



Authorization systems in the Balkan countires

Experience from RO, BG, HR and former Yugoslav republics of SRB, MCD, BIH, MTN

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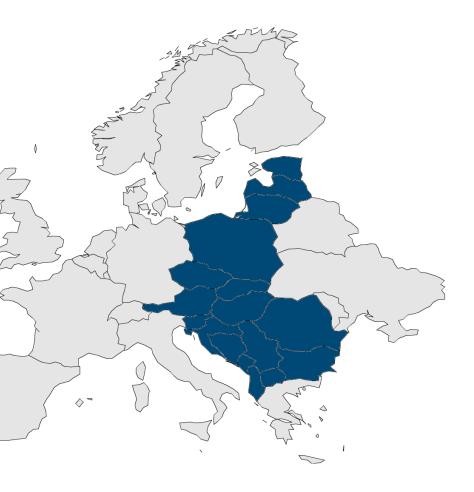
About Artemisa

A team of experts, specialized in covering the CEE region from the regulatory and linguistic point of view.





Regulatory Services



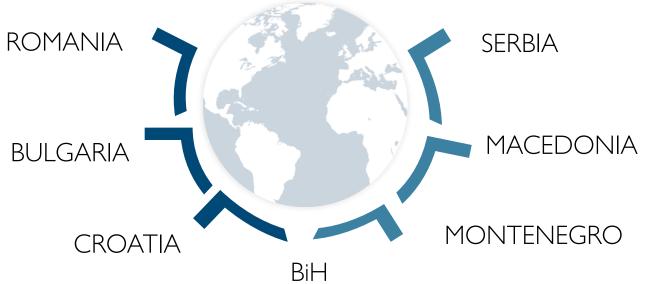




In this presentation focusing on...

EU Member States

Non - EU Countries



- Republika
 - Srpska
- Federation BiH





EU Member States

Bulgaria, Croatia, Romania

1. Bulgaria

- 111.002 km² (46.1 % agricultural)
- 7.6 mio inhabitants
- Agriculture 3.2 % of GDP
- 337.155 small farms (<5 ha = 91 % of all farmland)
- Traditional sectors (fruit, vegetable, livestock) underperforming
- High unemployment rate (> 40 %)





1. Bulgaria

Evaluation fee: Art. 43 as cMS 3.115 EUR LEX up to 2.658 EUR

No national addendum/requirements

National application forms
A, B, C, D1 and D2
depending on the
procedure

zRMS role for Art. 33 not

accepted

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cMS role most common Evaluation fee 4.040 EUR

MR from southern zone accepted Fee of 3.600 EUR

Parallel trade applications accepted Fee of 2.000 EUR

Minor uses not well defined



2. Romania

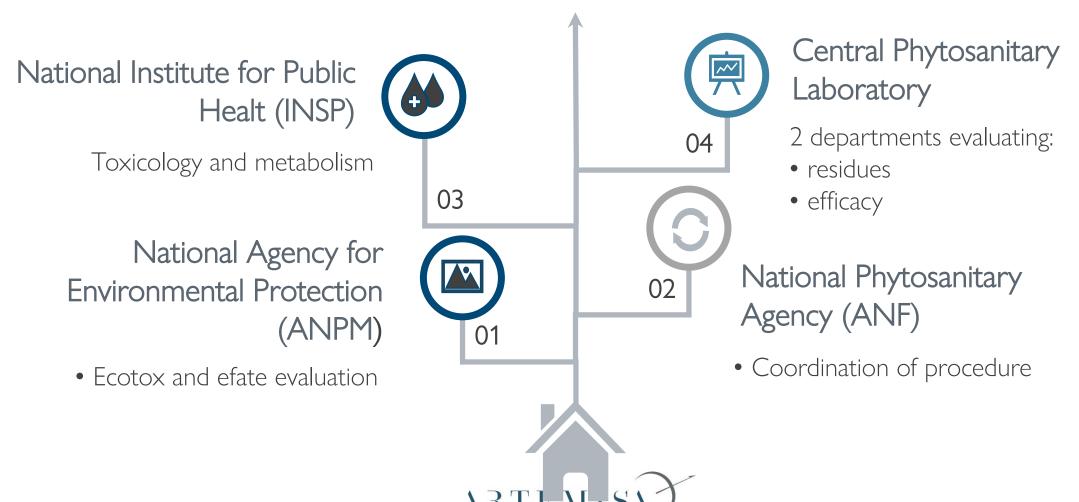
- 238.391 km² (57 % agricultural)
- 20 mio inhabitants
- Agriculture 4.7 % of GDP
- 3.9 mio farms:
 - 7 % large farms manage 70 % land
 - 93 % farms smaller than 5 ha
- Low productivity
- High employment rate in agriculture



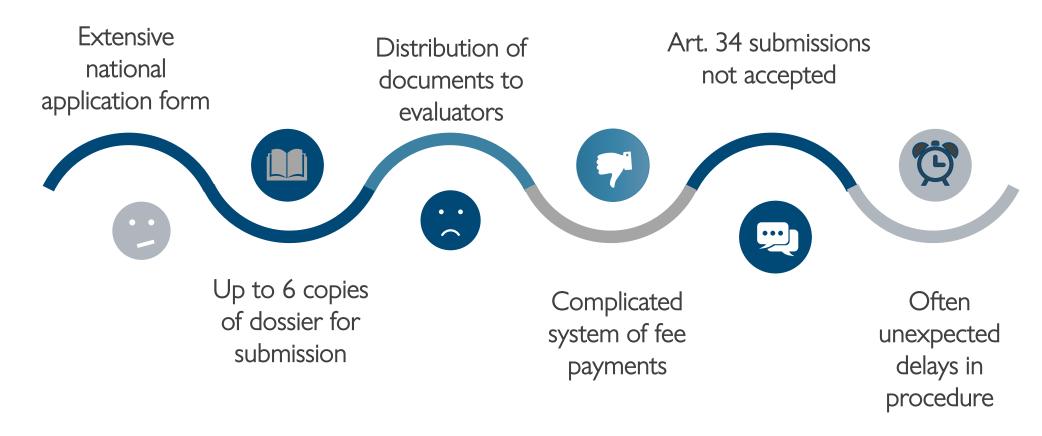


2. Romania – evaluating bodies

National Commission for Registration of PPP (CNOPPP)



2. Romania





3. Croatia

- 87.661 km² (31.067 m² coastal area)
- 4.3 mio inhabitants
- Agriculture 3.2 % of GDP
- 190 000 small farms (<3 ha = 70 % of all farmland)
- Favourable agro-climatic conditions





Croatia Milestones

Before 2005

2005 - 2007

2007

July 2013

July 2013

Old national procedure:

- Local testing
- Nation registration committee
- No recognition form other countries
- 5 different institutions involved
- Simplified registration procedure of identical products

Directive 91/414

Re-evaluation of old products starts

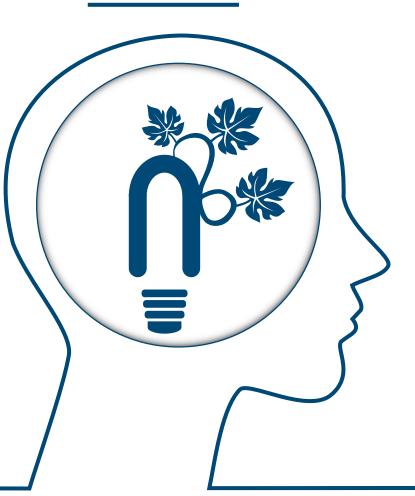
- 8 priority groups
- 45 a.s. banned
- Submission to MoA only
- Evaluation by local experts following UP

Joined EU

Introduced
Regulation
1107/2009
Assigned to south EU zone



Croatia - Specifics





Local representative responsible for placing on the market



National addendum:
Opex
Residue
Fate
Ecotox



National notification of MSDS-es by toxicological institute



Comparative assessment guidance



Post registration control fee payment at registration (25.000 HRK =3.300 EUR)



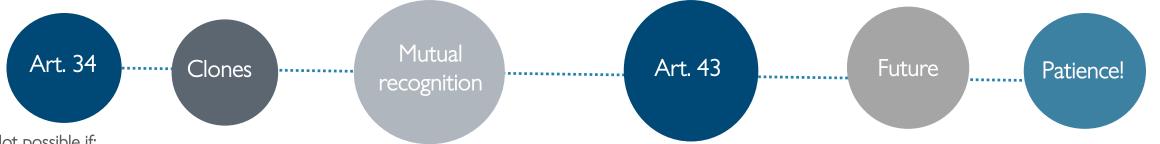
Croatia - Procedures



- For equivalent registrations
- Same registration holder

- Mostly acting as cMS
- Always waiting for zRMS conclusion
- Tend to accept all applications if only possible
- If zRMS refuses to accept additional studies big issue for cMS - lost time, need for new proceedings
- Encourage applicants to add uses not included in zonal registration - time saving

- zRMS for 2 a.s.
- 4 co-ordinators at MoA



Not possible if:

- no data available in CRO
- Very old PPPs not fully evaluated

Should include:

- Reference to 1 PPP only
- Be combination of art. 33 + 34 application

Issues with MR applications:

- Changes from ref. MS not solved/visible in certificate
- Free sales certificate inst. of registration certificate
 - Different source of a.s. from the one to be registered in CRO



- zRMS role from 2021/2022 on
 - 16 new evaluators



Non-EU countries

Serbia, Montenegro, BiH, Macedonia

1. Serbia

- 88.407 km2
- 7.2 mio inhabitants
- Agriculture 17 % of GDP
- 17.7 % unemployment rate
- Maize, cereals (wheat), sunflower, sugar beet, soybean,





1. Serbia



toxicology.

1. Serbia – new Act on PPPs

New ordinances missing

- Evaluation and registration fees
- GEP ordinance
- By the end of 2019/March 2020

Other

- Trade name protection not mandatory
- Local partner for placing on the market mandatory
- Re-evaluation of old PPPs by end of 2019





National procedure

- Old not possible anymore
- New still not possible
- Future: 2-4 local efficacy trials
- Adjuvants regulated.

Local evaluators

- Agreements partially in place
- Not taken on their role yet
- Evaluation fees not defined

1. Serbia – recognition of PPPs

SE EPPO efficacy tests accepted (HU, RO, BG, SK, SLO, CRO)

Statement, that those tests were evaluated by ref country following UP



Fee



Remains the same





- Admin: SE EPPO trials, 2 months
- Full evaluation: Comparative Assessment & additional efficacy
- Part or full range of uses can be registered



Act from 2016:

Local legal representative

Legislative frame

- Manufacturer is registration owner
- Expiry linked to ref country





2. Montenegro

- Independent since 1997
- 13.812 km²
- 625.000 inhabitants
- Agriculture 8.3 % of GDP
- 15 % unemployment rate
- Tobacco, potatoes, citrus fruits, olives, grapes





2. Montenegro

Recognition of PPPs

- Southern zone EU MS
- More countries combined
- Minor uses encouraged
- Expiry date linked to reference MS



Local legal entities

- Import by accredited importers (34)
- Distribution by accredited distributors (86)







Competent authority

- Administration for Food safety, Veterinary and Phytosanitary Affairs
- From 2016



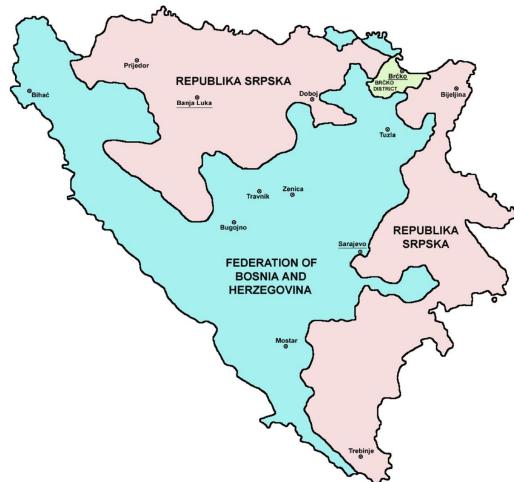


3. Bosnia and Hercegovina (BiH)

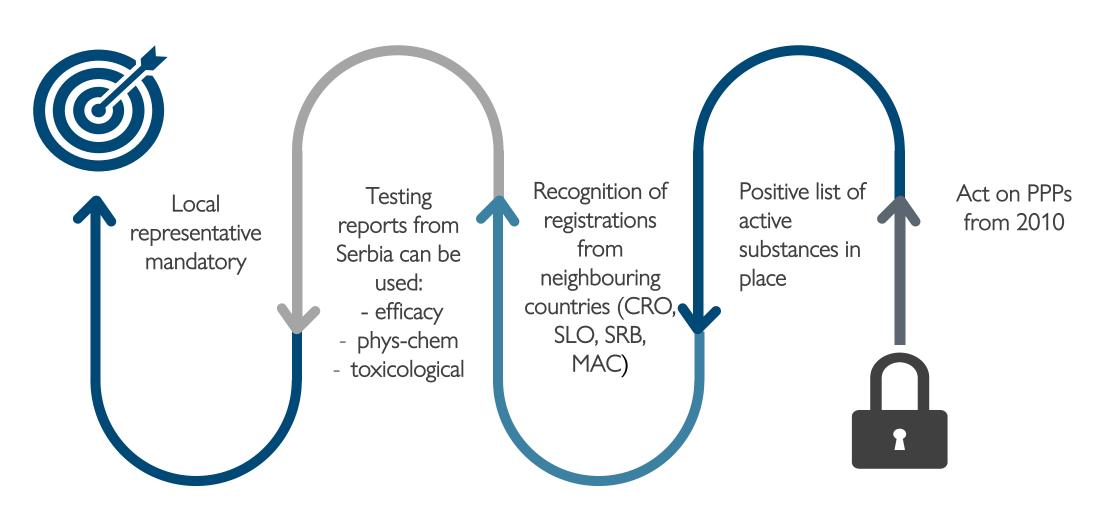


Two legal entities:

- Republika Srpska
- Federation BiH
- (Brčko district from 1999 self governing administrative unit)



3. BiH – Republika Srpska





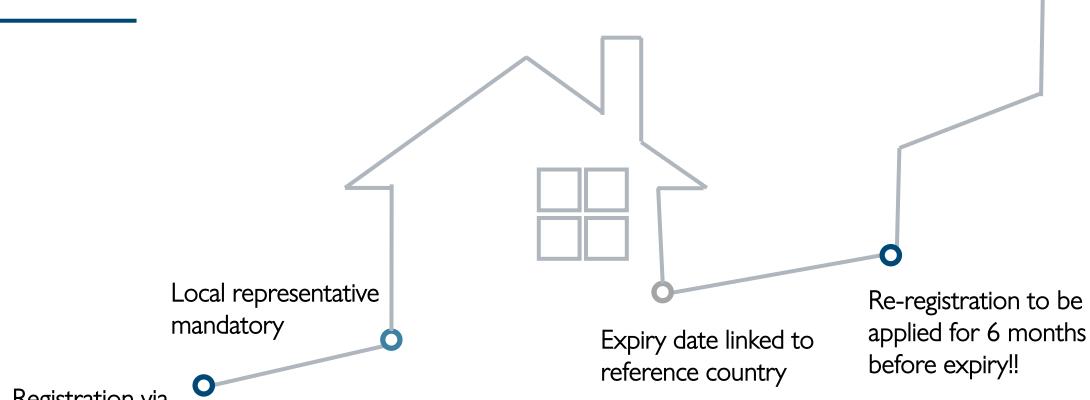
4. North Macedonia

- Independent since 1991
- new name since 12. 2. 2019
- 25.713 km²
- 2 mio inhabitants
- Agriculture 8.4 % of GDP
- 17.5 % unemployment rate
- Tobacco, fruits (apples, grapes), vegetables, wheat





4. North Macedonia



Registration via recognition only possible (southern zone)





Thank you

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