

# Application of the new (EU) **1009/2019 Fertilizer Regulation** – prospects and tasks before July 2022

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# **REGULATION (EU) 2019/1009**

OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 June 2019

**laying down rules on the making available  
on the market of EU fertilising products**

and amending Regulations  
(EC) No 1069/2009 and (EC) No 1107/2009

and repealing Regulation (EC) No 2003/2003

**- in force 16 July 2019  
- application 16 July 2022**

# Fertilizer legislation *EU – HU*



## EC Fertilizers

### 2003/2003 EC Regulation

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## All other fertilizers

Inorganic, Organic and Mineral fertilizers,  
Composts, Earthworm humus, Soil improvers,  
Soil-conditioners, Microbiological products,  
Growing media, Plant-conditioners

**Subject to authorisation**

**HU National legislation (decree 36/2006 FVM)**

~1500 authorized products on the market in HU



## *Background of new regulation (started 2016 – accepted 2019)*



- **EU – circular economy:** yield enhancers from organic materials or secondary raw materials
- **Standardization, elimination of authorization**
- **Products according to standards – post marketing control**
- **>90% of products will not be subject to registration**
- **Set up frames for environmental pollution concerning inorganic EC fertilizers (missing from 2003/2003 EC Reg.)**

# Optional harmonization

- Publication of regulation: **25 June 2019**
- Entry into force: **16 July 2019**
- Application : **from 16 July 2022**

**From 2022**

**national authorization still available for products:**

- **not fulfilling the new requirements**
- **voluntarily chosen by the manufacturer**

# PFC – product function categories – Annex I.

## **PFC 1. Fertiliser**

- A. Organic fertiliser (Solid, Liquid)
- B. Organo-mineral fertiliser
- C. Inorganic fertiliser

***Macronutrient***

***Micronutrient***

## **PFC 2. Liming material**

## **PFC 3. Soil improver**

- A. Organic soil improver
- B. Inorganic soil improver

## **PFC 4. Growing medium**

## **PFC 5. Inhibitor**

- A. Nitrification inhibitor
- B. Urease inhibitor
- C. Denitrification inhibitor

## **PFC 6. Plant biostimulant**

- A. Microbial plant biostimulant
- B. Non-microbial plant biostimulant

## **PFC 7. Fertilising product blend**

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*Definition of products, toxic elements, limits for pollutants and human pathogens, minimum nutrient content*

# CMC – component material categories – Annex II.

- CMC 1: Virgin material substances and mixtures
- CMC 2: Plants, plant parts or plant extracts
- CMC 3: Compost
- CMC 4: Fresh crop digestate
- CMC 5: Other digestate than fresh crop digestate
- CMC 6: Food industry by-products
- CMC 7: Micro-organisms
- CMC 8: Nutrient polymers
- CMC 9: Other polymers than nutrient polymers
- CMC 10: Certain products derived from animal by-products
- CMC 11: By-products within the meaning of Directive 2008/98/EC

Criteria – materials +/-, to be extended by Commission

## **Annex III.** - Labelling requirements (General and Product-specific) and tolerance rules

## **Annex IV.** - Conformity assessment procedures:

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-INTERNAL PRODUCTION CONTROL (**MODULE A**)

-INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING (**MODULE A1**)

-EU-TYPE EXAMINATION (**MODULE B**) FOLLOWED BY CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (**MODULE C**)

-QUALITY ASSURANCE OF THE PRODUCTION PROCESS (**MODULE D1**)

Executed by **notified bodies**



# Planned execution



## Member State

- To appoint notifying authorities → accreditation of notified bodies
- Market surveillance

## Manufacturer/producer, representative, distributor

- Responsible for quality
- Technical documentation
- Written EU declaration of conformity

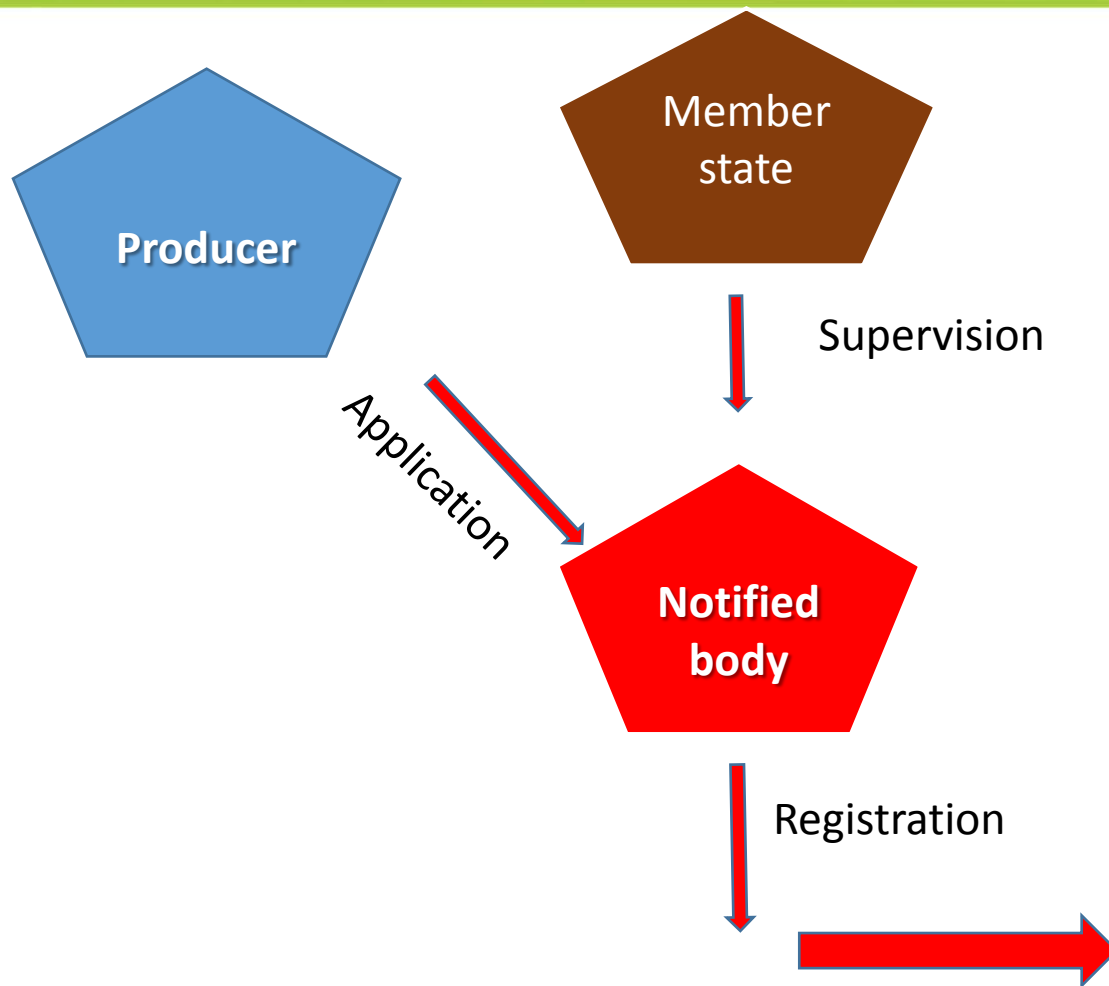
## Conformity assessment bodies (notified bodies)

- Conformity assessment
- EU-type examination

## EU Commission

- Amending Regulation - empowered to adopt **delegated acts**, add categories, materials

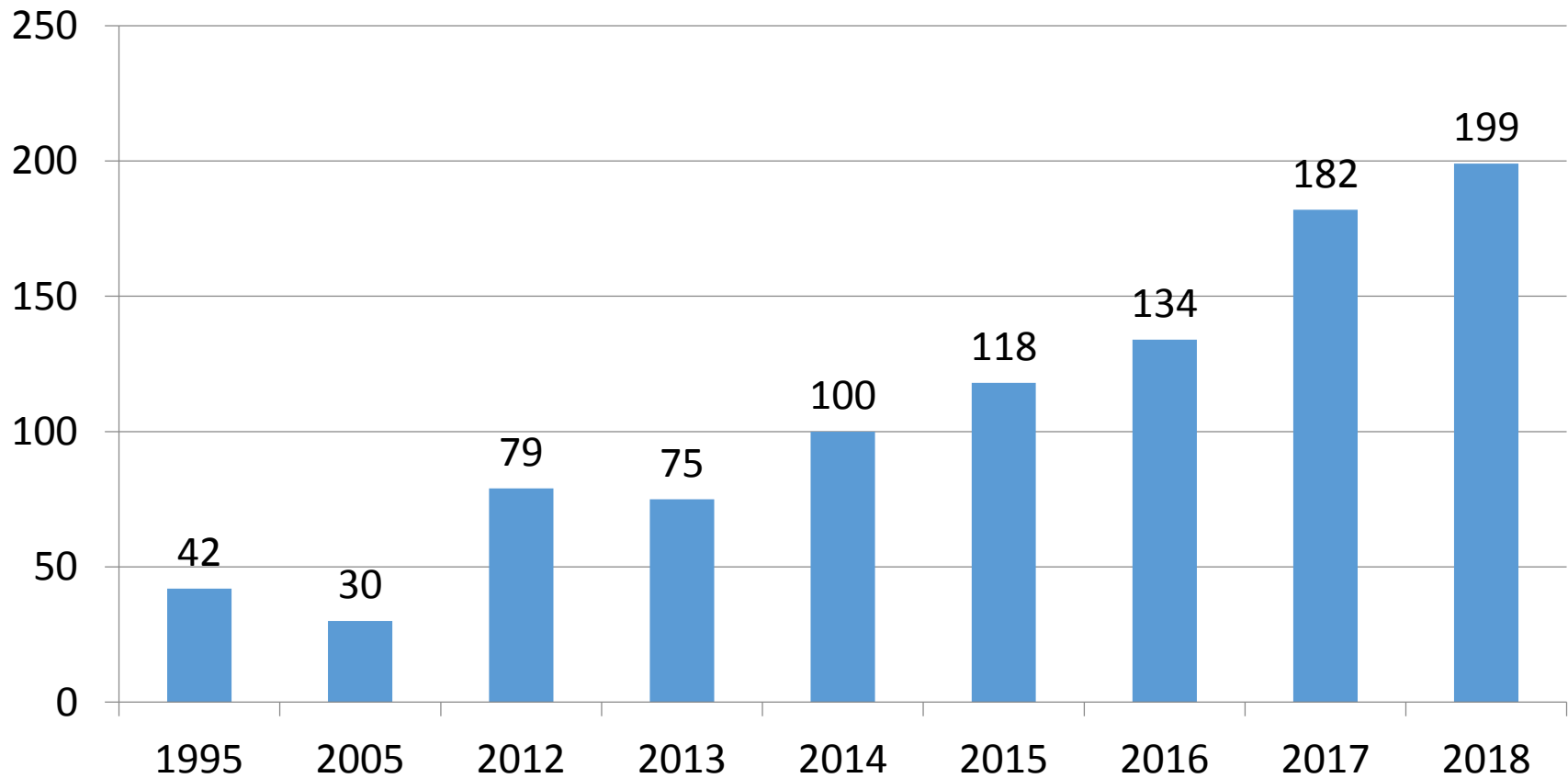
# Draft procedure



Free trade in EU MSs without further authorization



# *Number of total authorised plant conditioners in HU (valid registrations by the end of the year )*



# PFC 6: PLANT BIOSTIMULANT

1. A **plant biostimulant** shall be an EU fertilising product the function of which is to stimulate plant nutrition processes **independently of the product's nutrient content** with the sole aim of **improving** one or more of the following **characteristics** of the plant or the plant rhizosphere:

- (a) *nutrient use efficiency*,
- (b) *tolerance to abiotic stress*,
- (c) *quality traits*, or
- (d) *availability of confined nutrients* in the soil or rhizosphere.

## PFC 6. Plant biostimulant

A. Microbial plant biostimulant

B. Non-microbial plant biostimulant

## PFC 6(B): NON-MICROBIAL PLANT BIOSTIMULANT

*1. A non-microbial plant biostimulant shall be a plant biostimulant other than a microbial plant biostimulant.*



LIMIT VALUES (mg/kg dry matter) and tests required:

As	40
Cd	1,5
hexavalent chromium (Cr VI)	2
Cu	600
Hg	1
Ni	50
Pb	120
Zn	1500
Escherichia coli or Enterococcaceae (pc/1g)	1000
Salmonella sp. (pc/25 g)	0

4. The plant biostimulant shall have the effects that are claimed on the label for the plants specified thereon. (manufacturer responsible)



As	10
Cd	2
Co	50
Cr	100
Cu	100
Hg	1
Ni	50
Pb	100
Se	5
Fecal coliform (pc/g)	10
Fecal streptococcus (pc/g)	10
Pseudomonas aeruginosa (pc/g)	10
Salmonella sp. (pc/2 x 10 g)	0
Eggs human intestinal worms (pc/100 g)	0
total PAH content (19 compounds)	1 mg/kg d.m.
benz(a)pyrene content	0,1 mg/kg d.m.
mineral oil content (TPH C5-C40)	100 mg/kg d.m.
total marker PCB content	0,1 mg/kg d.m.
total PCDD/F content	5 ng/kg d.m. T.E.Q

Biological efficacy:  
3-6 field trials for each crop group

# *Efficacy is essential part of authorization – consumer protection*

**In general 3-6 field or glasshouse trials are necessary**

**Trial number determined by crop groups or cultivation branches**

**5.000-10.000 €**



# Registration cost of biostimulants

legislation	national decrees, in HU 36/2006 FVM
development	5.000-50.000€
procedure time (without studies)	5 months (HU)
procedure cost (without studies)	300-600 € (HU)
cost of studies	5.000-10.000 € (HU)

# *Fertilizer products may contain*

- **Cadmium** – highly toxic, carcinogenic (IARC 1.), endocrine disruptor heavy metal with accumulative properties
- **Ivermectin** (used in organic farming!) – antiparasitic biocide
- **Phosphonate** – authorizations withdrawn
- **Copper / Sulphur** - Micro and macro elements - **use** makes it PPP
- **Ricinus communis** to kill moles – plant poisons
- **Plant hormones** - algae, Plant Growth Regulator?
- **Microbial products, e.g. Trichoderma** – strains not on PPP active substances list
- **PPP basic substances** – mixed, for seed treatment
- **Nothing** – nothing at all (water as active substance)



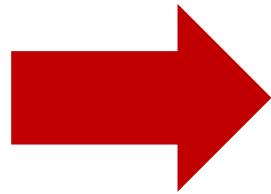


# *Concerns about the new system*

- Delegated acts by COM (instead of implemented act)
- Notified body – far from control of the concerned MSs
- Priority : free movement and easy marketing as opposed to human health and environment
- Ignorance of consumer protection (eg. no efficacy)
- Competition in misleading users  
(Experience with 2003/2003 EC Regulation)



# Necessary steps to be taken



## **Need to strengthen market surveillance**

- Member States shall entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks.  
(REGULATION (EC) No 765/2008 Article 18. (3))
- MSs to exchange information!

Thank you for the attention!

