



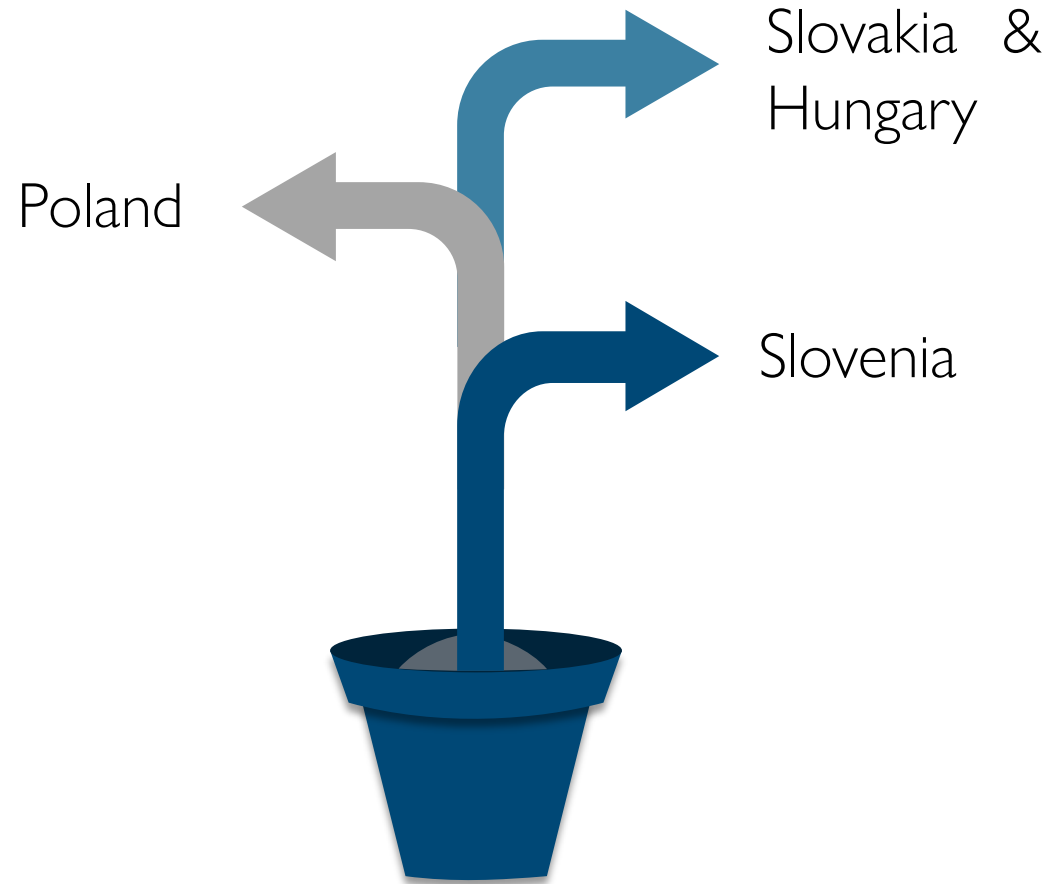
Authorization systems in the Balkan countries

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

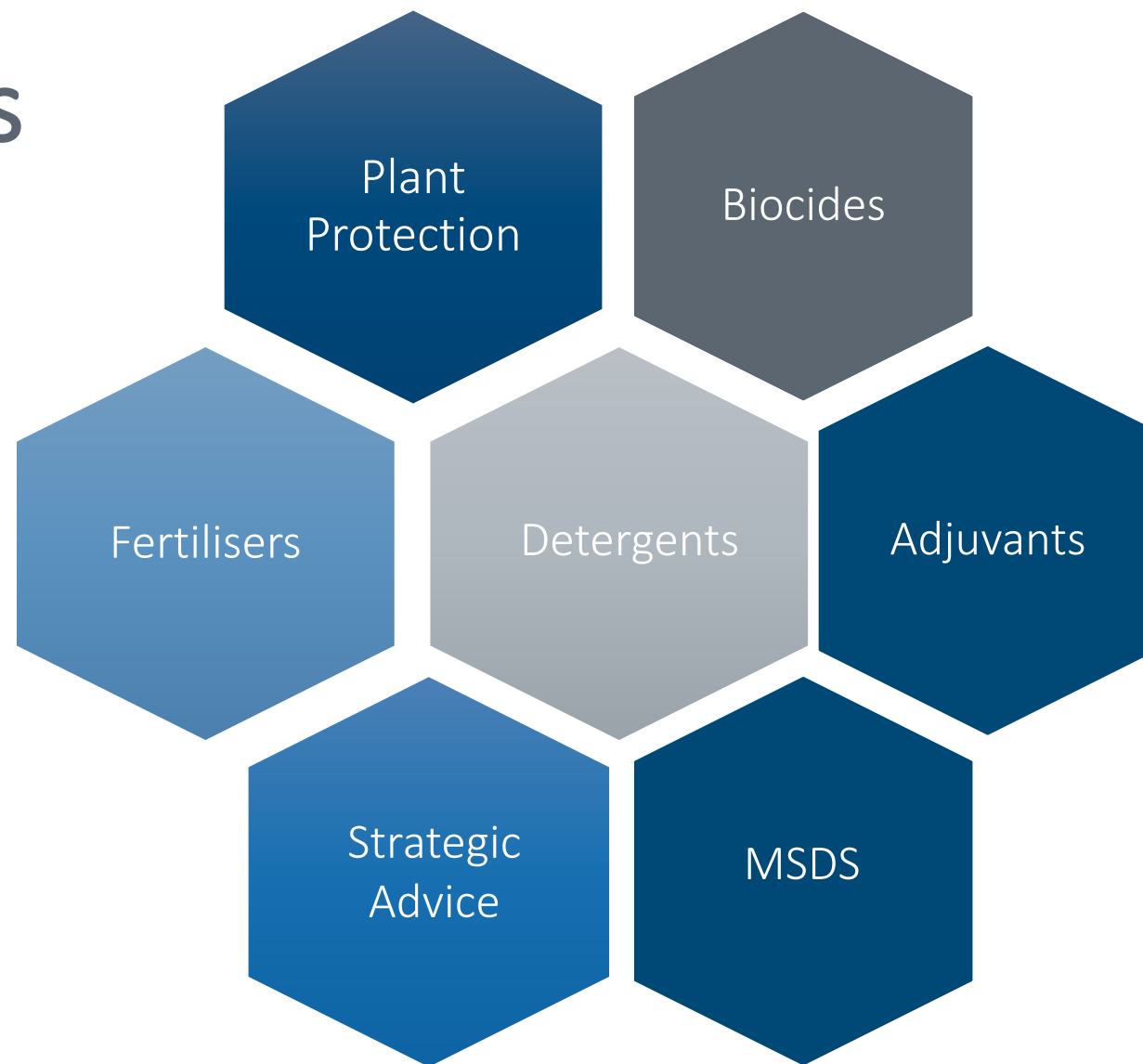
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About Artemisa

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



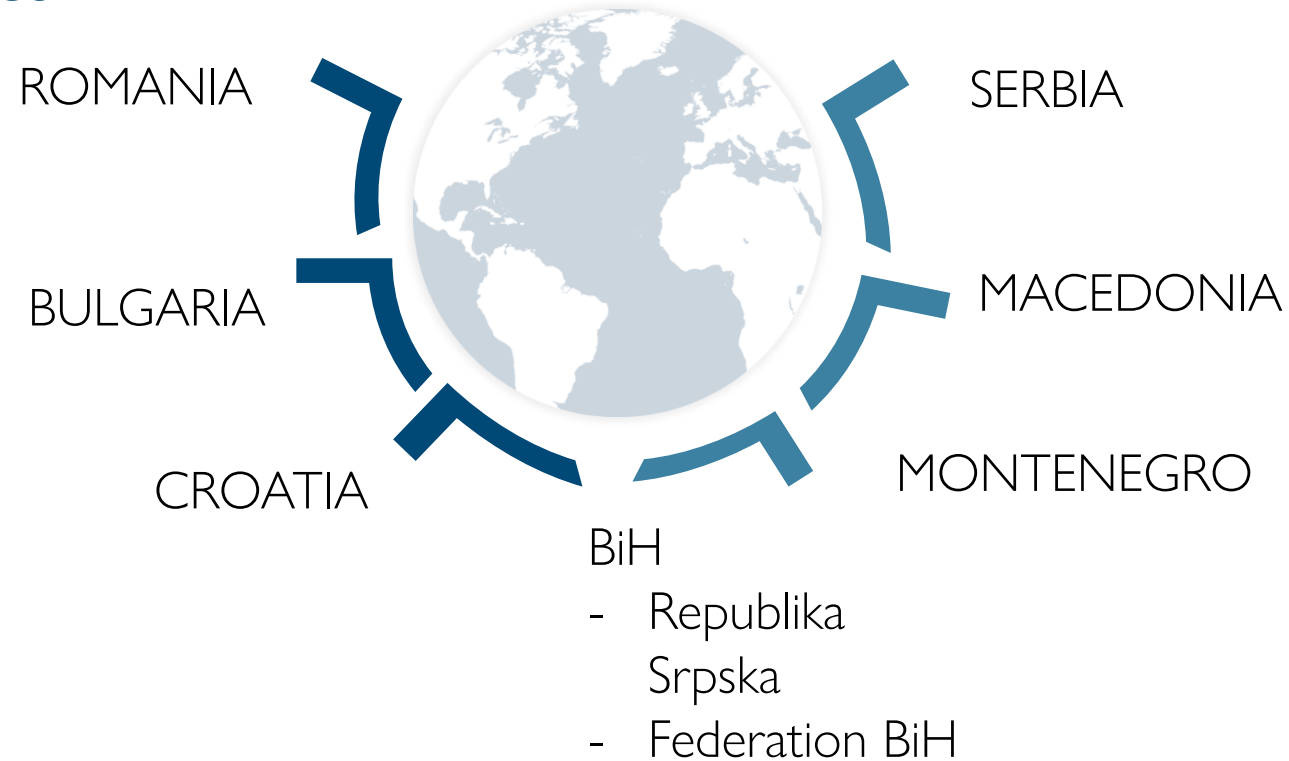
Regulatory Services



In this presentation focusing on...

EU Member States

Non - EU Countries





EU Member States

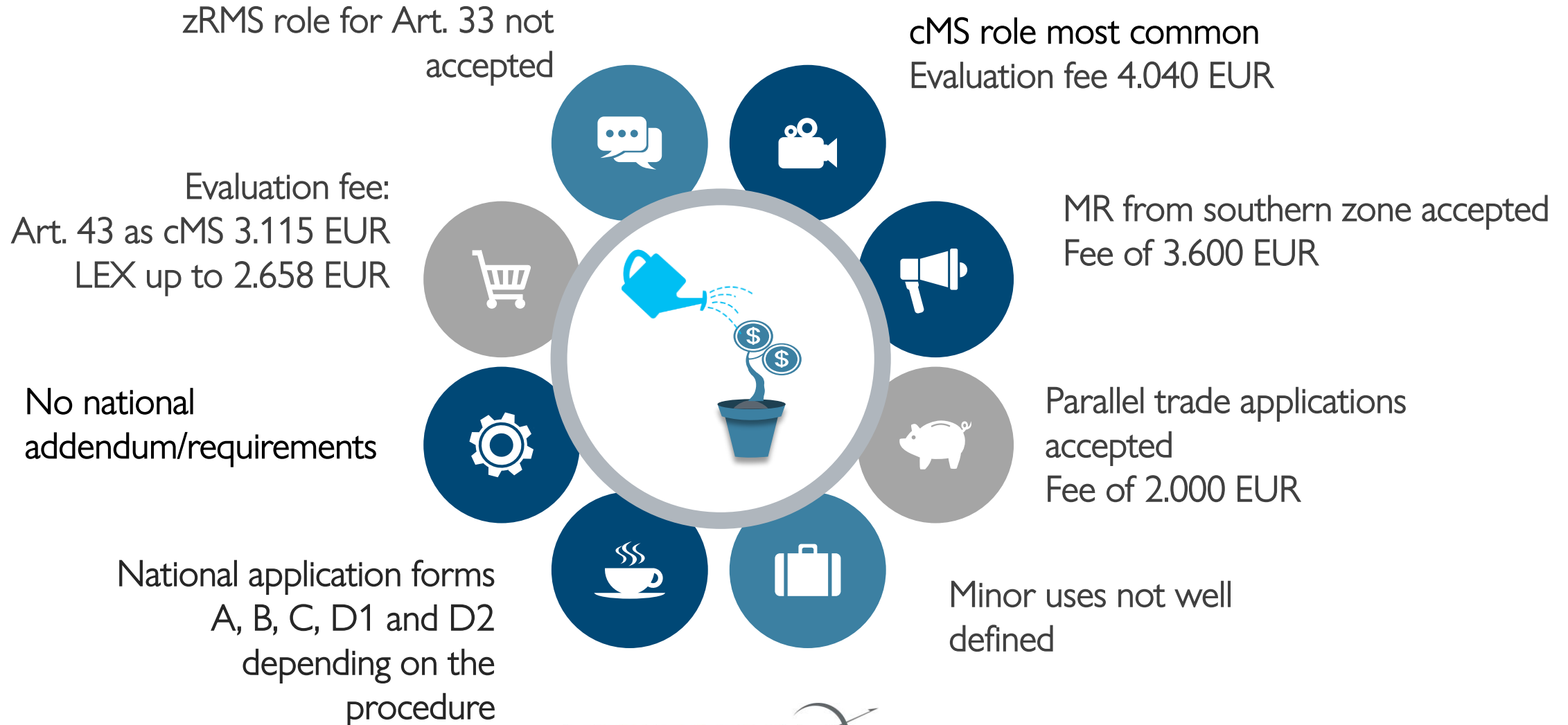
Bulgaria, Croatia, Romania

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



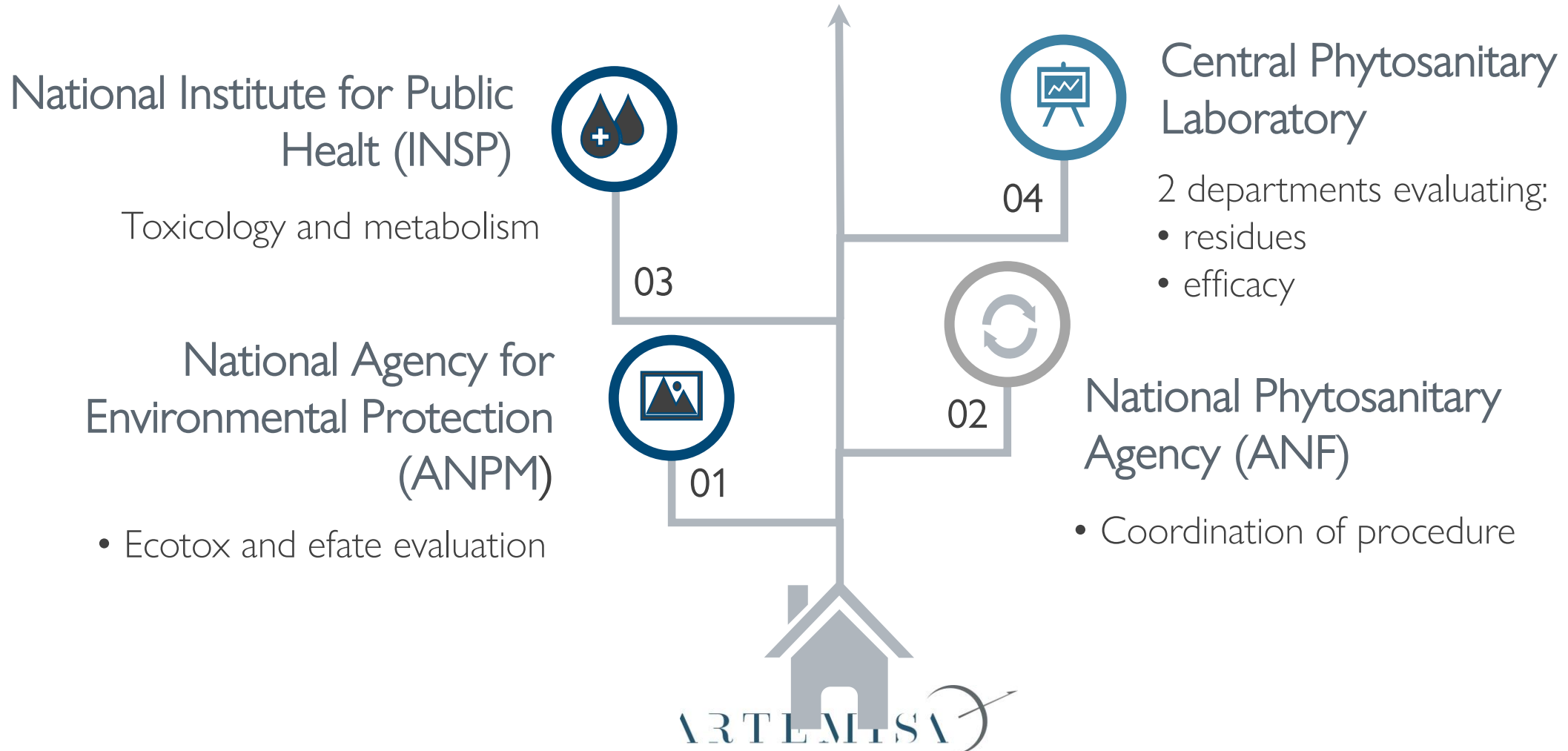
2. Romania

- 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

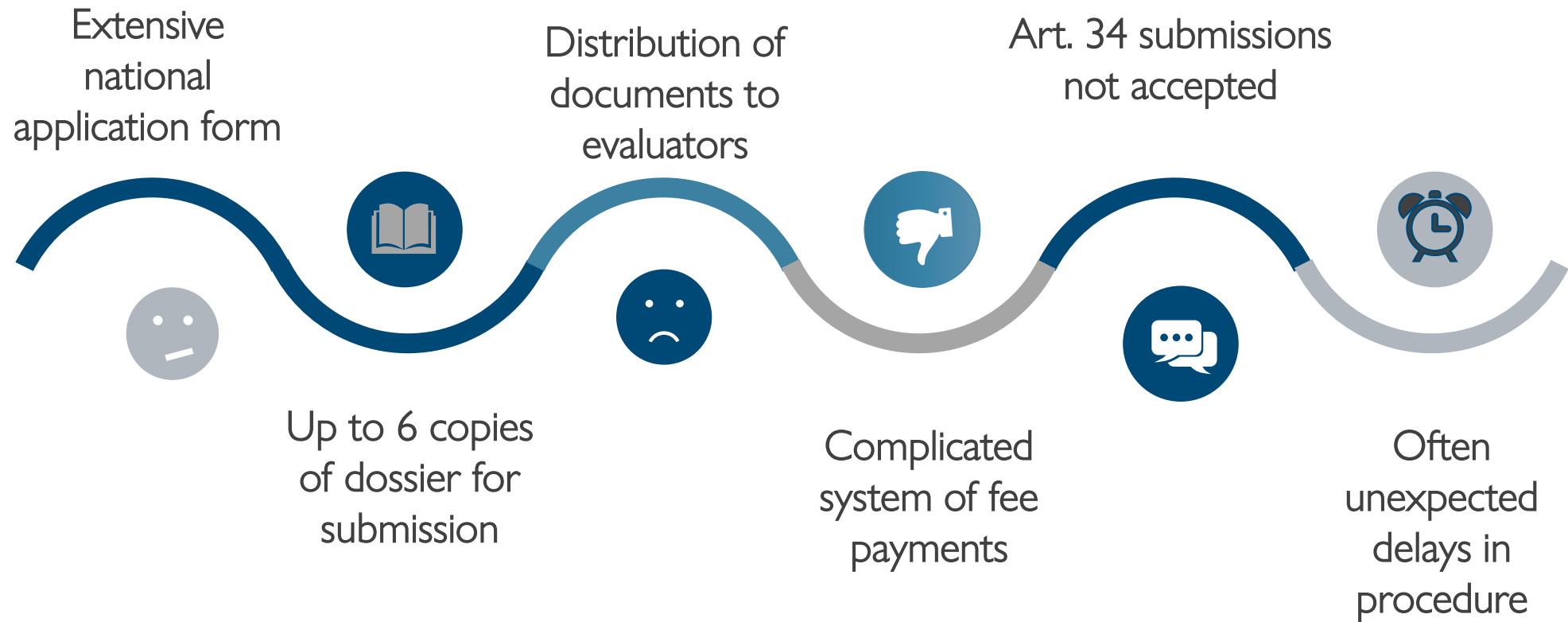


2. Romania – evaluating bodies

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



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

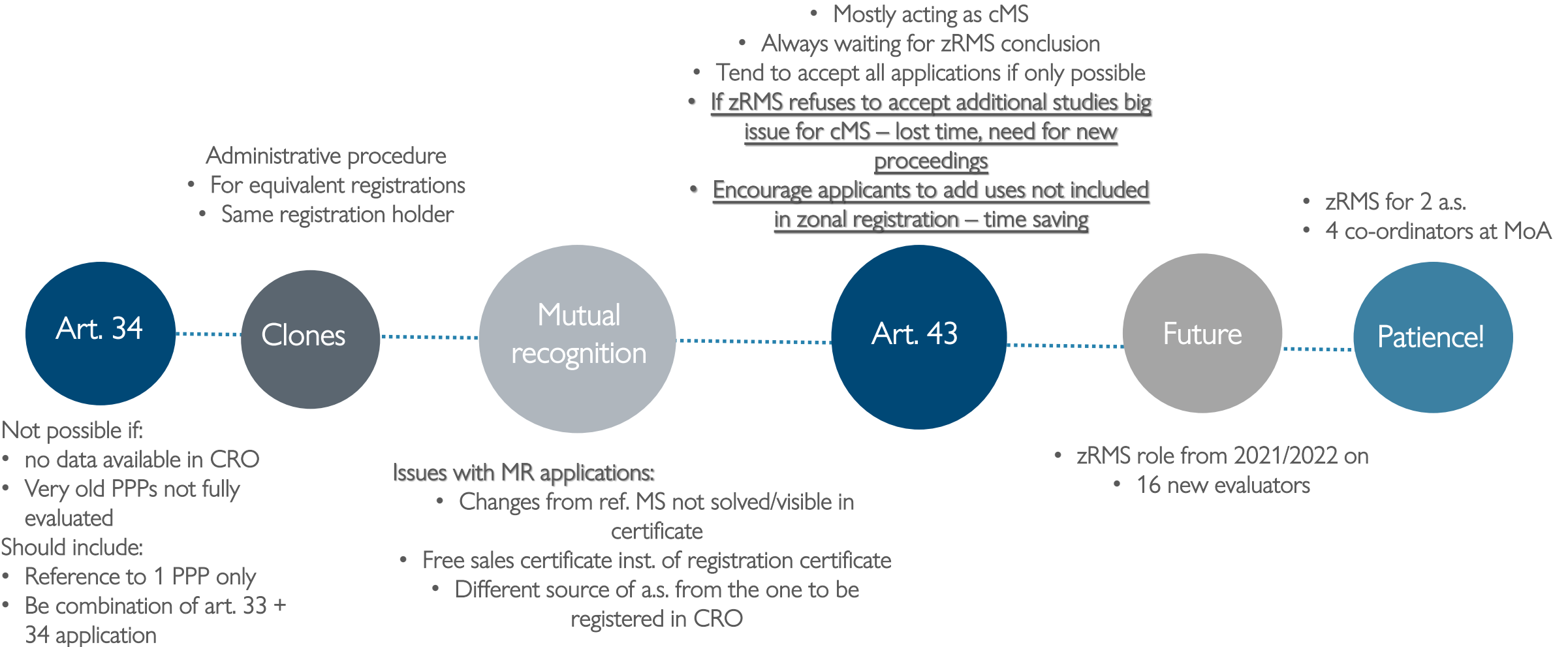


Comparative assessment guidance



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

Croatia - Procedures





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



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.

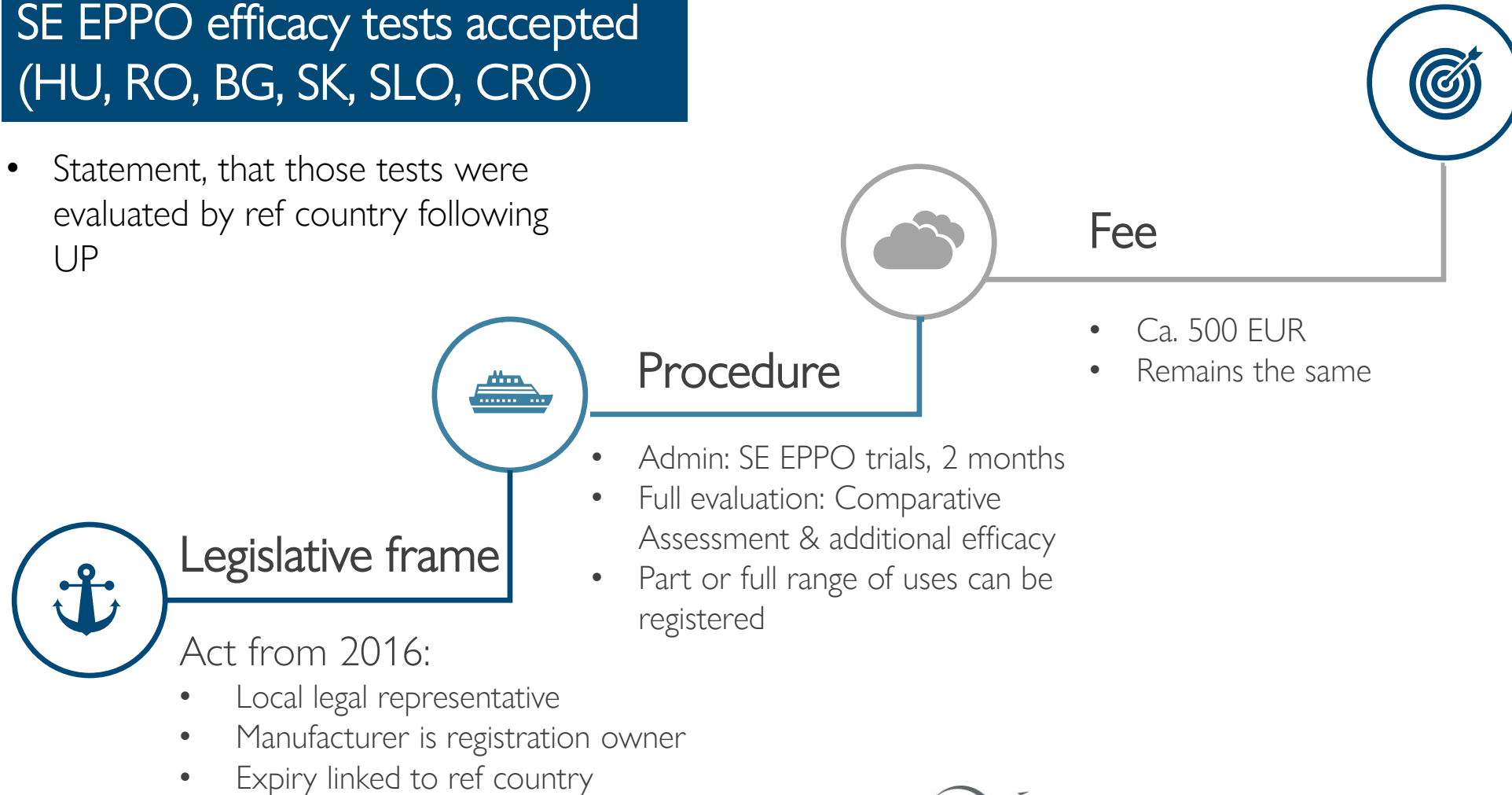
Local evaluators

- 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



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

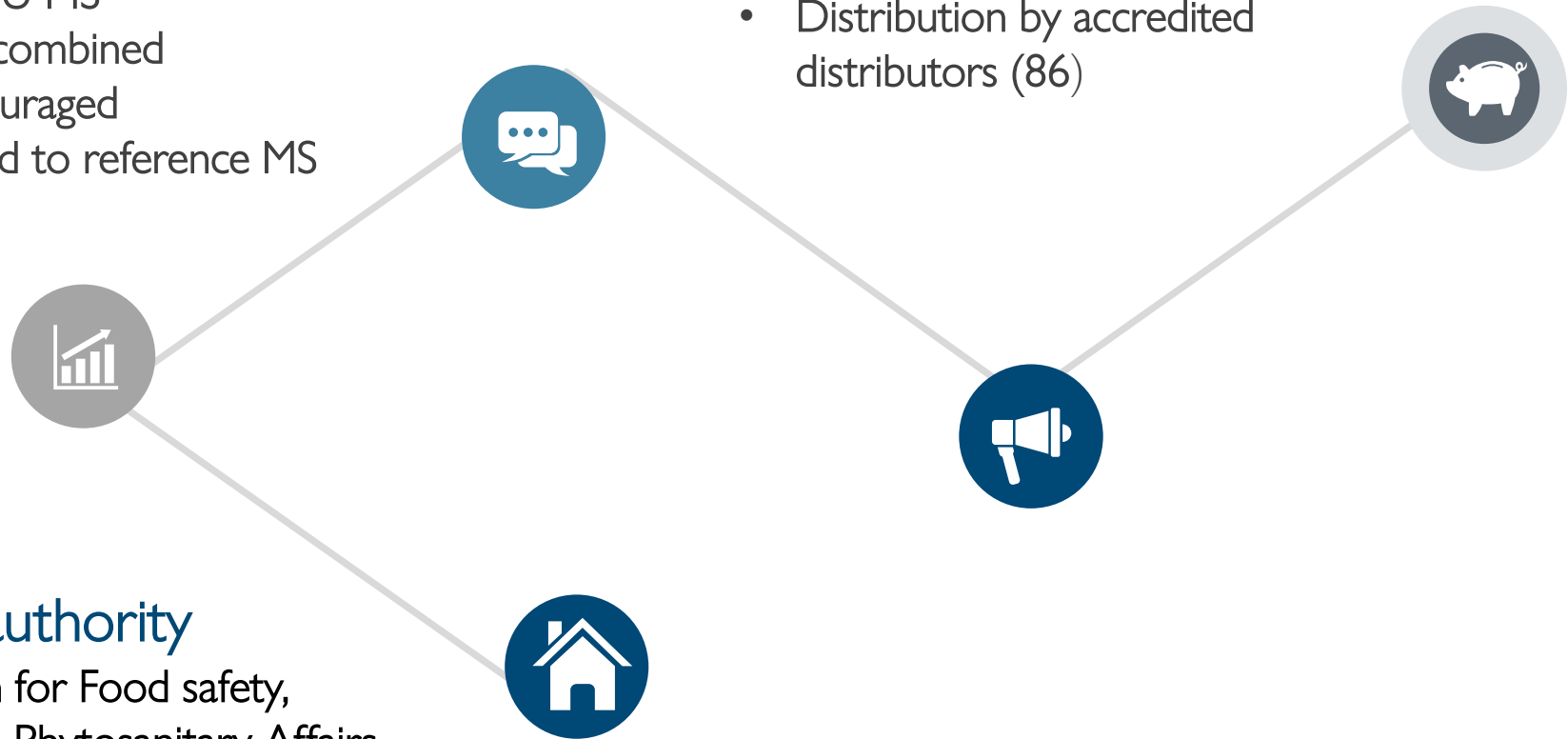
- Southern zone EU MS
- More countries combined
- Minor uses encouraged
- Expiry date linked to reference MS

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

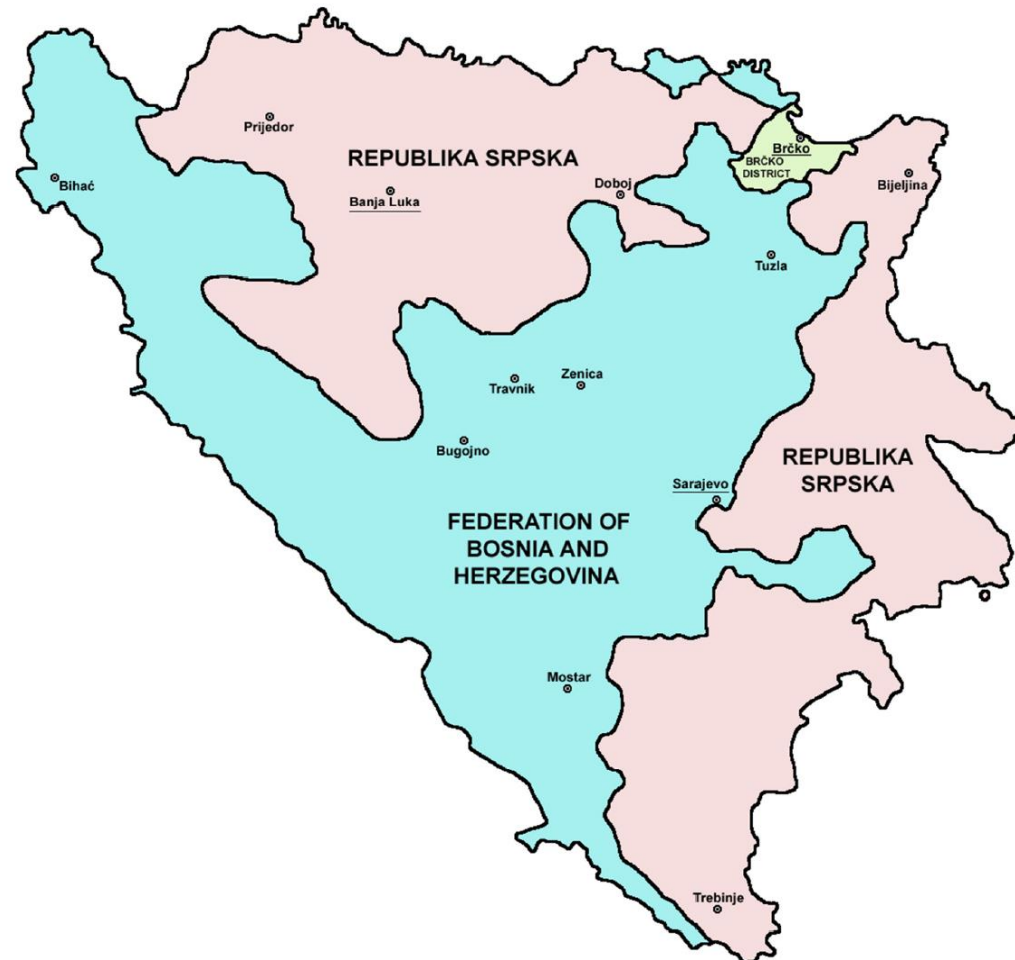


3. Bosnia and Herzegovina (BiH)

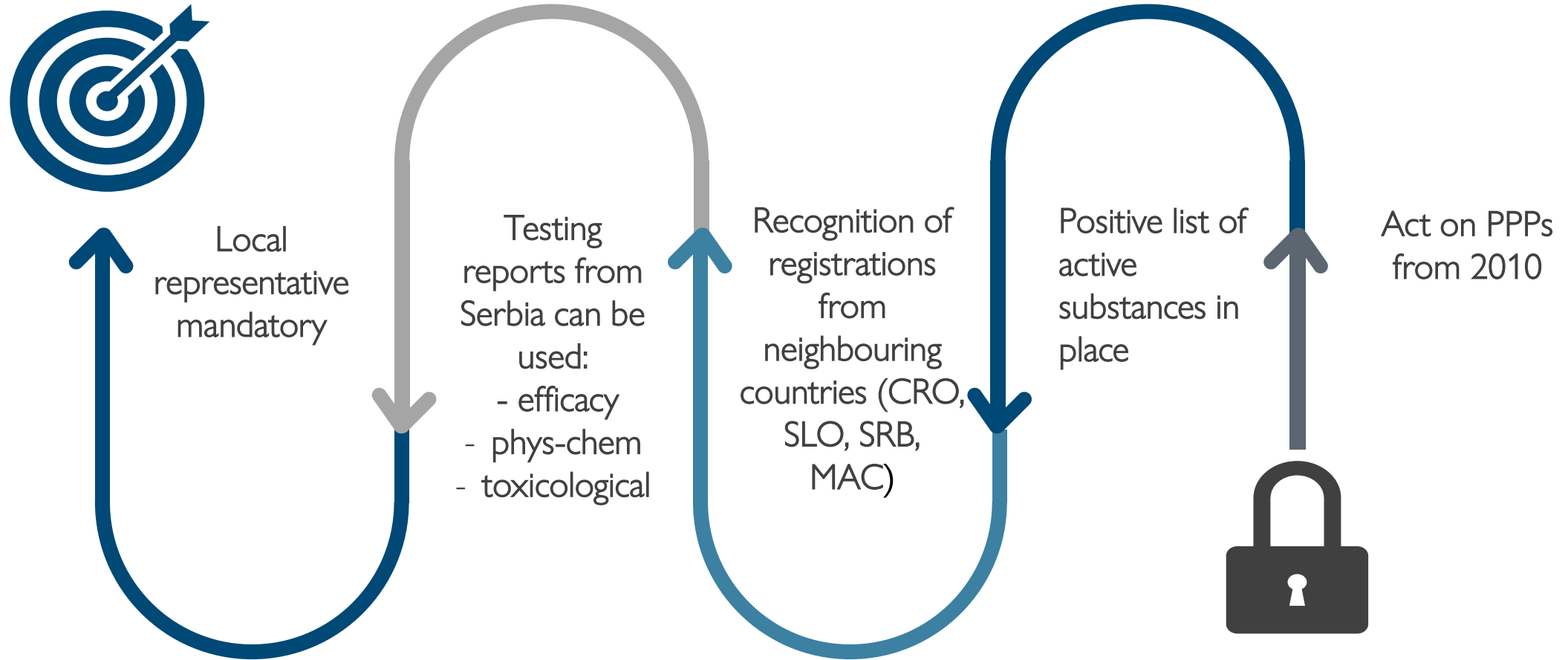


Two legal entities:

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



3. BiH – Republika Srpska

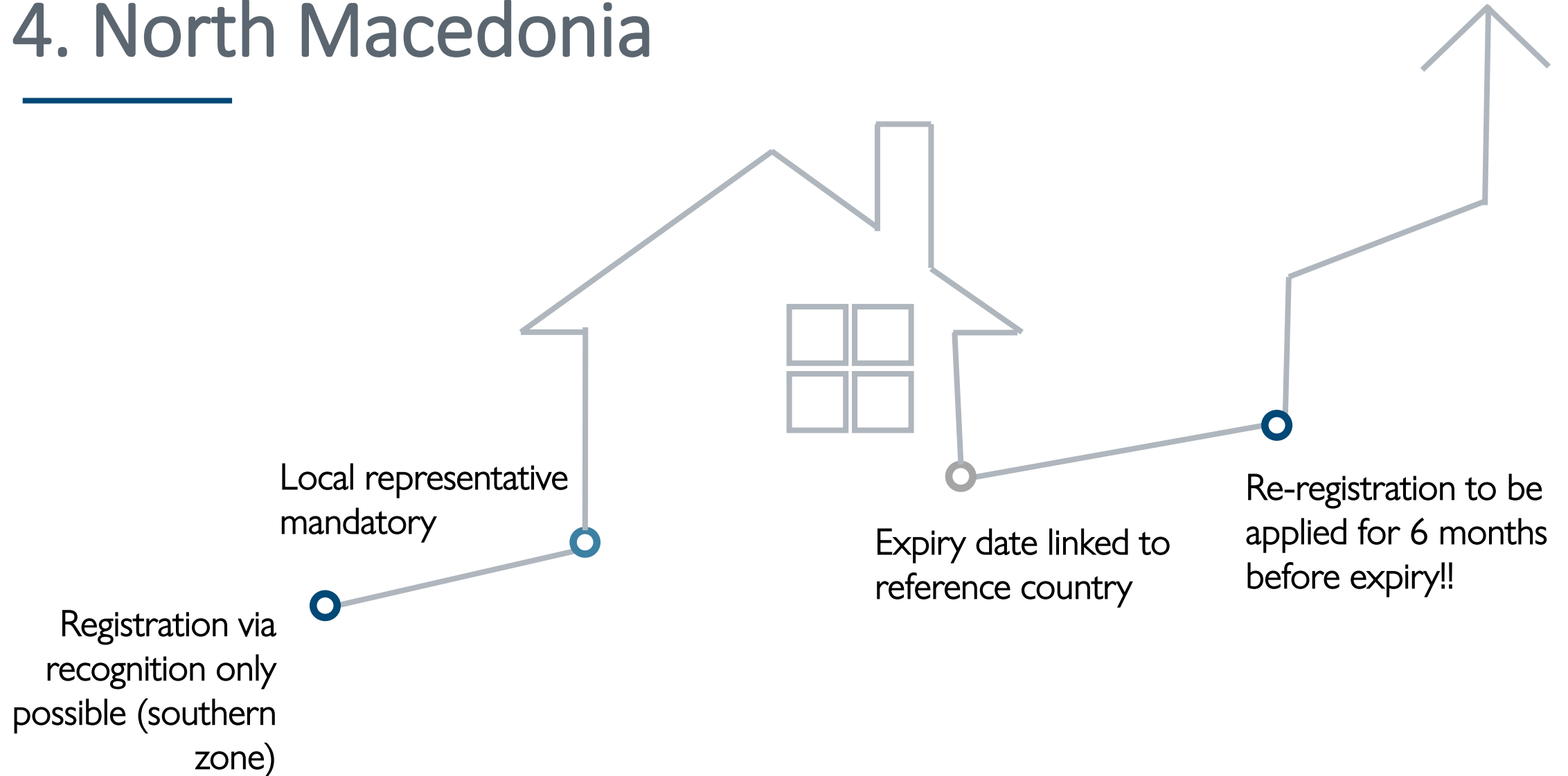


4. North Macedonia

- 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





Thank you

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