



2

## Romania – submission types

Placing on the market following Regulation 2019/515

**NOT POSSIBLE** 

EC fertiliser placing on the market

**POSSIBLE** 

MR from another EU MS NOT POSSIBLE

National procedure
POSSIBLE

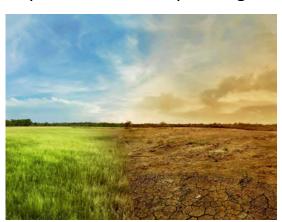




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# National procedure for non-EC fertiliser

### 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





## 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





# 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



