



# National legal framework for the placing of fertilisers on the Greek Market

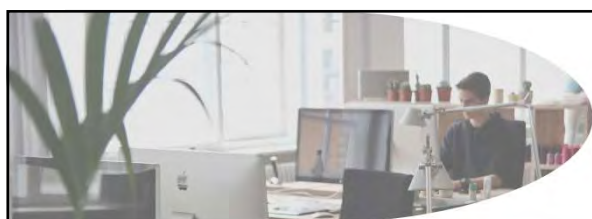
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| • Civil Engineers      | • Toxicologists | • Sanitary Engineers               |
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| • Electrical Engineers | • Chemists      |                                    |

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### Regulatory Compliance

- ✓ Pharma
- ✓ Medical Devices
- ✓ Cosmetics
- ✓ Food Stuff, Novel Foods  
Supplementary Food
- ✓ Tobacco Products
- ✓ Chemicals (Detergents, etc.)
- ✓ Agrochemicals (Fertilisers, Plant  
protection products)
- ✓ Biocidal Products (Local  
Authorisation & BPR)

### Agrochemicals Sector Services

- ✓ New Type Fertiliser Authorisation
- ✓ Regulatory compliance check
- ✓ EU Fertilising Products Regulation  
(FPR) (EU) 2019/1009
- ✓ Fertiliser Manufacturing Plant  
Design & Engineering
- ✓ REACH & CLP Compliance
- ✓ Poison Centre Notification (PCN)
- ✓ REACH registration/ authorisation
- ✓ Safety – Toxicological Assessment
- ✓ Environmental Product  
Declaration (EPD) Authorisation
- ✓ Ecolabel Certification

### Sustainability & Environment

- ✓ Environmental Impact  
Assessments
- ✓ Energy Efficiency
- ✓ Management Systems &  
Certifications
- ✓ Environmental Neutrality
- ✓ Carbon & Water Footprint
- ✓ Environmental  
Measurements
- ✓ Waste Management  
Consulting

### Health & Safety

- ✓ Occupational Risk Assessment
- ✓ SEVESO
- ✓ ATEX
- ✓ Safety Management Systems (SQAS, ISO)
- ✓ Field Measurements

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## Regulatory Framework

- EC Fertilisers**
  - Regulation 2003/2003
- New Type Fertilisers**
  - National Law 1565/85 (A'164)
  - Ministerial Decision 291180/11034/02 (B' 1274)
- Biostimulants, Soil Mixtures, etc.**
  - Ministerial Decision 217217/04 (B' 35)

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## EC Fertilisers Regulation 2003/2003

*Lays down rules relating to the placing of fertilisers on the market as well as the provision regarding the labelling and packaging of fertilisers. It aims at gathering all rules applying to fertilisers into one piece of legislation in order to ensure "the uniform application of a package of very technical provisions". Imposes precise requirements on manufacturers which have to be applied "at the same time and in the same manner throughout the Community"*

- In its Annex I, the regulation lists fertiliser types according to their specific characteristics. Once a fertiliser meets this type designation it may bear the letters '**EC**' (**EC fertiliser**) and may circulate freely on the European market. This way, the internal market and the free movement of goods are promoted.
- For a new type designation to be listed in the Annex I to the regulation, the manufacturer of a fertiliser corresponding to that type designation must lodge a request with a national competent authority. This request is forwarded to the European Commission, which consults the other EU countries and decides to accept or reject the application based on the advice of a committee set up by the regulation. → Time consuming procedure ~ 5 years

**The regulation only applies to mineral fertilisers consisting of one or more plant nutrients. Other fertilisers are governed by EU countries' national legislation.**



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## EC Fertilisers Regulation 2003/2003

- There is a lack of provisions on environmental protection (e.g. no specific limits for heavy metals) to be considered to have weakened the level of environmental protection and public safety, compared to national legislation.
- Also, the chemical processes to produce e.g. nitrogen fertilisers are energy consuming and involve high CO<sub>2</sub> emissions.
- Almost all product types currently included in the Annex I of Regulation 2003/2003 are conventional inorganic fertilisers which are mainly mined or chemically produced following a linear economy model.
- **Significant percentage (at least 50%) of the fertilisers currently on the market remains outside the scope of the regulation.**



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## New Type Fertilisers National Legislation

- **National Law 1565/85 (A'164), Ministerial Decision 291180/11034/02 (B' 1274)** In Greece any fertiliser which does not fall within the scope of the European fertiliser Regulation 2003/2003 is classified as a **new type of fertiliser**.
- New type fertilisers are divided in **7 subgroups**. The most important are:
  - **Inorganic fertilisers** with primary and/or secondary nutrients with or without trace elements (Micro-nutrients) that are **not** covered according to Annex I of Regulation 2003/2003
  - **Organic fertilisers** with primary and/or secondary nutrients with or without trace elements (Micro-nutrients)
  - **Organo-inorganic fertilisers** with primary and/or secondary nutrients with or without trace elements (Micro-nutrients)
  - **Micro-nutrients**



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## New Type Fertilisers Requirements

- ☐ Must not present danger for humans or animals.
- ☐ Its main action must be due to the nutrients it contains.
- ☐ Must not contain Hexavalent Chromium ( $\text{Cr}^{6+}$ ).
- ☐ The content of organic substances, such as polychlorinated biphenyls, azo dyes, nitrophenols, aromatic hydrocarbons, etc., should not exceed 0.0005 mg per Kg of product
- ☐ Contains at least:
  - ☐ 3 % for nutrients ( $\text{N}, \text{P}_2\text{O}_5, \text{K}_2\text{O}, \text{CaO}$ ) and/or
  - ☐ 2% for nutrients  $\text{MgO}$ , S and/or
  - ☐ 1000 mg/kg (ppm) trace elements (Micro-nutrients) Fe, Mn, Zn, Cu, Mo, B, Co, cumulatively or individually.
- ☐ In addition to the above, a new type of fertiliser may contain:
  - ☐ Substances that have an improving effect on the physicochemical properties of the soil
  - ☐ Substances that enhance the availability of nutrients contained in the product
  - ☐ Growth factors, microbial cultures (nitrogenous bacteria, free or symbiotic), fungi or other microorganisms that increase the availability of nutrients in soil.



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## New Type Fertilisers Requirements

The content of the product for the elements listed in the table below should not exceed the limits indicated:

Heavy Metal	Upper acceptable limit
Cd	12mg/kg of product
Ni	30 mg/kg of product
Pb	50 mg/kg of product
Hg	2 mg/kg of product
Cr <sup>3+</sup>	300 mg/kg of product
Cr(VI)(Hexavalent)	None / not detectable
As	4 mg/kg of product
Cu*	200 mg/kg of product
Zn*	750 mg/kg of product

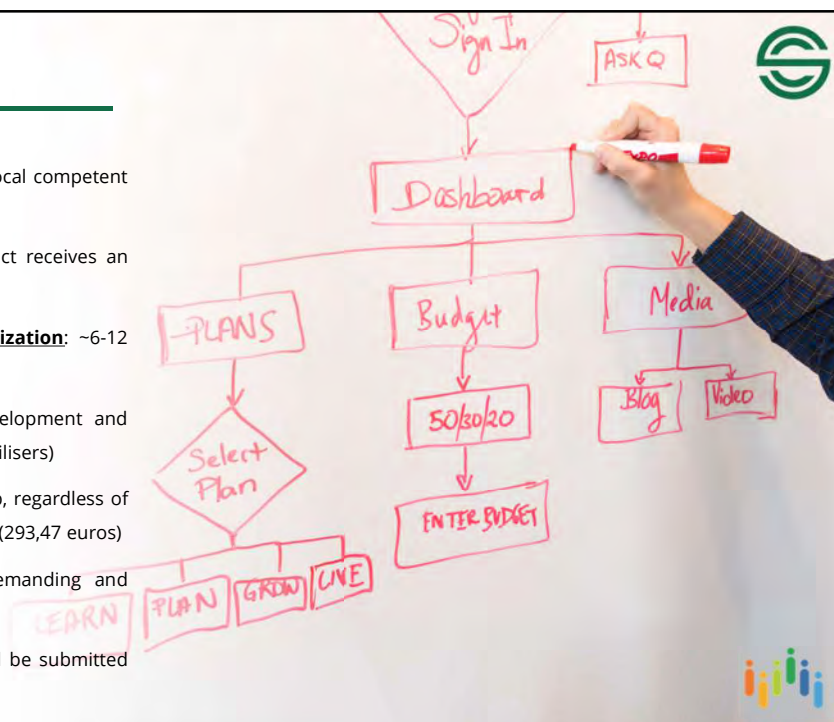
\* The restriction applies in case the product contains municipal and / or industrial waste



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## New Type Fertilisers Product Authorization

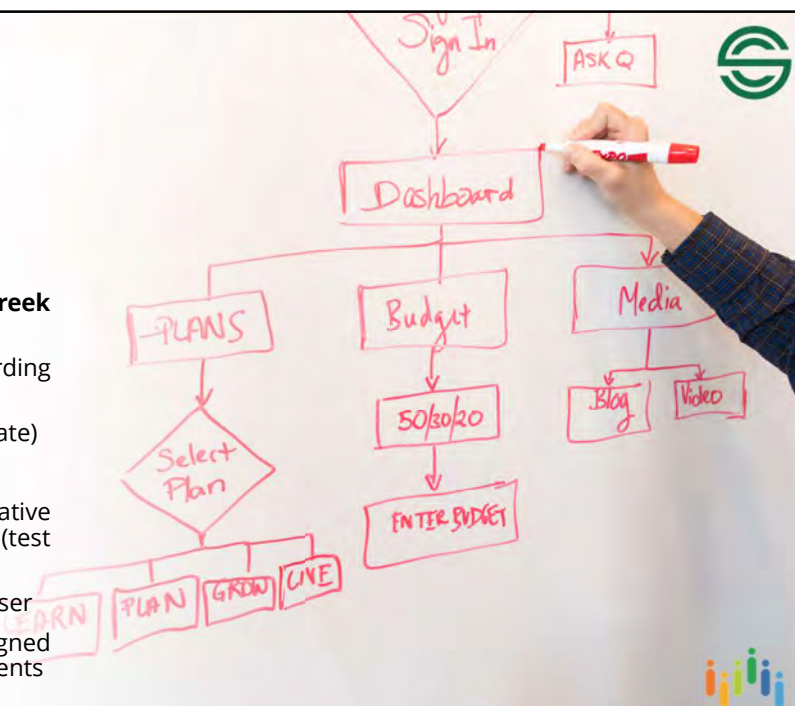
- ❖ Authorization dossier is submitted to the local competent authorities.
- ❖ After the successful evaluation, the product receives an authorization number.
- ❖ **Duration for the completion of authorization:** ~6-12 months
- ❖ **Competent Body:** Ministry of Rural Development and Food (Technical Advisory Committee on Fertilisers)
- ❖ **Administration fee:** One fee per subgroup, regardless of the amount of products that are registered. (293,47 euros)
- ❖ Preparation of technical dossier is a demanding and complicated procedure.
- ❖ All the dossier contents/documents should be submitted in Greek language.



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## New Type Fertilisers Data Requirements

- National application form
- Product characterization
- MSDS of raw materials
- MSDS of the final product in **Greek Language**
- Classification and Labeling study according CLP Regulation (1272/2008/EC)
- % chemical composition (full and accurate)
- Manufacturing process
- Certificate of qualitative and quantitative analysis and analytical method used (test reports)
- Documentation on the efficacy of fertiliser
- Label of the product properly designed according to specific national requirements



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## Soil Improvers, Soil Mixtures, Biostimulants and Crop - Livestock Residues



In Greece, Soil Improvers, Soil Mixtures, Biostimulants and Crop - Livestock Residues, which are not considered as fertilisers, are governed by the legal framework defined by specific Ministerial Decision 217217/2004 (B' 35).

- **Soil improvers:** They are natural or synthetic inorganic or organic substances that do not contain significant amounts of nutrients and their use contributes to the improvement of the physicochemical and biological properties of the soil, as well as to increase the effectiveness and the availability of fertilisers
- **Crop Substrates (Soil Mixtures):** These are products that mainly serve to create a means of plant growth (root layer) instead of natural soil (or its supplement) with suitable physicochemical properties that favor germination, rooting and rapid plant growth, such as peat, topsoil, peat-based mixtures, expanded perlite, sand, manure, newer mineral coals and more.
- **Auxiliary substances for plant growth (Biostimulants etc):** These are substances that, without containing significant amounts of nutrients, mainly have a beneficial effect on the physiology of plants and / or the stimulation of plant nutrition.
- **Crop - Livestock Residues:** By-products of livestock, such as animal excrement (manure, urine, urine mixed with water, straw etc.), compost, straw and other similar crop residues.



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## **Soil Improvers, Soil Mixtures, Biostimulants and Crop - Livestock Residues**



### **Data Requirements and Product Registration**

- The procedure provided is significantly simpler than that for new types fertilisers.
- The data required are significantly less than those required for new type fertilisers.
- No technical dossier preparation and evaluation is required in order for a product to be circulated in Greek market
- It is enough to submit at the beginning an application for notification of product circulation, to the competent authority
- Necessary documents: Safety Data Sheet in Greek, label properly formatted according to the national legislation, technical data sheet and a certificate of analysis (%composition).



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## **Mutual Recognition**

The elephant in the room...



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## Mutual Recognition

### Greek Reality

**In Greece, Mutual Recognition is not possible for New Type Fertilisers!**

- However, Greece is required to incorporate a mutual recognition procedure to its legislation.
- It is unknown when and how this will happen.

**So, what happens to fertilisers, that are authorized in other MS?**

- The Greek national legislation for new type fertilisers exists and has specific (strict) requirements. Therefore, a marketing authorization (pre-approval) is required for the placing of fertilisers on the market, even if they have been previously authorized in different member state.
- As a result, in practice every economic operator who wants to circulate a fertiliser should prepare and submit a technical dossier for evaluation in the national competent authority.
- EC Fertilisers and biostimulants do not require authorisation procedures but should be compliant to the EU and national regulatory framework.



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## Coming Soon

### REGULATION (EU) 2019/1009

- The implementation of Regulation (EU) 2019/1009 in Europe is expected to affect rapidly and significantly the Fertiliser registration framework.
- Major changes in fertilising sector will take place.
- National legislative framework for Fertilising products is expected to be affected seriously.
- Towards this direction, many products will have to change significantly in order to be able to keep up with the upcoming demands.
- Mutual Recognition will probably (and should) play a much more crucial role.
- **In Greece national legislation is expected to be revised in order to include New Type Fertilisers, Biostimulants and former EC Fertilisers.**



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## In a Nutshell...

*The fertiliser regulatory framework can be a very demanding maze of European and various National legislations (Regulations, Laws, Ministerial Decisions, Decree, Circulars...).*

Specific Requirements for placing fertilisers on the Greek Market:

- **EC Fertilisers** do not require authorisation but do require notification and fall within the scope of REACH, CLP Regulations and other local legislations.
- **New Type Fertilisers** require authorisation by the local authorities, have various restrictions and fall within the scope of REACH, CLP Regulations and local legislations. **There is no Mutual Recognition!**
- **Biostimulants and other fertilising products** do not require authorization but do require notification and fall within the scope of REACH, CLP Regulations and other local legislations

Always ask your local Regulatory Consultant, when placing fertilisers (or fertilising products) on the Greek market, there are a lot of local restrictions!



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**Thank you for your  
attention**

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