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National Food Chain Safety Office

Hungary

Zonal Evaluation, Mutual Recognition and Amendment of Authorisations

Hungarian experiences

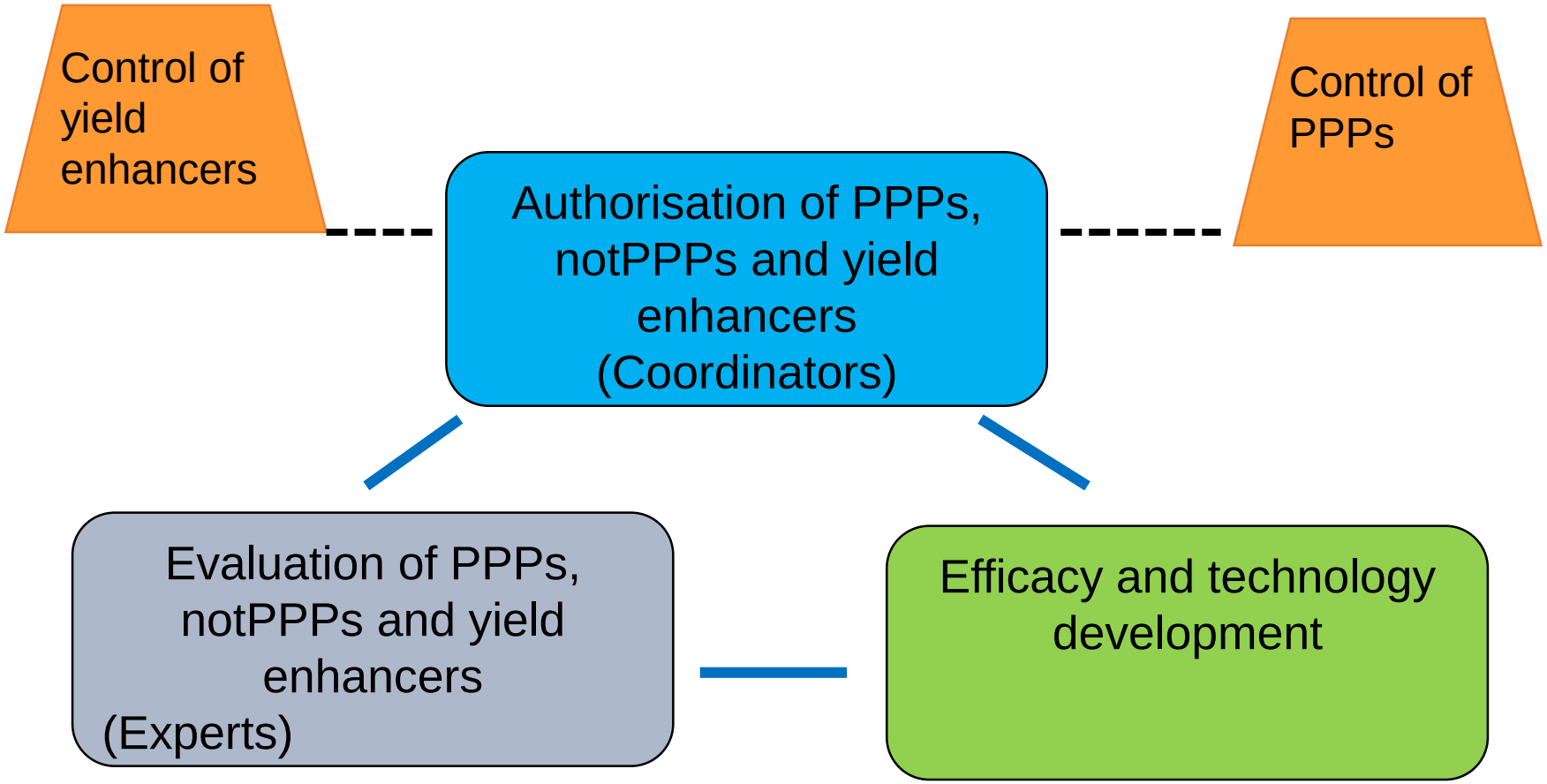
CEUREG XXI. Bratislava 2017-10-24

National Food Chain Safety Office

Directorate for Plant Protection, Soil Conservation and Agri-Environment

Staff & structure

within the directorate



cc. 25 people dealing with registration
Hope for some increase

Authorizations/ year (2015-16)

New authorizations	60
HU=zRMS	2-4
Re-registrations (Step2)	15
HU=zRMS (Step2)	1
Modification with evaluation	110
notPPP	15
Active substances (HU=RMS)	2

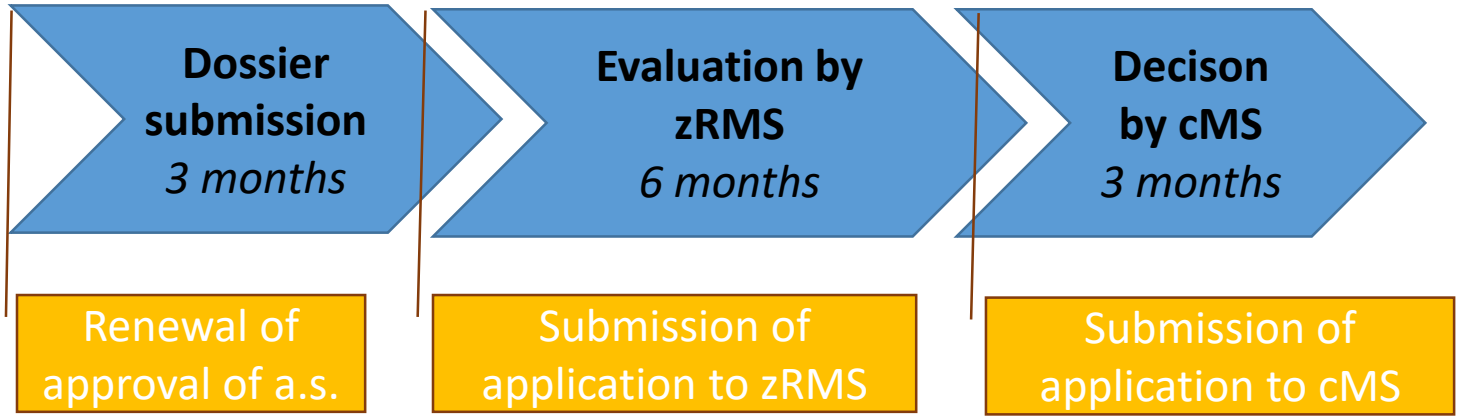
Timelines

HU=zRMS: 13 months kept or little delay

Mutual recognition (Art 40) or HU = cMS (Art 36):
1 year instead of 120 days

Art 43 renewal (HU=cMS) : 6 months instead of 3 months

Art 43 – PPP renewal
Efficacy
How to handle?



Art 43 – Efficacy at PPP renewal

Efficacy 4 options

1. Step 2 has been carried out – no problem with efficacy - no evaluation needed
2. Old certificate, no Step2 → technology is out of date → GAP has to be updated, no new evaluation
3. Small changes in the GAP by the applicant (e.g. water volume or extended growth scale)
   If not proved, not accepted ! → old GAP remains
4. New endpoint in a.s. → dose reduction is necessary → efficacy from S.E.EPPO zone
   2 cases : lower dose is *not* authorised in Hungary, and submitted trials aren't satisfactory - Efficacy issue!

Solution: withdrawal OR provisional renewal of the product - confirmatory studies should be submitted by a given deadline.

Art 34 of Regulation 1107/2009

- Art. 34 enables the **exemption from supplying the test and study reports** referred to Art. 33 (3).
- Prerequisits:
  - MS has the test and study reports – **reference product**
  - certain data are **out of protection** or
  - the applicant has a **letter of access** to the protected data.

No harmonised approach for the implementation of Art.34.
GD for Art 34 was objected by lawyers of 3 MSs.
GD is included into Zonal GD

Art 34 of Regulation 1107/2009

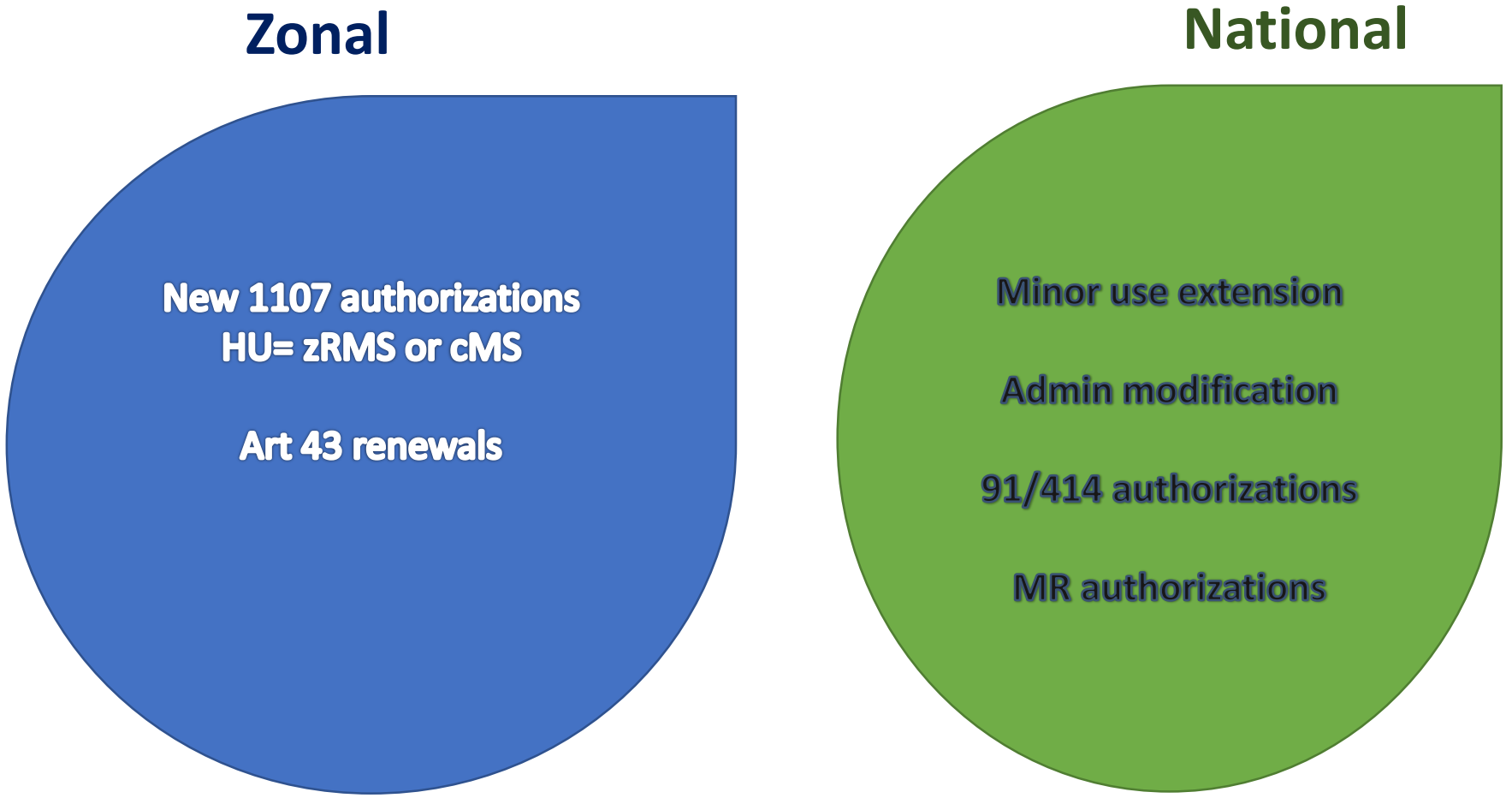
- No more than one authorised reference product allowed (no picking from different dossiers)
- Valid Uniform Principle authorisation - issued in accordance with Directive 91/414/EEC or Regulation (EC) No 1107/2009
- Same reference product should exist in the zRMS and in all other cMSs
- Availability of the RR of the reference product

Art 34 – HU approach

- RR part A and part C is required
- HU requires phys-chem data to prove similarity
- Proposed uses - same as reference product (fewer uses are acceptable)
- Efficacy check according to Art 34
- Domino effect refused – if reference PPP was authorised based on another dossier
- After renewal generic PPP withdrawn (lack of data access) – suspension is not legal

Zonal or national way?

Amendments



MR – differences in authorization certificates

Mutual recognition means no essential deviation can be between authorization of ref MS and of accepting MS

BUT

No uniform certificate in EU, thus facultative parts can be different (e.g. trade category, risk mitigation measures)

Light differences in efficacy (e.g. in growth stage) can be allowed

No new crops !

Any significant change, extension can be done in a different procedure

Refusal cases

REFUSAL

Case 1

Request for data access of GA3 referring to ECJ

RMS: HU; Applicant: GA3 Task Force – including 7 companies
One company requested the Tox studies (reasoning: data protection expired) – HU denied (2015)
2017 - Company asked again Analytical method, Tox, Residue, E-fate, Ecotox full studies (reasoning : 'information on emissions into environment' should be accessed freely (Court of Justice C-442/14).
Studies hurting business interests should be separated – how?
No definite opinion was recieved from COM

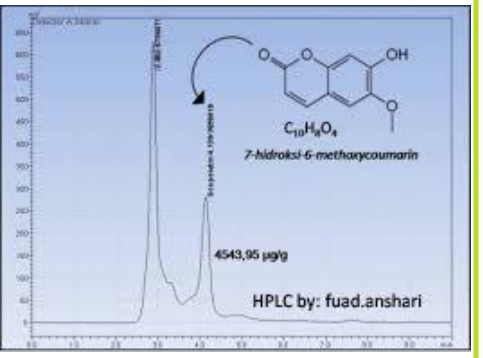
HU contacted the leader of the Task Force
After 1 week the lawyer office of requesting company (after examining the TF agreement again) withdrew its request.

REFUSAL

Case 2

MR refusal due to residue section

Villám (200 g/l acetamiprid)



Applicant asked MR for generic PPP containing acetamipride from a ref. MS

Experts checked the dossier - all sections were OK but residue was missing

Residue section referred to EFSA evaluation and MRL . It is not allowed but ref MS accepted it.

Do we have to investigate procedure of ref MS ?

Data protection of residue data is valid till Decemeber 2018 in HU

HU refused MR due to data protection problem

REFUSAL

Case 2

CONCLUSION

MR refusal due to residue section

Accepting MS does not need to investigate procedure of ref. MS.

But in case of data protection problem or presence of unacceptable risk MR may be refused

REFUSAL

Case 3

Refusal of PPP due to efficacy problem

Oblix (500 g/L ethofumesate)

Reasons for refusal:

- requirements of Commission Regulation (EU) No 284/2013 and of EPPO guidelines not fulfilled
- application rates and application numbers of the trials are not in line with the GAP requested for authorisation in Hungary
- for mutual recognition there is no possibility to request further data

The applicant has been given the opportunity to apply for the mutual recognition of the product later on, after the Art 43. evaluation by the zRMS based on ethofumesate renewal. New, proper biological trials should be carried out in the SE-EPPO zone.

REFUSAL

Case 3

CONCLUSION
Refusal of PPP due to efficacy problem

- Art 36(3) - Mentions only on health and environmental reasons but not exclusively !!
- Art 41(1) – reference to the circumstances in cMS
- Art 29 – Efficacy is essential for authorisation
- EPPO and EU efficacy guidances – 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

Minimum and maximum dose in certificates

Illegal low dose business

HU certificates determine minimum and maximum dose (e.g. 2-3 l/ha)
Deviation is not allowed to avoid inefficiency and occuring resistency

2015: Rumors about consultancy for farmers by a French company
Topic: use of PPP under minimum effective dose in mixtures
2016: Discussions with company - they intend to change HU practice
Almost all big manufacturers are against this method
2017: Discussion between NÉBIH and company – efficacy is not proven by trials
2017: Company tries to raise topic to political level - efficacy still not proven

HU did not change its policy concerning minimum dose


Thank you for your attention !