

Fertiliser Consultants Network Free Webinar

29 June 2021

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- ❖ **13:00 - Short introduction of the FCN network – why is it needed?
Critical points of the Regulation (EU) 2019/1009**
(Mariano ALESSIO VERNI' - SILC Fertilizzanti)
- ❖ **13:15 - How to manage fertiliser registration in the transitional period
2021-2024? MR possibilities**
(Ferran SOLDEVILA ELIAS - Sun Chemicals Services)
- ❖ **13:30 - Fertilizer registration for placing on the market in France**
(Pascale CHENON – Voxgaia)
- ❖ **13:45 - Fertiliser registration in Romania**
(Bojana ZGONEC – Artemisa)
- ❖ **14:00 - Fertiliser registration in Morocco, Algeria and Egypt**
(Isidoro D'ISIDORO – Openagri)
- ❖ **14:15 - Biostimulant registration in India**
(Pooja VISHNOI – Auxilife)
- ❖ **14:30 - National legal framework for the circulation of fertilizers in
Greece**
(Ippokratis LYGIZOS –SustChem)
- ❖ **14:45 - Q & A 15:00 - END**

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Short introduction of the FCN - Critical points of the Reg. (EU) 2019/1009

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WHY A NETWORK?

- **Preliminary Remarks:**

1) Globalisation and new markets;

2) Innovative fertilisers (eg. biostimulants) and the need to regulate them properly;

3) Reg. (EU) 2019/1009 delayed and not applicable to several types of fertilisers already in use at a national level;

4) More extensive use of EU procedures on Mutual Recognition after the entry into force of Reg. (EU) 2019/515;

5) Need to have an in-depth knowledge of National Rules, their development and good relationships with local authorities;

6) Increase in the number of customers wishing to expand their market and the difficulties of helping them on a local basis;

7) It is impossible to know everything and stay up to date;

8) Language issues.

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WHO and WHERE



A group of **extremely specialised** regulatory experts with knowledge of the EU as well as worldwide **regulations and requirements** in place

OUR NETWORK IS YOUR NET WORTH

FCN Fertiliser Consultants Network

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REG. (EU) 2019/1009: problems

- Some types of the «old» Reg. 2003/03 **do not fulfill** the «new» in terms of minimum nutrient content (eg: crude potassium salt, calcium borate, etc.)
- The types *element-based* fertiliser provided in the «old» allow the presence of **oxide or hydroxide micronutrients**; the «new» typology *Micronutrient-based fertiliser* only allows the combination of water-soluble **micronutrient salt** fertilisers
- The category of ORGANO-MINERAL FERTILISER (solid and liquid) **do not provide** minimum content for the secondary macronutrients (eg. Mg, S)
- In a solid organo-mineral fertiliser, each *physical unit* must contain organic carbon (C_{org}) and all the nutrients in their declared content. A *physical unit* refers to one of the component pieces of a product, such as granules or pellets: **impossible requirement**
- CMC 10 (DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) 1069/2009): **empty**
- CMC 11 (BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC): **waiting** for a “delegated act”



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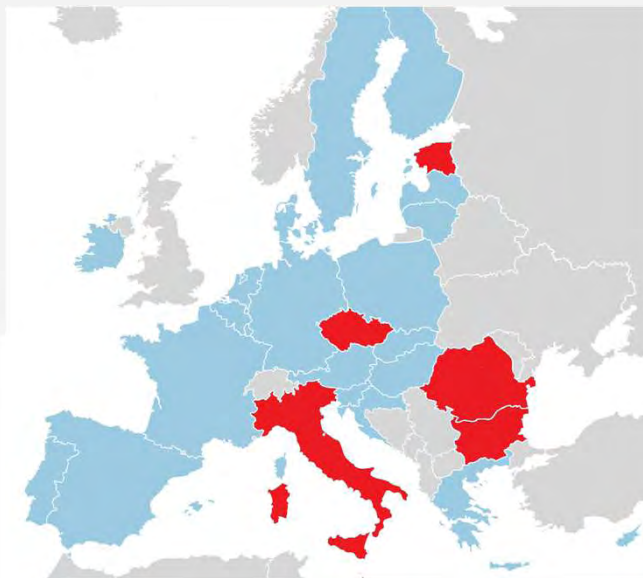
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REACH references

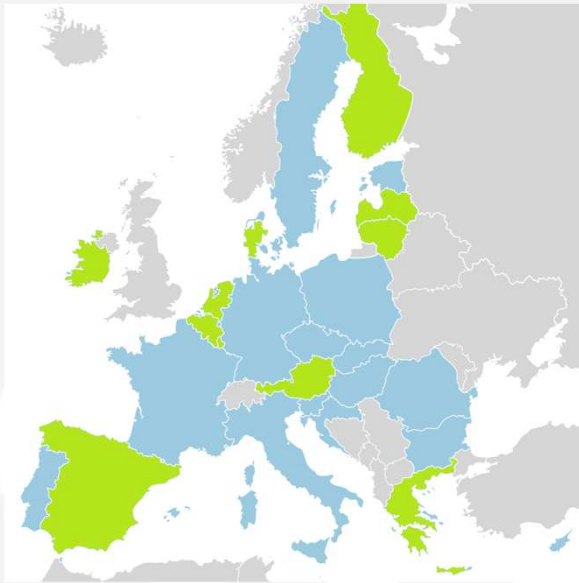
- Substance and mixture definitions are defined as art. 3 of Reach
- For: CMC1 + CMC3 compost additives + CMC4/5 digestate additives + CMC6 Food industry by products + CMC11 by-products, is mandatory..
All substances incorporated into the EU fertilising product, on their own or in a mixture, shall have been registered pursuant to Regulation (EC) No 1907/2006 (?), with a dossier containing:
 - (a) the information provided for by Annexes VI, VII and VIII to Regulation (EC) No 1907/2006, and
 - (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product, **CSR**unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, or 9 of Annex V to that Regulation.
- Registration dossier <10 tonnage band does not include Annex VIII and CSR is not mandatory
- Probably «the use **as a**» should be «the use **in a**»
- The CSR of a substance «*not dangerous*» does not include identified uses
- A large part of the **Reach exemptions** seem not to be applicable (eg. recovered substances)

Notifying Authorities

- From 16 April 2020 Member States have to designate a **notifying authority**
- **Bulgaria, Czech Republic, Estonia, Italy, Malta and Romania** have **not yet designated** their notifying authorities to the Commission



Notification Procedures



- **Notifying authorities** are responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies
- **Austria, Belgium, Denmark, Finland, Greece, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Spain** have communicated the notification procedures to the Commission
- For most EU Member States we don't know the procedures yet
- As a consequence: a **potential Notified Body does not know how to proceed**

Notified Bodies

- The Regulation provides 4 Assessment Procedures: **Module A, Module A1, Modules B+C and Module D1**
- **A1, B and D1 need a Notified Body's assessment**
- In absence of notified bodies, **we can only apply** the «Internal production control» procedure (**Module A**)
- As a consequence, **we cannot assess** a fertiliser if it contains: **Inhibitor - Plants, plant parts or plant extracts – Compost - Digestate** (other than fresh crop digestate) - **Polymers** (other than nutrient polymers) – **Animal-by-products**
- Additionally, **we cannot assess** the following Product Function Categories: **Nitrification inhibitor, Denitrification inhibitor, Urease inhibitor, Microbial plant biostimulant, Non-microbial plant biostimulant** and the **Fertilising product blend** containing such products
- In July 2022 **we will be able to assess only**: PFC 1, 2, 3, 4 (and their blends) manufactured with CMC 1 (excl. inhibitors), 4, 6, 7, 8, 11

I have a dream: notified body

- Only a few weeks ago, the Commission has realised the **lack of interest** by the EU notified bodies **to be involved in the fertilisers assessment**
- It seems that an **estimation about the market potential** for future FPR notified bodies in the coming years will be undertaken
- **Fertiliser manufacturers, Observers of the Commission Expert Group and the Commission itself believe that it will be at least one Notified Body per Member State**
- In my opinion **only 8-10 Notified Bodies** will arise in the coming months/years to assist the manufacturers
- Other sectors have very few notified bodies: Medical device 20, Pyrotecnic article 12, In vitro diagnostic medical devices 18, Explosives for civil uses 10
- Unfortunately, a chemistry-based sector (like fertilisers) where **“Modules” approach** is in force and **Notified Bodies** are active **does not exist**
- At the moment it would be a *“leap in the dark”* (high risk) because **we have no idea** of the market potential, the number of clients, the annual turnover, the **professional skills needed**, etc.

Annex V: EU Declaration of conformity

- Point 6 provides to **include**: references to the relevant **harmonised standards** or to the **common specifications** used or references to the **other technical specifications** in relation to which conformity is declared
- **Technical specification** means a **document** that prescribes technical requirements to be fulfilled by an EU fertilising product, by its production process or by the **methods** for its sampling and **analysis**
- **Common specifications** are **«Implementig acts»** that the Commission may adopt in some restricted cases (eg. when requirements or tests are not covered by harmonised standards)
- **Harmonised standard** as defined in point 1(c) of Article 2 of Regulation (EU) No 1025/2012 (*European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation*)
- **Where are we with the works on harmonised standards?**

CEN works

- The **European Committee for Standardisation** (CEN) has been requested to draft **harmonised standards** and European standardisation deliverables in support of Regulation (EU) 2019/1009 for EU fertilising products

Committee	Description	Published Standards	Ongoing	Status
CEN TC 223	Soil improvers and growing media	24	41	6 under approval 4 under draft 31 preliminary NO scheduled voting dates for almost all standards
CEN TC 260	Fertilizers and liming materials	114	76	0 under approval 51 under draft 1 under inquiry 24 preliminary NO scheduled voting dates for some standards, where indicated: end 2022-middle 2023
CEN TC 455	Plant Biostimulants	0	59	33 under approval 0 under draft 26 preliminary NO scheduled voting dates

CONCLUSIONS

- In July 2022 there will be **more things that cannot be done** than can be done
- Whole parts of the regulation are the result of an **unfortunate copy/paste**, forgetting that the **large variability of the fertiliser sector** is uncomparable with other sectors
- In the meantime, in July 2022, **Regulation 2003/03 will no longer apply**
- The “Transitional provisions” (art. 52) **does not consider the manufacturer’s stocks** (both products and bags) on 16 July 2022, **in conformity with Reg. (EC) 2003/03**
- If the free movement of fertilisers** (other than inorganic) **is to be promoted**, the Commission must **encourage the use of Mutual Recognition**
- Reg. (EU) 2019/515 is **helpful**, but the Commission **must force its application in all Member States** and must indicate **common procedures to avoid differences**
- It could be useful to think about delaying** the application of Reg. (UE) 2019/1009 **by one year**



THANK YOU

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