



National Food Chain Safety Office

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

Authorization of plant protection products and the zonal evaluation system Central Zone view

Gábor Tőkés

CropLife Europe videoconference

10. March 2021

Authorisation activity

ZRMS evaluation

Re-registration - renewal

Withdrawals

Modifications

Emergency use

Clones

**Art 34 „generic” process
(2nd name)**

Takeover as CMS

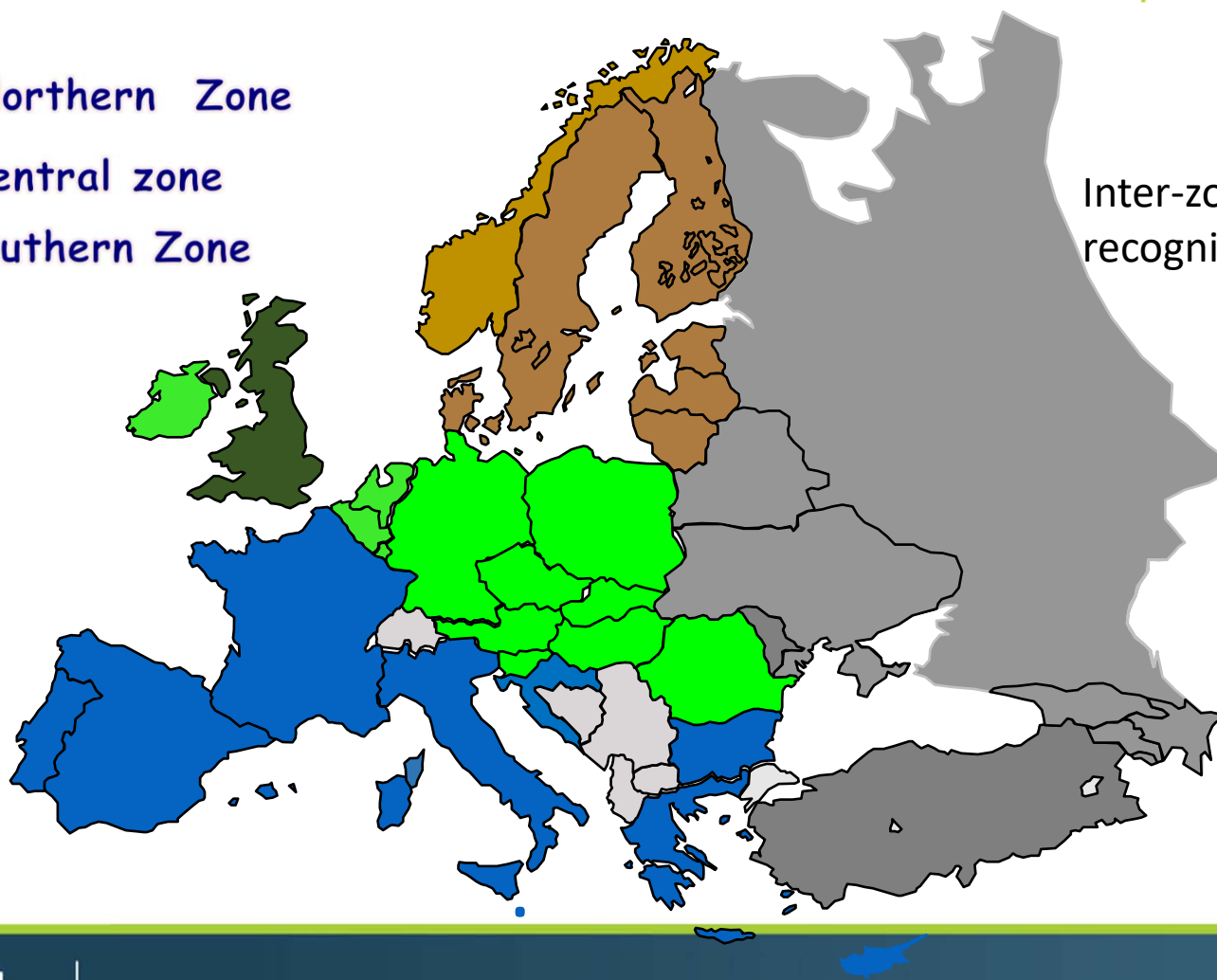
Mutual Recognition

Parallel import

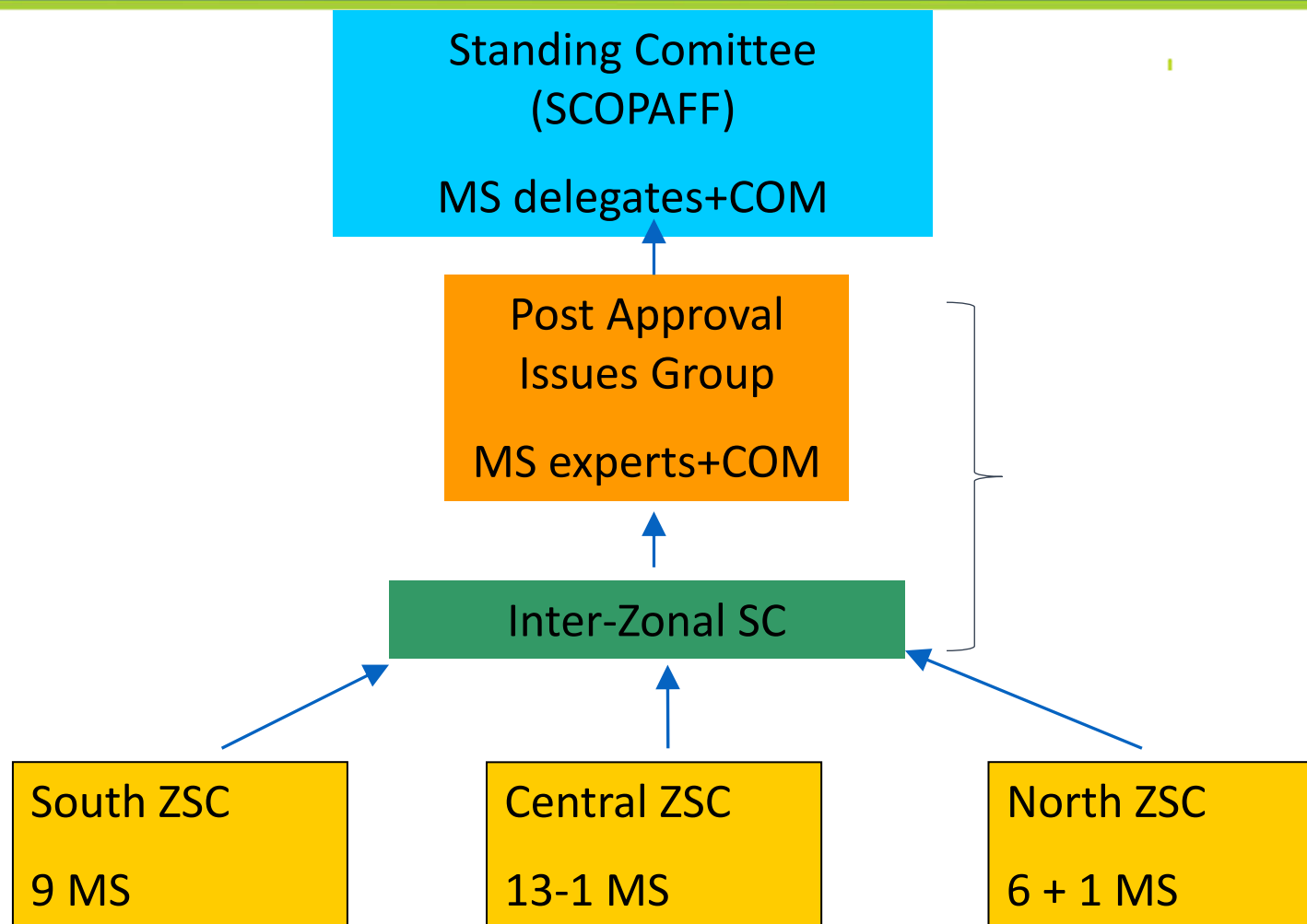
Minor use extension

3 zonal system – PPP evaluation by 1 MS/zone

- Northern Zone
- Central zone
- Southern Zone



STRUCTURE OF GROUPS



Meetings in Central Zone

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
TC		TC		PM		TC		TC		TC	

teleconferences



Personal meeting

Consultation with industry
(since 2014)

*COVID 2020: TC changed to
video meetings – much better!*



Chairs of Central Zone

Yearly rotation of chairing the Central Zone

2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
DE	UK	AT	NL	PL	CZ	DE	AT	BE	SI	IE

- **Main tasks:**

- Collecting and proposing topics to discuss
- Organising teleconferences
- Organising personal meeting
- Writing minutes
- Bullet point, agreements, tables



**Extra workload
for chair MS**



Zonal Secretariat

- Established in 2017
- Not rotating
- Located in DE & NL
- Financed by MSs
- Continuous contact with the Chair



Administrative support on
high level of competence
Great help in the cooperation !

Director's Consultation Group (DCG)



- Proposal of Luuk van Duijn (NL)
- Exchange on director's level
- DCG established in 2014 (Wageningen)
- Min. two telephone conferences and one „face to face meeting“ per year
- Aim: 'shortcut' of problems not solved on expert level
- Proposal on RMM
- 2020 Dec: Extension for 3 zones, HLM



Important documents for work

List of agreements

*Minutes of
teleconferences and
meetings*

No special zonal guidance

Table of National Requirements

Bullet points (public)

[illegible]

Protected crops

- Only a part of protected use can be strictly considered as 'greenhouse'
- Harmonise the risk assessment under protected conditions
- GD on protected crops (EFSA Journal 2014;12(3):3615)
- Questionnaire on MS's practices in assessment of protected crops
- Working group initiated by DE
- Aim: solution for all 3 zones
- 2 dRR : high tech interzonal+ low tech zonal?
protected interzonal + nonprotected zonal ?
- Topic not closed



Non-professional uses

- Systems differing by Member states (SUD directive)
- Criteria: PPP classification, package size (area to be sprayed) , OPEX
- Questioner summarized by PL
- Provide information about the national definitions
- Bullet point published in Feb 2020
- Incorporated into National Requirement table (CIRCABC)



Leaf Wall Area – obligatory from 01.01.2020

EPPO standard 1/239 – LWA is dose expression in high growing crops

Introduced in grapevine, pome fruit and high growing vegetables

Application for new products from 01.01.2020



Art 43 – renewal topics

Active substance data submitted after renewal: not zonal issue, task of RMS

2nd a.s is postponed by COM – more than 1 year after 1st a.s. : WAIT for 2nd

Minor use under frozen period – if no change in ADI, ARfD, residue def.

Ecotox evaluation share – all should be in the core including refinements (task of zRMS)

Combination human tox: (more a.s.) should be in the core – see Bullet point

If worst case GAP fails : zRMS task to handle efficacy of 'lower risk' GAP
(later submission as Cat4+ ??)



Relation with industry

- Industry's need for participation on PoAI
- ECPA yearly consultation with PoAI 2010-2013 – separate meeting
- ECPA-ECCA conference after PoAI (COM+EFSA+MSs) since 2014, Bruxelles

Central Zone:

Industry is invited for last half day of CZSC meeting (since 2014)

Public part of CIRCABC

Zonal agreements in form of 'Bullet points'

National requirements

Agenda and short minutes

<https://circabc.europa.eu/w/browse/20a444e2-21c3-4e4b-85e3-671844b50135>



BREXIT

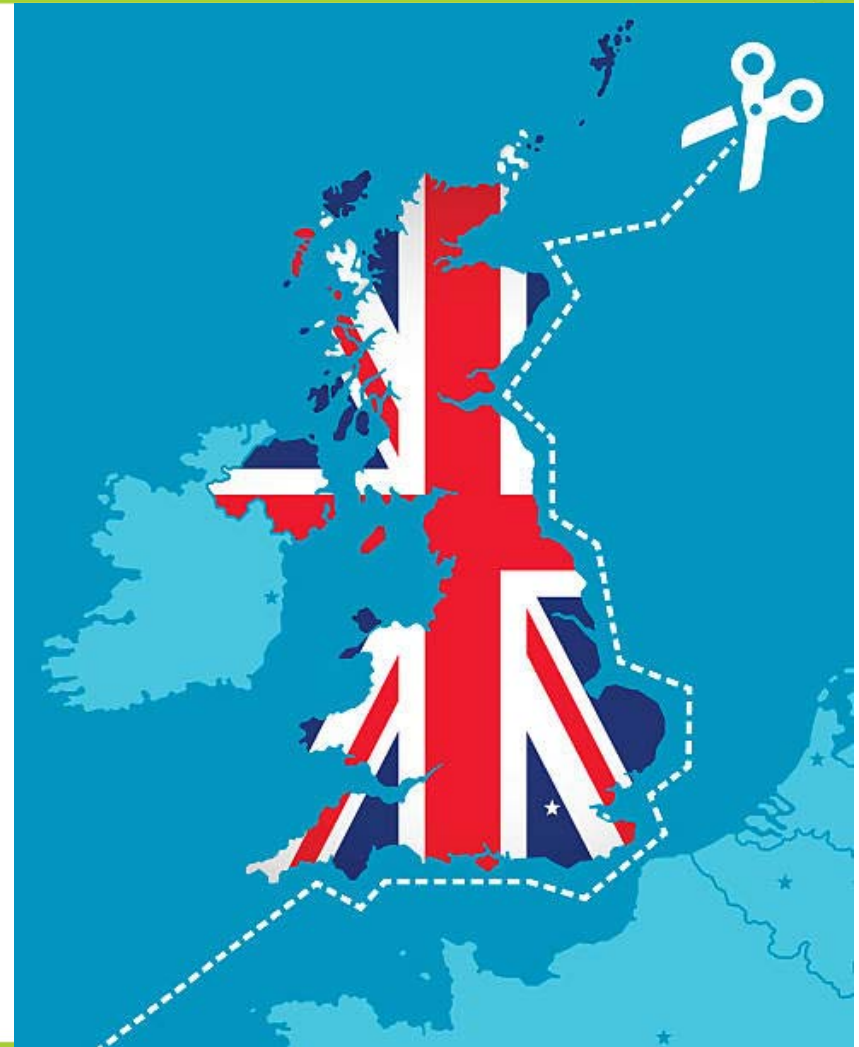
31.01.2020 / 31.12.2020

Cut off capacity, expertize

Fall-back zRMS system
rely on UK, no reassessment

UK efficacy trials can be accepted
as Maritime EPPO zone after Brexit

Stop accepting MR, cMS from UK
Withdrawal of parallels



Personal changes due to Brexit



Darren Flynn (UK)
Founder and chair of
PAI (&IZSC)



Christian Prohaska (AT)
New chair of PAI & IZSC



José Luis Alonso Prados (ES)
Vice chair of PAI & IZSC

HU attempt for enhancing authorizations

2020: Small staff (total 25) - Increasing backlog and delay

Proposal for political level

Principle of fee and work balance



1st step: taking up 4 evaluation experts (March 2020)

2nd step: coordinators training for simplified evaluations (MR and Art34) - avoid the queue at experts

Result: 50% more new authorization in 2020

In case of political decision staff increase can be continued

Results of analysis about the bee mortality

Hungary 2018

2018: Unusual bee mortality in almost all counties (climbing bees)

Incidents can not be linked to individual pesticide use mistakes

Beekeepers blame pesticides in general
- political issue

Minister orders wide investigation and analyses

Work lasted 1 year

Results: no correlation with pesticide use
Reason can be too high bee density and bad health of bees



climbing bees HU 2018

Summary

Central zone has the most member states (although decreasing ☹)

Harmonisation and cooperation needs much work

Secretariat is very effective to reduce the workload of MSs

The experiences of Directors meetings show there is need for higher level consultations



Europe

Thank you for the attention

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