



Progress and hurdles in biocontrol regulation in Eastern EU

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The left side of the slide features a decorative vertical border. It consists of alternating dark blue and white vertical stripes. Scattered across these stripes are several stylized flowers. The flowers are primarily white with yellow or light blue accents on their petals. One large flower is positioned near the top left, while several smaller ones are distributed vertically down the stripes.

Topics

01

Who we are

02

Current EU situation

03

Progress and hurdles in Eastern Europe

04

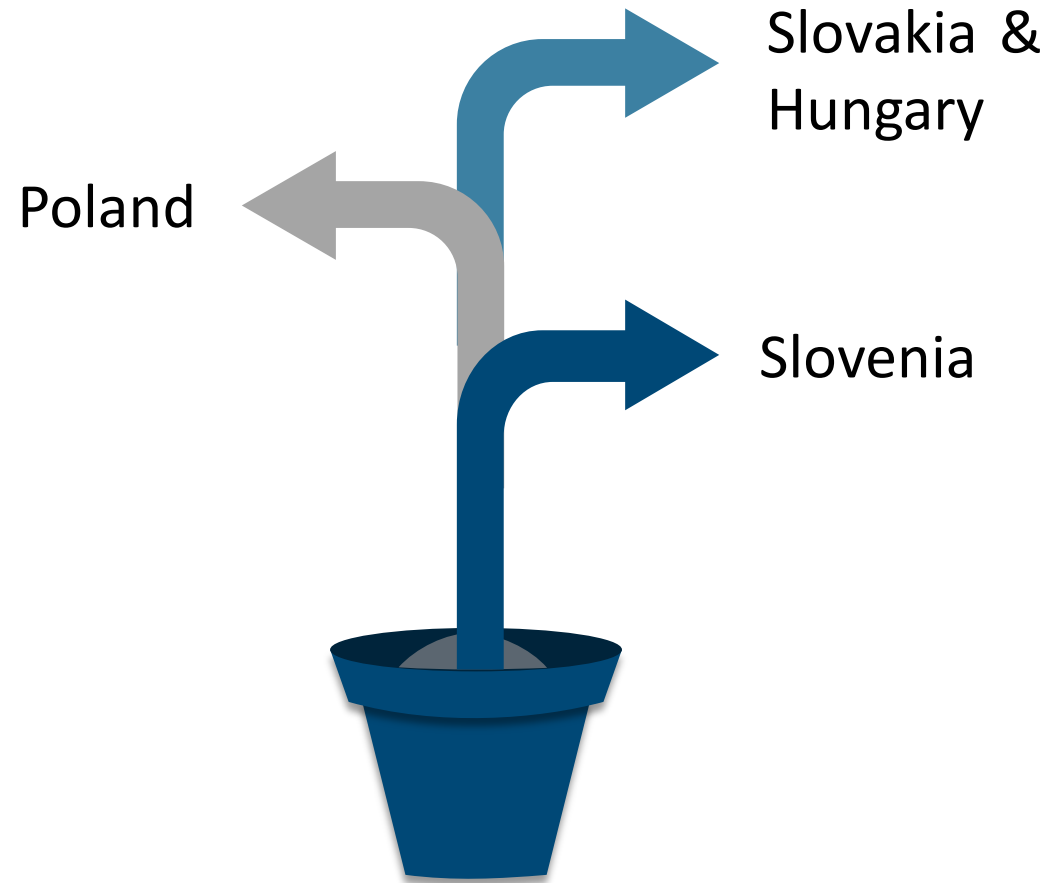
Conclusions



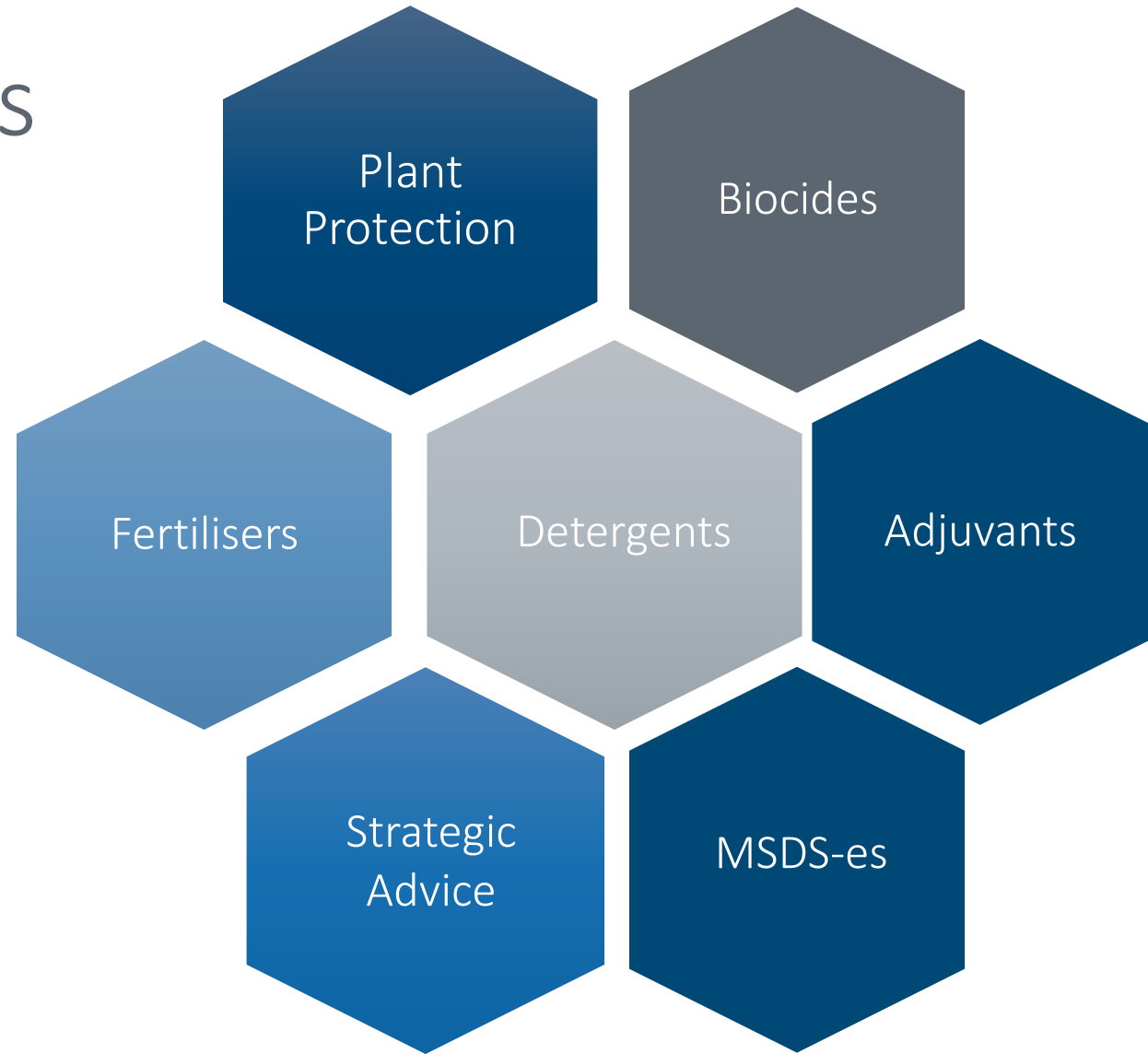
Who we are

About Us

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



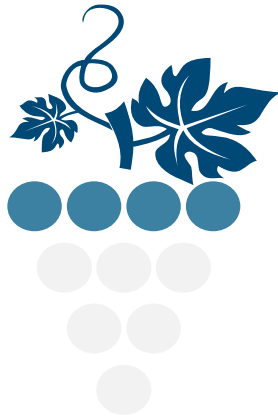
Regulatory Services





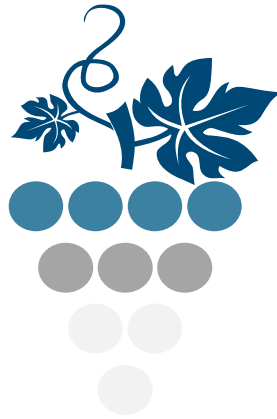
Current EU situation

Product categories as defined by IBMA



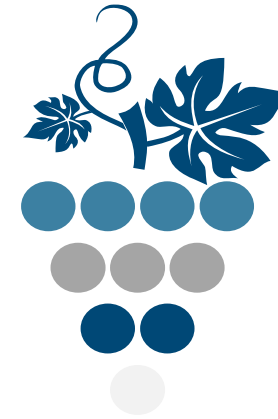
Semiochemicals

- Substances emitted by plants, animals, other organisms
- Target-specific, non-toxic mode of action.



Microbials

Microorganisms such as bacterial, fungi, viruses, viroids...



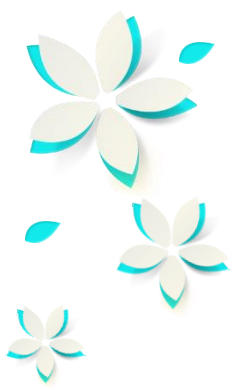
Natural substances

- Consist of one or more components originating from nature
- Are nature identical if synthesizes



Invertebrate control agents (macrobiols)

Natural enemies (insects, mites, nematodes)



Advantages of bioprotectants



Minimal impact on the environment



Low or no residue



Support sustainable use of PPPs



Respond to the public demand for safer food and environment



Encourage innovation



Able to cover niche markets and demands



Great tool for IPM programme



Opportunity for SMEs

Regulation (EC) No 1107/2009

Intended to regulate conventional chemical products

Based on hazard and not risk assessment

Need for a completely new/separate regulatory approach?

Hindering access of bioprotectants to the market in different ways:

- Not appropriate for bioprotection technologies
- Disproportionate registration cost
- Very long evaluation timelines and delays



Directive 2009/128/EC on sustainable use of PPPs

Responsible use
of PPPs and
compliance

Promotion of:

- Alternative approaches/techniques to conventional PPPs
- Long-term prevention of environment
- Careful monitoring before applying PPPs

Reduction of risk and
impact of PPPs on
human/animals/environment

IPM
Techniques:

- Biological control
- Habitat manipulation/managing of ecosystem
- Modification of cultural practices
- Use of resistant plant varieties



Other legislative acts

on organic production and
labelling of organic products

Regulation (EC)
No. 834/2007

Regulation (EC)
No. 396/2005

MRL of pesticides on food
and feed of plant and animal
origin

implementation of Reg. 834/2007
Annex II, Art.2
list of approved substances

Regulation
889/2008

Reg. 283/2013
Reg. 284/2013

GD on:

- Semiochemicals
- Botanicals
- Microbials (...)





Progress and hurdles in Eastern Europe

EU Member States tool box

Low risk substances

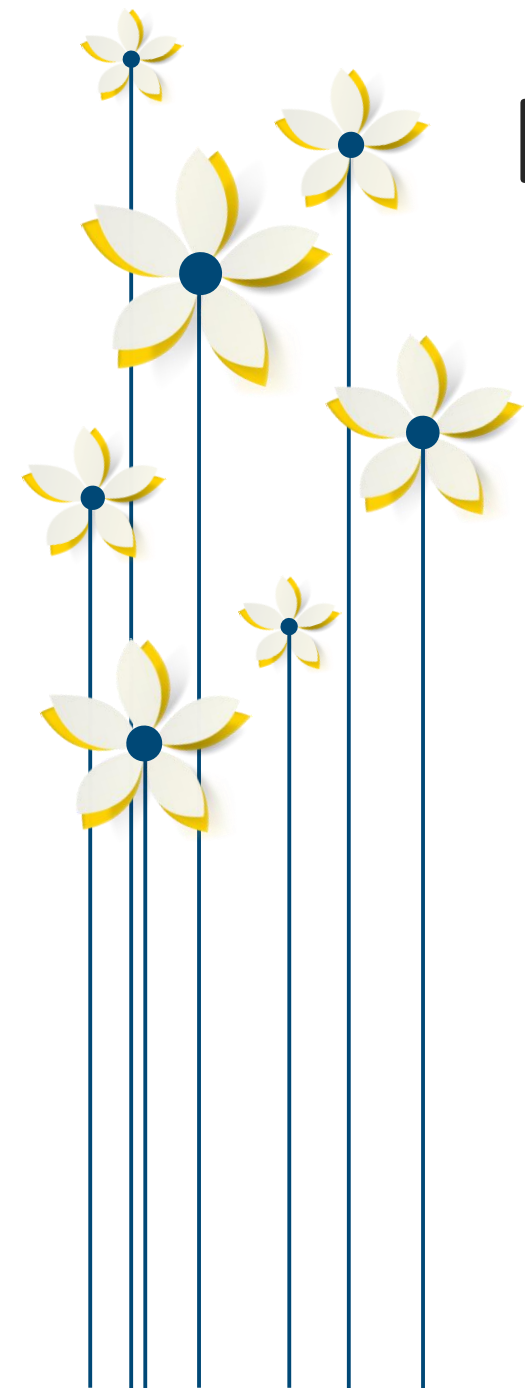
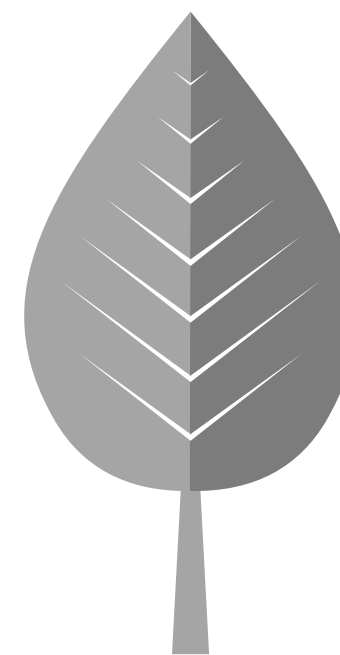
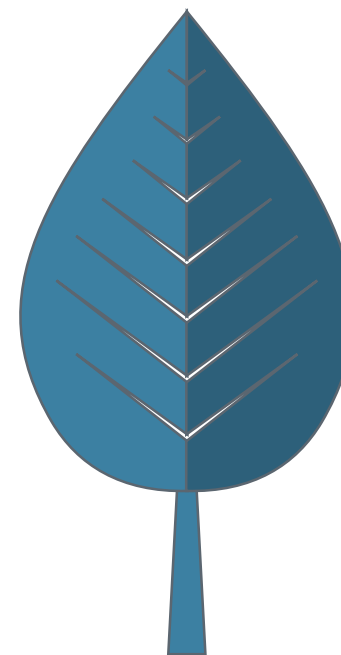
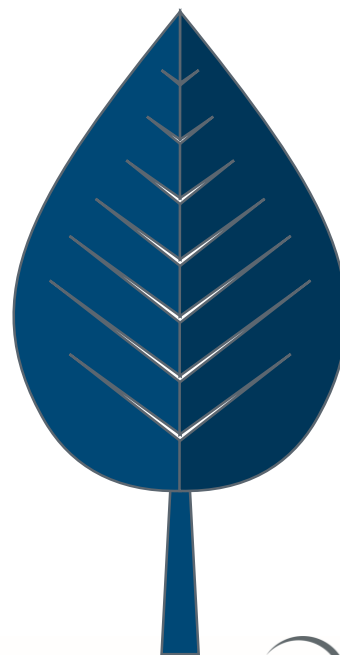
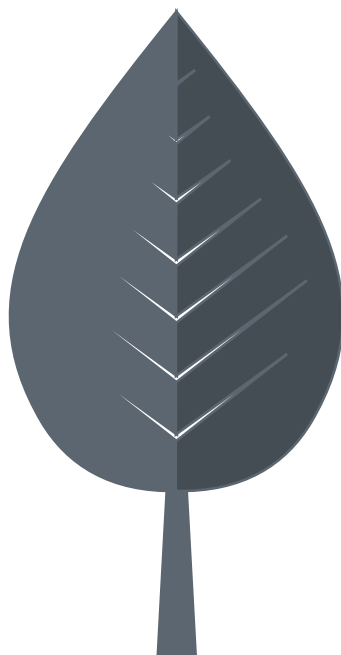
Basic substances

Minor uses

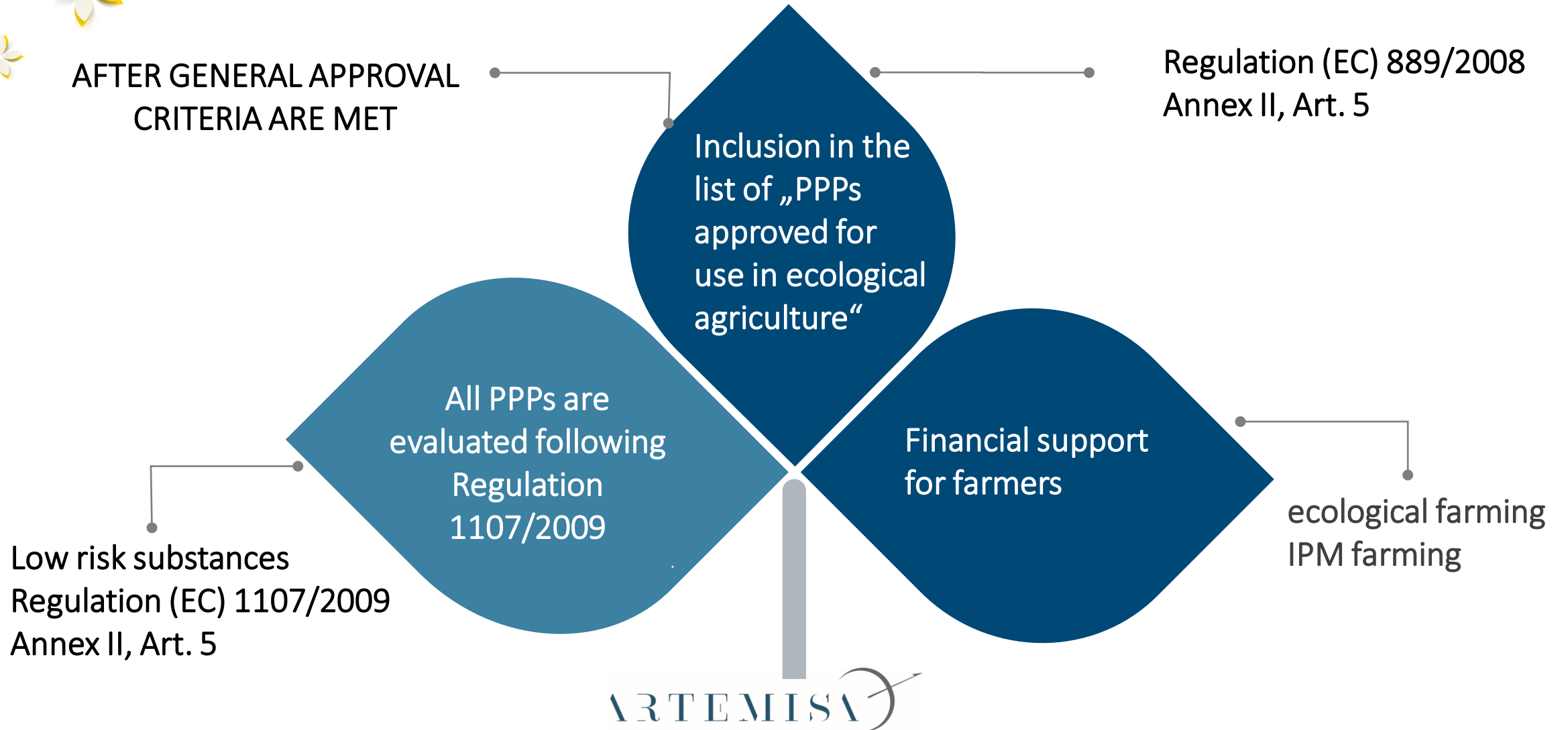
Regulation (EC) 1107/2009

PPPs for use in
ecological agriculture

Regulation (EC) 889/2008



EU Member States (SK, CZ, HU, PL...)





Poland

Listing as „Product used in ecological production“

01

General approval criteria following 1107/2009 have to be fulfilled

02

Application to IOR Institute

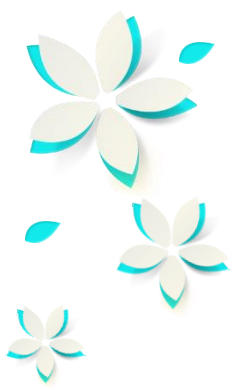
- Simplified procedure 1m
- Reduced fee 500 PLN
- Reduced data requirements

03

- Institute in Poznan issues certificate
- Inclusion in the list

04

- Producer allowed to promote product accordingly
- Farmers allowed to use it in ecological/organic farming



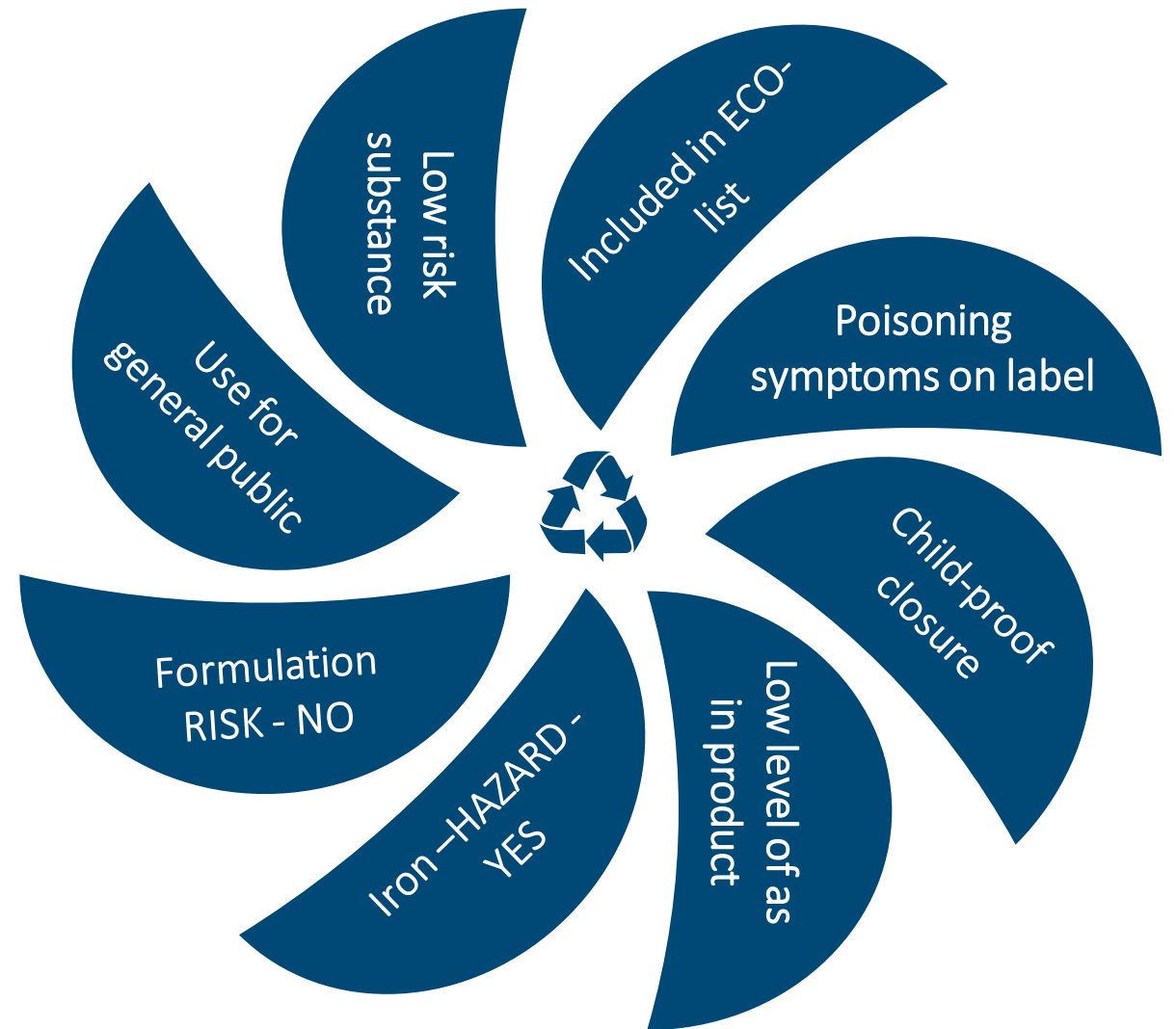
Experiences

Ferric phosphate

Naturally occurring ground mineral
Iron

- structurally bound as Fe-PO₄
- poorly soluble salt
- in anhydrous form

Delays in handling the
applications in all MS



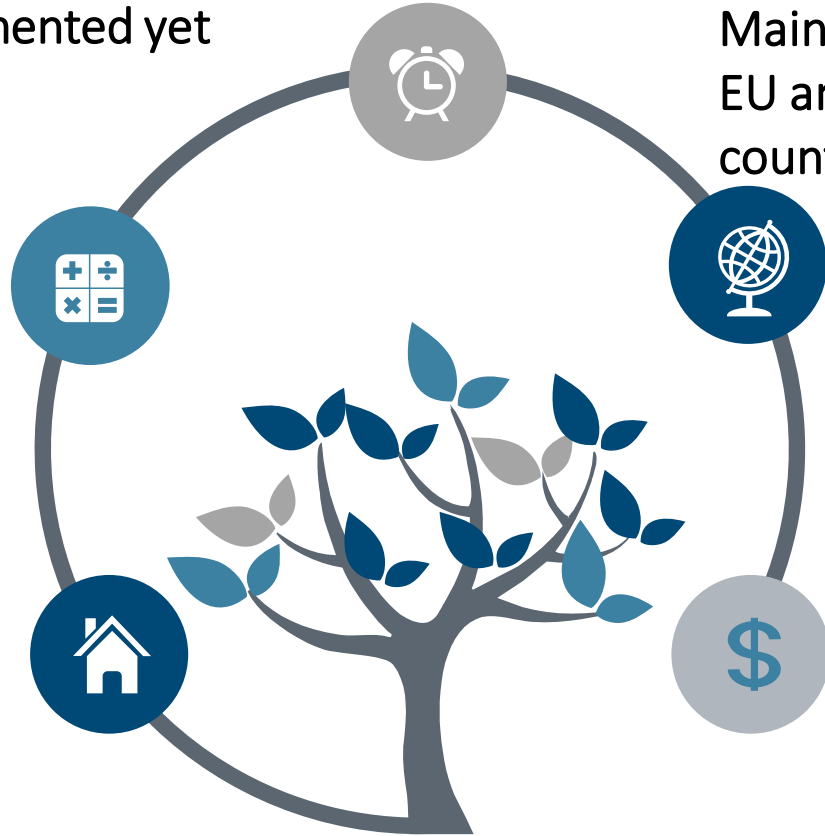
Non-EU countries

Regulation (EC)1107/2009 not fully implemented yet

Mainly recognition from EU and/or neighbouring countries

Counterfeit products/open borders issues

Very small/micro markets



Agriculture important for BDP
High unemployment rates






Conclusions

EU Member States & Non-EU countries

- Highly regulated market
- High awareness on the market
- Focused on low risk products
- Incomplete dossiers for PPP use – difficult to meet regulatory criteria
- Registration as different type of products (fertilisers), promotion as PPP

VS

- Regulatory framework not entirely implemented yet
- Lower awareness on the market
- Not primarily focused on low risk
- Priority to secure conventional PPPs on the market
- Pricing drives the market
- Serbia - example



Everyone seems to like
them, but...

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ARTEMISA 