

**ARTEMISA**  
 Regulatory Services Translation Services Events

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Member of:

fcn Fertiliser Consultants Network

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 CONSULTANCY SERVICES  
 EXPERIENCED, RELIABLE, FAST AND DEDICATED

**Regulatory services**

- Agrochemicals submissions
- Fertilisers and supplementary soil substances
- Adjuvants
- Biopesticides submissions
- Biocide submissions
- REACH and industrial chemicals
- Medical devices
- Detergents
- Classification and labelling
- Strategic advice
- Translation services
- Training and events

**Countries we cover**

**EU:** Slovenia, Croatia, Hungary, Poland, Czech Republic, Slovakia, Bulgaria, Romania, Baltics, Italy, Greece, Austria

**Beyond EU:** Serbia, Bosnia, Albania, Kosovo, Montenegro, Macedonia, Turkey, Ukraine, Russia, Moldova

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Contact our offices in Slovenia, Slovakia, Poland or Hungary:  
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## Romania – submission types

Placing on the market following  
Regulation 2019/515

NOT POSSIBLE

MR from another EU MS

NOT POSSIBLE

EC fertiliser placing on the  
market

POSSIBLE

National procedure

POSSIBLE

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## National procedure for non-EC fertiliser

### 2-years local efficacy testing



### Data requirements

- Short company presentation
- National application form
- Letter of authorization + letter of acceptance for local representative
- Product characterisation
- Effects on human health and environment + safety measures
- Certificate of analysis & analytical method used
- Product composition
- MSDS and product label with instructions for use

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## National procedure for biostimulants

### 2-years local efficacy testing



### Data requirements

- Short company presentation
- National application form
- Letter of authorization + letter of acceptance for local representative
- Product characterisation
- **Product composition indicating content of nutrients & heavy metals**
- **Description of raw materials used & their origin with analytical certificates**
- **Description of the production process**
- MSDS and product label with instructions for use

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## Local efficacy testing

### Who and what

- Executed by ICPA (agreement)
- Minimum 3 crops/crop groups
- 3 testing locations
- Test different crops in 2nd year
- Import of samples to cover 1 ha  
Import permit needed from non-EU countries
- Additional sample for chemical analysis

### Paperwork

- Submission 5-6 m before planting the crop
- MoA completeness check 2 m

### Expense

- 1.500 EUR/year
- Payment:
  - 30 % 2 months after signature
  - 70 % at the end of the trials

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## Timelines, Fees, Responsibilities

### National procedure

- ICPA 2 y efficacy testing & expert conclusions
- Limited placing on the market after 1 year:
  - Field crops to cover max. 9.000 ha
  - Orchards: 1.000 ha
  - Vineyards: 1.000 ha
- Ministry of Environment
  - environmental permit,
  - no fee
- Public Health Institute
  - health permit,
  - 50 EUR/product
- Full registration in year 4

### Future

- Regulation 2019/1009 in force from 16.7.2022
- What happens with ongoing national procedures?
- Will Regulation (EU) No. 2019/515 be applied?



\* ICPA – Institutul National de Cercetare-Dezvoltare Pentru Pedologie, Agrochimie si Protectia Mediului

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## Thank you!

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