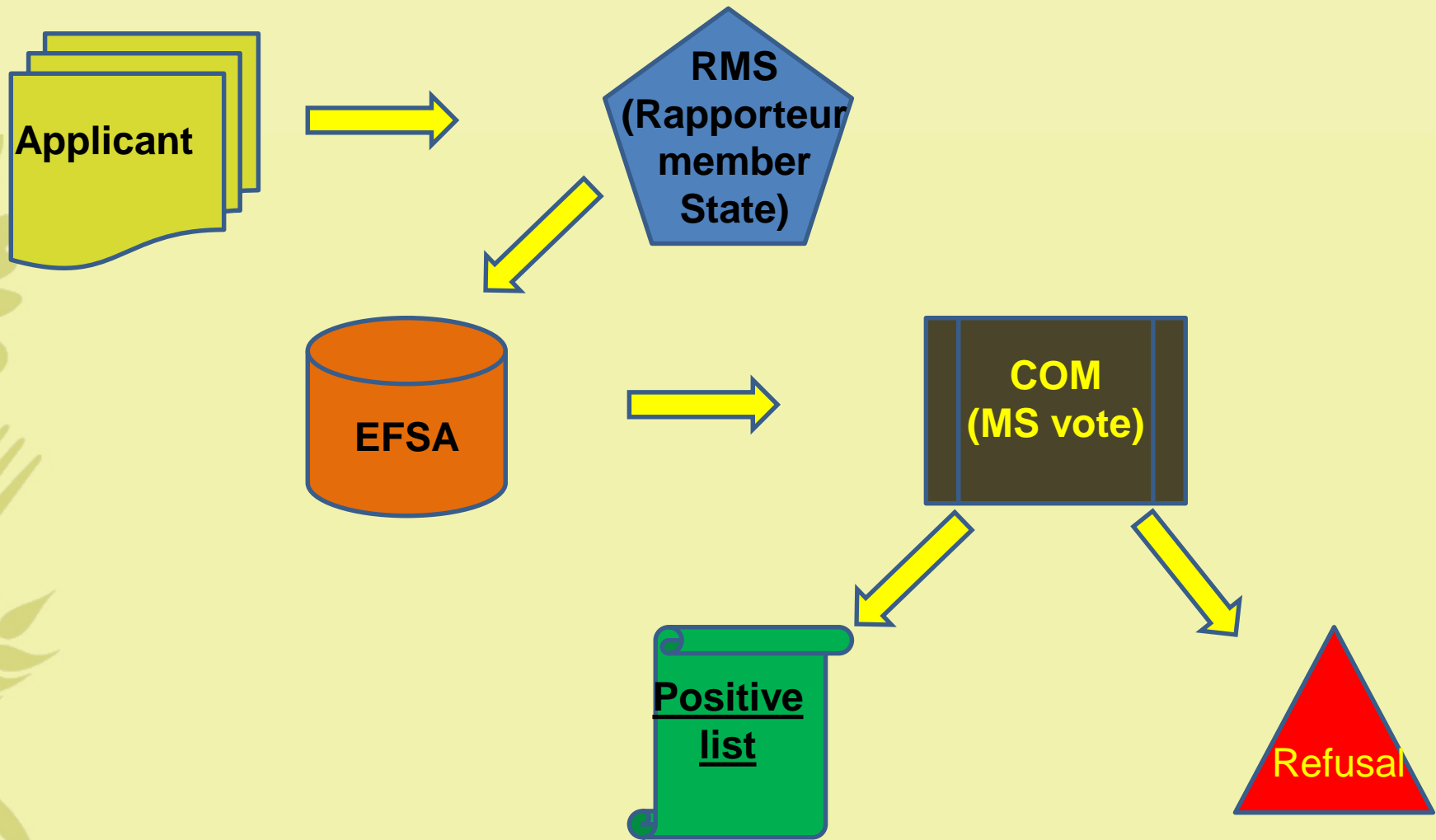
Gábor Tőkés, Adél Janka

National Food Chain Safety Office

Directorate of Plant Protection ,
Soil Conservation and Agri-environment
HUNGARY, Budapest



PPP can be registered in EU member states only if the active substance is taken to the positive list



If no qualified majority....



Appeal committee - attachee



Council of ministers



With-
drawal



With-
drawal



Appro-
val



Appro-
val

Updated data requirements (DR)



Old DR

544/2011/EU

For dossiers submitted for
renewal

(AIR I & II)

and new approval until

31.12.2013



New DR

283/2013/EU

For dossiers submitted for
renewal

(AIR III & IV)

and new approval from

01.01.2014



Updated EFSA Guidances during the review



Ecotoxicity:

- Aquatic GD – 2015
- GD on birds and mammals – 2015
- Draft GD on Bees – officially not accepted !
...but used by EFSA as 'new scientific evidence' (1st Tier)
(not harmonised approach)

Human toxicity:

- Updated OECD testing guidelines, EFSA Scientific opinion 2011 on genotox. testing strategies
- Operators, workers, residents and bystanders GD – 2014
- Dermal absorption GD - 2014



Active substance withdrawals

2012: diphenylamine , novaluron

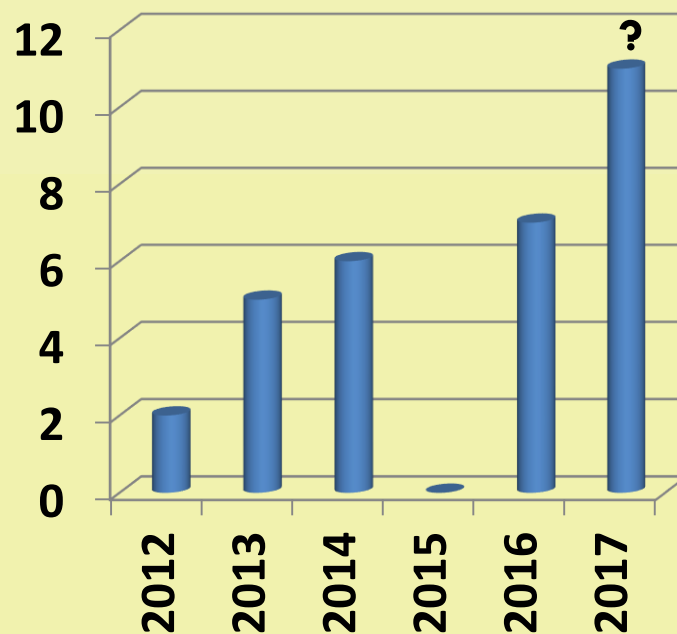
2013: didecyldimethylammonium chloride –
bitertanol, flusilasole, potassium-iodide
and potassium-thiocyanate

2014 fenbutanin-oxide ethoxysulfuron, oxadiargyl,
warfarin, cyfluthrin, carbendazim

2016: isoproturon, triasulfuron, amitrol, tryciclazole
3-decen-2-one,
(Z,Z,Z,Z)-7,13,16,19-Docosatetraen-1-yl
isobutyrate,,
(Z)-13-Hexadecen-11-yn-1-yl acetate,

2017: Further negative conclusions published by EFSA for AIRII and AIRIII ASs:

**diquat, linuron, maleic-hydrazide, fenamidone, isoxaflutole, imazamox,
2,4-DB, famoxadone, mesotrione, pendimethalin, picoxystrobin...**



Drastic increase in the near future ?

Serious restrictions



Chlorpyrifos – acute consumer risk

MRL to LOD – more crops deleted

(apple, pear, cabbage, savoy cabbage, brussels sprouts, cauliflower, broccoli, grapes)

Neonicotinoides – use restrictions referring to bee health

Glyphosate – withdrawal of PPPs with tallow-amine



Reasons for negative EFSA conclusions on a.s. dossiers

- 2015/2016: EFSA changes towards a more conservative approach
RMS → ← EFSA
- Weight of evidence approach not followed
- Endpoints are not set referring to lack of data
- EFSA does not accept new data after application
- New scientific results → new GDs - from what date to be applied? (dossier preparation is before implementation date, how to conduct new studies?)
- Genotoxicity and new bee GD are two critical issues



- **Genotoxicity**

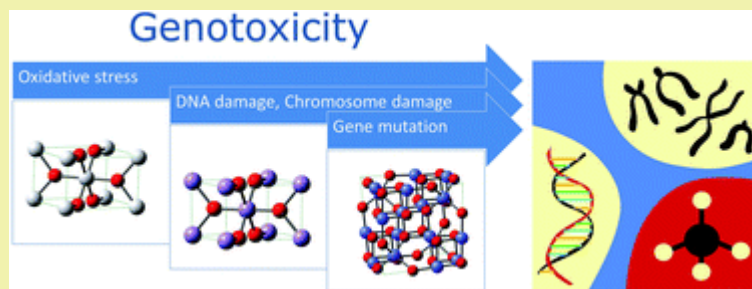
different approach between RMS and EFSA

EFSA needs new in vivo trials but no way for submission

COM will send a mandate to EFSA for clarifying the

differences in conclusions

till then no decisions



- **Bee GD**

more detailed GD was necessary

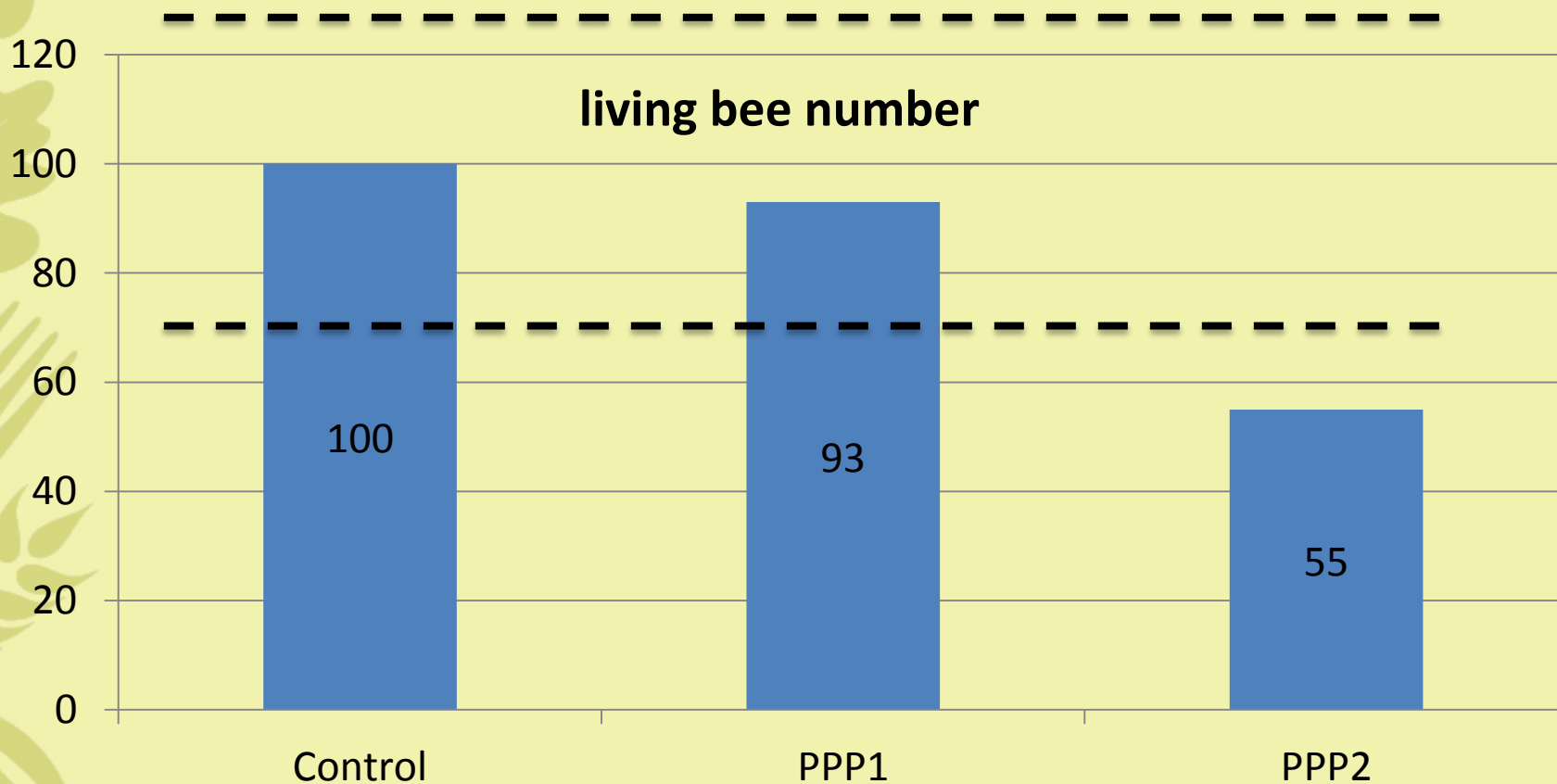
(recent GD is too short and weak)

irrealistic requirements – 7% protection goal

if Tier 1 fails, almost no chance for field trials



7% difference can not be detected statistically in a field trial with bees – only in extreme large areas and number of replicates

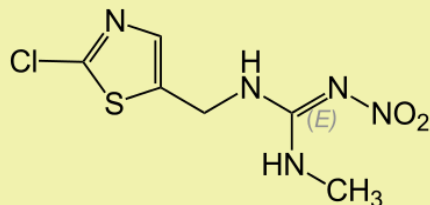


If $CV < 7\%$ → it is a good plant trial but not a bee trial 😊

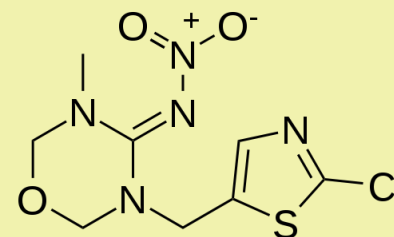
Politically influenced decisions 1

Neonicotinoids

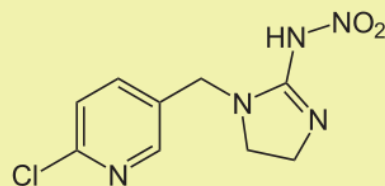
- **Clothianidin**
(Bayer)



- **Thiametoxam**
(Syngenta)



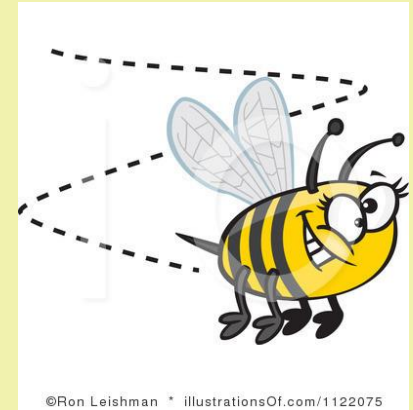
- **Imidacloprid**
(Syngenta)



SCIENCE conclusions

After neonic feeding with neo concentration occurring on fields:

- Decrease in number of queens
- Disturbance of orientation ability
- Reproductibility of trials is questionable
- Feeding was carried out in laboratory , not in field !



485/2013/EU regulation

in lack of qualified majority of MSs



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Termőföldtől az asztalig

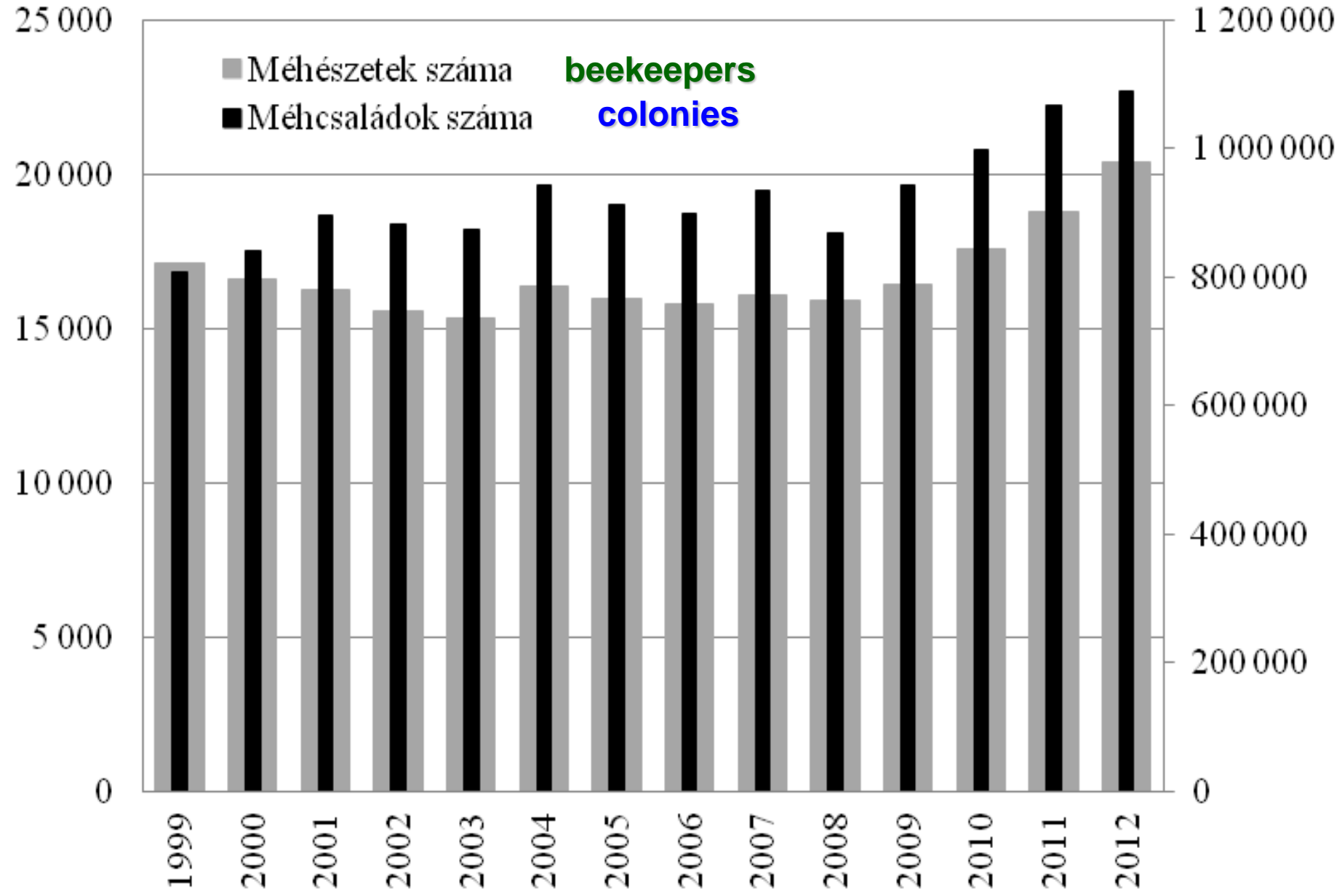
- ***Since 1st December 2013 seed dressing and use of such seeds is prohibited in spring cereals and all bee-attractive crops (e.g. sunflower, maize, rape)***
- ***Soil disinfection is prohibited in attractive crops***
- **No evidence for harmful effect in field**



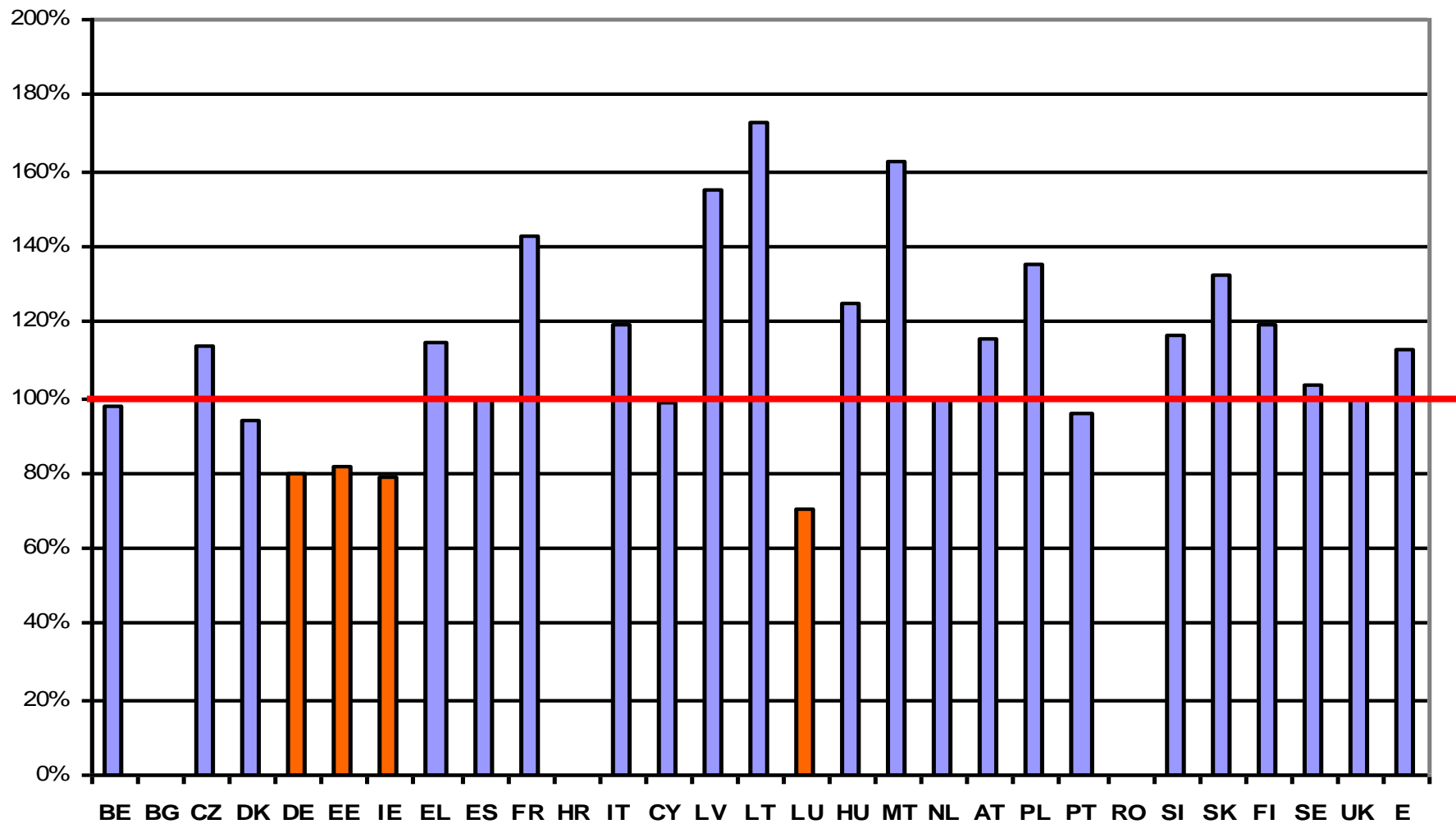
Méhészetek
beekeepers

Number of bees in Hungary

Méhcsaládok
colonies



Number of bee colonies in EU 25 between 2004-2013



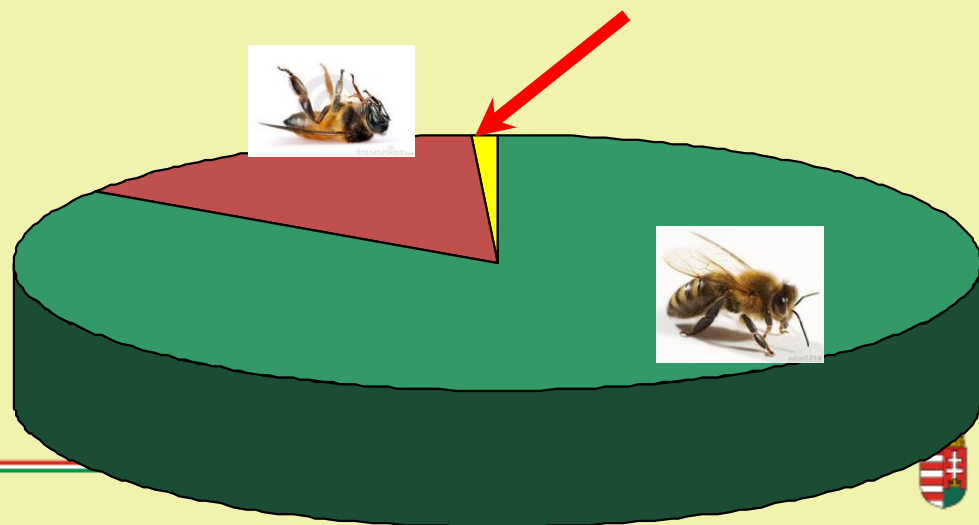
Why did we oppose restrictions?

- Bee density is highest in Europe >1 100 000 colonies, **12 hives /km²**
- Number of bee mortality : 150-200.000 colonies / year
- 5-10 % of mortality is caused by pesticides (0,5-1% of total hives)
- Reasons are mostly inappropriate use
- Most of mortality is caused by pests, diseases (Varroa mite, nosema disease)



Varroa destructor

- Healthy
- Infected
- PPP



Result of two years without neonics in HU



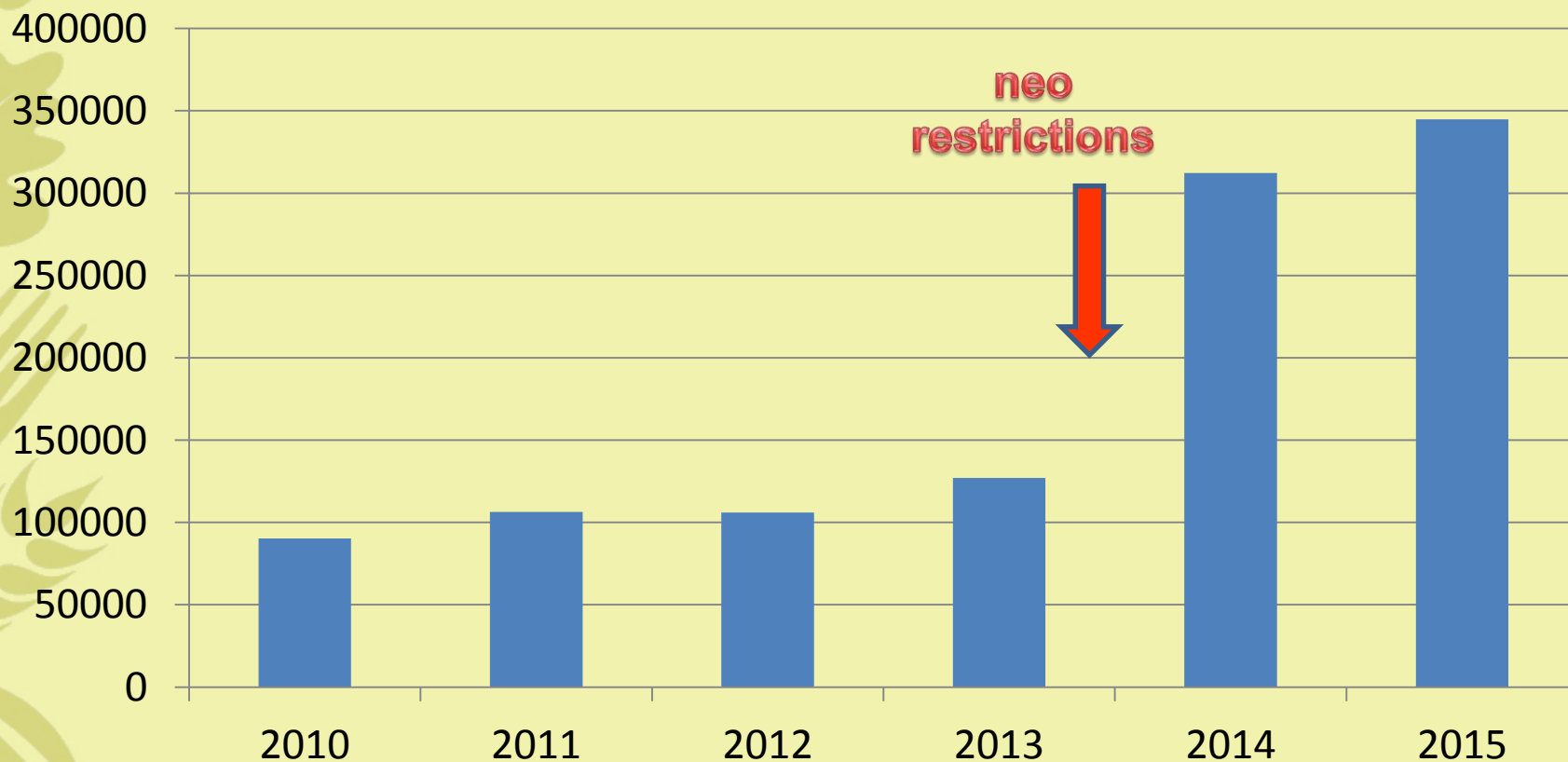
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- No emergency use in 2014 and 2015
- No improvement in bee health – more disease problems
- Increase of leaf spray in sunflower, maize and rape
- Extreme increase of chlorpyrifos



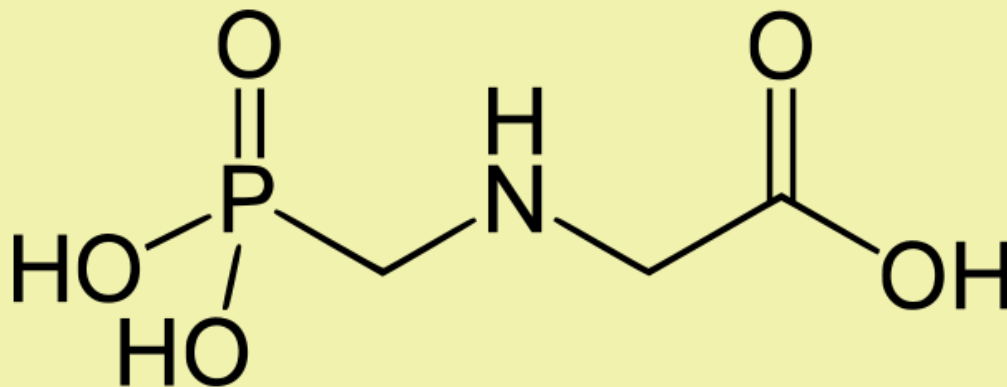
Use of chlorpyrifos in Hungary

chlorpyrifos kg





GLYPHOSATE



N-(phosphonomethyl)glycine



Wide spectrum herbicide



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Post-emergent

‘Clears all’

Use for cleaning of stubble and non-agricultural lands

Minimum tillage

Use: as isopropil-amine, potassium or ammonium salt spray

Also used as dessiccant



Properties

- Binding to soil granules
- No uptake through root
- Not bioaccumulative, depletes from body
- Can occur in urine
- Metabolite: amino-methyl-phosphonic acid (AMPA)
- DT 50: 1-2 weeks (but AMPA more months)



GMO

- Effective weed killing of glyphosate tolerant crops
- More spray onto crop !
- Risk of weed resistency



2004
Fejér m. NTSZ

Renewal of glyphosate



Annex I. inclusion: **2002.07.01**

Expiry: 2012.06.30 → 2015.12.31 → **2016.06.30**

RMS: Germany co-RMS: Slovakia

Dossier submission : 2012. May

RMS assessment (RAR): 2013. December 20.

Member state comments : 2014. Jan-Apr

Supplementary data, evaluation



Unexpected turn in renewal



International Agency for Research on Cancer



IARC 2015.03. :(probable carcinogenity, Carc.Cat. 2 = EU Carc1B ekv.)

Expert meeting (EFSA + MSs):
2015. September

RAR addenda: 2015. October

EFSA summary: 2015. November 12.
carcinogenity not justified and no other cut-off reason

27 MSs agree with EFSA opinion



EFSA & IARC conclusions



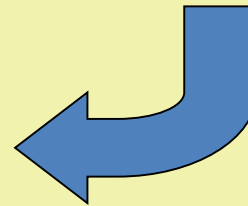
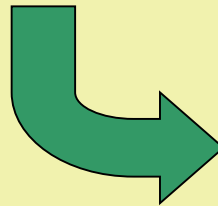
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EFSA

- GLP studies
- Relevant scientific articles
- Legally binding data requirements and assessment principles

IARC

- Based on articles (nonreproducible, missing methodics etc.)
- Not known assesment criteria
- Uncontrollable studies – with unproportional weight



ECHA

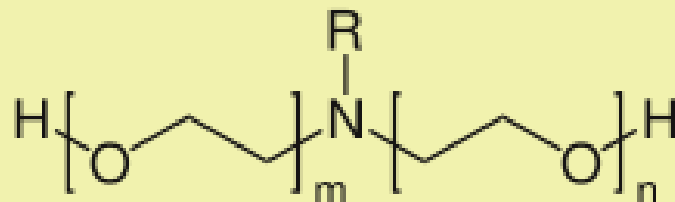
Nemzeti Élelmiszerlánc-biztonsági Hivatal





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POE tallow-amine



- Properties of PPPs are much worse than of a.s.
- Reason: POE tallow-amine
- Plan: ban of this additive in glyphosate PPPs



Green lobby (Greenpeace, PAN etc.)



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1000 l/day?

IARC study
Increasing use
glyphosate in beer
glyphosate in urine



Attempts for and against renewal



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Termőföldtől az asztalig

2016. March 7-8. SCOPAFF

COM proposal: renewal for 15 years, ban of tallow-amine

No qualified majority

2016. April 5. European Parliament

Declaration for withdrawing COM proposal

2016. May 16.

Joint Meeting for Pesticide Residues (JMPR) - glyphosate is not carcinogenic

2016. May 17.

Green NGOs call for ignoring JMPR opinion



Attempts for and against renewal



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Termőföldtől az asztalig

2016. May 18-19. SCOPAFF

COM proposal : renewal for 15 years, ban of tallow-amine

-No qualified majority

2016. June 6. SCOPAFF

COM proposal : Prolongation till end of 2017.

- No qualified majority

2016. June 24. Appeal Committee

COM proposal : Prolongation till end of 2017.

- No qualified majority

2016. June 27. SC Plant Health

COM proposal : restriction of tallow-amine

-No qualified majority (64,69% instead of 65 %) voting postponed



Decision



- **2016. June 29. (1 day before expiry)**
COM prolongation till end of 2017 or 6 months after ECHA RAC opinion (2016/1056 EU r.)
- **2016. July 11-12 SCOPAFF** voting on restrictions
- **2016. August 1.**
- COM regulation about restrictions (2016/1313 EU)
 1. **Ban of POE tallow-amine (CAS 61791-26-2)**
 2. **Dessiccation is not good agricultural practice**
 3. **Attention to ground water**



Health reasons?

- 3 evaluations excluded carcinogenicity:
RMS, EFSA, JMPR
- Real reason for fight against the substance:

*If no glyphosate,
fight against GMO
production can
strengthen*



Glyphosate in Hungary



- Authorisation certificates

37 basic + 16 clone (2nd brand name) = Σ 53

- With POE tallow-amine

15 basic + 10 clone = Σ 25

PPPs with POE tallow-amine will be withdrawn in November 2016

Grace period: 6 month trade + 12 month use
(1107/2009 EC r. Art. 46.)



Change of tallow-amine in existing PPP?

'minor change' GD

- Under 0,5 % yes (2 PPPs in HU)
- Under 10% : (1 PPP in HU)
phys-chem data for new composition
tox-ecotox data during renewal
- Above 10% – new authorization



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Revision of certificates

- Withdrawal of POE tallow-amine containing products
- Ban of use on playgrounds, hospitals and other sensitive areas
- Ban of dessiccation (diquat nonrenewal?)
- Weed killing before harvest?



Renewal in 2017 ?

ECHA assessment

Positive vote of Germany
can decide

In case of deadlock –
COM decides





Moving towards successful agriculture....