REACH requirements in the Fertilising Products Regulation
Highlights from key COM policies

Innovation & safety of EU Fertilising Products
REACH & FPR

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2.3. Simplifying and consolidating the legal framework

2.3.1. One substance, one assessment

EU chemicals legislation delivers results as intended and is fit-for-purpose

- Need to ensure simplification, consolidation and full implementation of the EU rules on chemicals.
- One substance, one assessment approach

Commission Expert Group on One Substance, One Assessment (E03792)

European Commission

Interplay between REACH and FPR

- CE-marked fertilising products => FPR compliant which freely circulate in the single market
- Agronomic efficiency criteria set for each PFC
- Safety criteria for «*providing a high level of protection of public interests such as human, animal and plant health, safety and the environment* » set for CMCs

REACH was chosen as the safety net

demonstration of a safe use as fertilising product (Chemicals Safety Report)

backed up by a set of data included in Annex VI, VII, VIII

For which components?

- Annex II FPR (CMCs) describes which substances/materials shall be registered under REACH

  - virgin material substances (CMC 1)
  - compost additives (CMC 3)
  - digestate additives (CMC 4, CMC 5)
  - food industry by-products (CMC 6)
  - polymers (CMC 8)
  - by-products (CMC 11)
  - precipitated phosphate salts and derivates (CMC 12)
  - thermal oxidation materials or derivates (CMC 13)
  - pyrolysis and gasification materials (CMC 14)
  - high purity materials (CMC 15)
  - (Possibly new future CMCs?)

How to register under REACH and FPR?

- An active registration dossier under REACH
- Meeting the minimum requirements of:
  - Data required in Annex VI, VII and VIII (tonnage band 1-10 tons per years)
  - A Chemical Safety Report (CSR)
  - Including a demonstration of a **safe use** of the substance **as a fertilising product**
  - Unless the substance is eligible to a derogation in **<u>both FPR and REACH</u>**

CHEMICAL SAFETY REPORT FORMAT

PART A

1. **SUMMARY OF RISK MANAGEMENT MEASURES**
2. **DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED**
3. **DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED**

PART B

1. **IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES**
2. **MANUFACTURE AND USES**

2.1. Manufacture

2.2. Identified uses

2.3. Uses advised against

10. **RISK CHARACTERISATION**

10.[illegible] **(Title of exposure scenario 1)**

10.1.1. **Human health**

10.1.1.1. Workers

10.1.1.2. Consumers

10.1.1.3. Indirect exposure to humans via the environment

10.1.2. **Environment**

10.1.2.1. Aquatic compartment (including sediment)

10.1.2.2. Terrestrial compartment

10.1.2.3. Atmospheric compartment

10.1.2.4. Microbiological activity in sewage treatment systems

10.x. **Overall exposure (combined for all relevant emission/release sources)**

10.x.1. **Human health (combined for all exposure routes)**

10.x.1.1.

10.x.2. **Environment (combined for all emission sources)**

10.x.2.1.

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Appendix R.12 - List of use descriptors

Table R.12- 10: Descriptor list for Chemical Products Categories (PC)

Code	Name	Explanation and examples
PC1	Adhesives, sealants	
PC2	Adsorbents	
PC12	Fertilizers	
PC13	Fuels	

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EU’s better regulation – what it is about?

working to ensure that policy is prepared, implemented and reviewed in an open, transparent manner, informed by the best available evidence and backed up by the comprehensive involvement of stakeholders

- ➢ the Commission assesses the expected and actual impacts of policies, legislation, and other important measures at every stage of the policy cycle

- Before the action

- During the action

Once implemented for a sufficient period of time, initiatives/laws are evaluated to check their performance against standard criteria

➢ study in support of the evaluation of the FPR is starting in 2024
(COM reporting obligation to co-legislators by July 2026)

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Thank you

Slides 7-9: photos, source: Fotolia.com, iStock.com, Fertilizers Europe, Wikipedia, ECHA and REACH/CLP HelpDesk LU

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