

# 1. Conformity assessment under the Fertilising Products Regulation

Info-session: EU fertilising products How to CE-mark your products?

23 May 2022

DG GROW-F2 – Bioeconomy, chemicals and cosmetics

## What is Conformity assessment?



### Conformity assessment is

no exception for EC fertilisers

\* a process carried out by the manufacturer

\* to demonstrate whether specific requirements related to a fertilising product in FPR have been fulfilled



**Conformity** assessment

Placing the product on the market

**Market** surveillance



## Who is involved in conformity assessment?



#### The main actors are:



#### FPR sets:

- 1) The essential requirements for EU fertilising product
- **2) The procedure** to be followed for conformity assessment the Modules



The manufacturer follows the conformity assessment procedure before placing a product on the market

**Notified bodies** are involved in some conformity assessment procedures



#### What procedures apply?



## The modules are set depending on the component material category (CMC) or the product function category (PFC) of the EU fertilising product

#### NO NOTIFIED BODY

#### **MODULE A**

PFC 1(\*) – 4, if composed exclusively of one or more of CMC 1 (excl. inhibitors), CMC 4, 6, 7, 8 and/or 11 PFC 7 (\*\*)

#### **NEED NOTIFIED BODY**

MODULE A1	MODULES B+C	MODULE D1
PFC 1(C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content) and PFC 7 with 28% or more of nitrogen from such a fertiliser	PFC 1 (*) – 6, if composed exclusively of one or more of CMC 1 (incl. inhibitors), CMC 2, 4, 6, 7, 8, 9, 10 and/or 11 PFC 7 (**)	PFC 1(*) – 6, if composed of one or more of CMC 1 (incl. inhibitors), CMC 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and/or 15 PFC 7 (**)

<sup>(\*)</sup> except PFC 1(C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory.

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<sup>(\*\*)</sup> except PFC 7 with 28% or more of nitrogen from a fertiliser belonging to PFC 1(C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory.

#### What module A means?



#### *The manufacturer:*

draws up the technical documentation

manufactures the fertilising product

Self

assessment

draws up the EU declaration of conformity





#### What module A1 means?

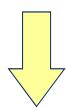


#### *The manufacturer:*

manufactures the fertilising product

draws up the technical documentation





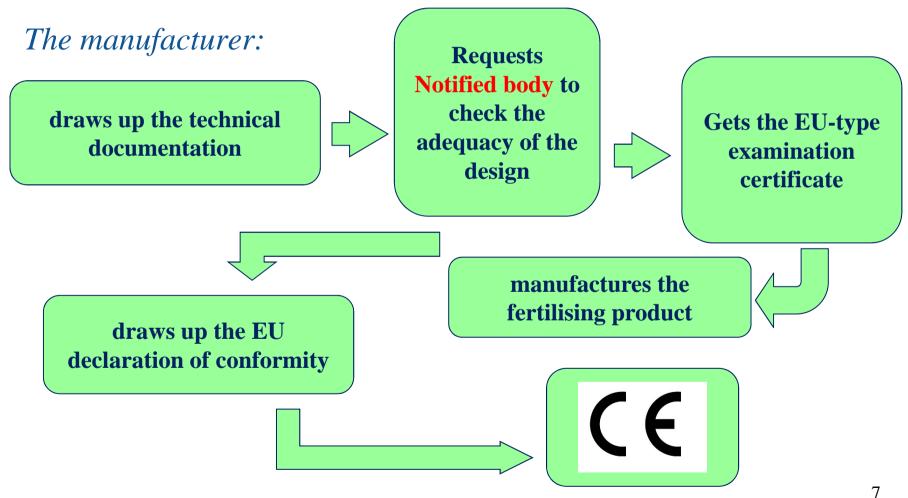
contacts a notified body for the detonation resistance test and the oil retention tests

draws up the EU declaration of conformity



#### What means module B+C?





#### What module D1 means?



*The manufacturer:* 

draws up the technical documentation

draws up the EU declaration of conformity

manufactures the fertilising product



sets up a quality system and contacts a notified body to approve it



# Do we need standards for the conformity assessment? European Commission

#### Yes and no.

Harmonised standards the references of which have been published in the Official Journal of the EU create a

# PRESUMPTION OF CONFORMITY.

They create a level playing field for manufacturers.

But they **are not mandatory**.





# Technical Documentation (manufacturer's responsibility)

- product's description, claimed function, intended use
- description of product's manufacturing process
- list of product's component materials, their origin/manufacturing process

common

- harmonised standards' list (or other specifications)
- specimen of label/leaflet
- tests' reports from product's checks and calculations made
- documentation proving materials' status (by-products) or proving that materials have reached end-point in manufacturing chain (derived ABPs)
- for blends: EU declarations of conformity of component products

## How are notified bodies set?



Notifying authority

National accreditation body

**Notified bodies** 

**Conformity assessment bodies** 

Members States have the obligation to designate a Notifying Authority and set up procedures for assessment and notification of CABs and for monitoring of NBs

## How are notified bodies set?



Notifying authority

National accreditation body

**Notified bodies** 

**Conformity assessment bodies** 

Public or private independent CAB

Demonstration of meeting the requirements by accreditation May be notified for one or more Modules, and for all or some EU fertilising products, depending on their accreditation



#### **The European Commission**

Makes publicly available information on Notified Bodies via NANDO



Nando (New Approach Notified and Designated Organisations) Information System

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir\_id=159361

Organizes the exchange of experience between notified bodies



**Cooperation Group of Notified Bodies for EU fertilising products**(FORUM of NBs)

#### What is COM planning?



# Guidance Document on the elaboration of the technical documentation for EU fertilising products

Externalised study
Targeted consultation foreseen to collect technical information

The ex-ante publicity of this call may be found at <a href="https://ec.europa.eu/growth/low-value-contracts-procedures\_en">https://ec.europa.eu/growth/low-value-contracts-procedures\_en</a>.

GROW/2022/MVP/0014-ExA- Technical study in support of a guidance document for the elaboration of the technical documentation of EU fertilising product

The deadline for submitting interest at <u>GROW-FERTILISING-PRODUCTS@ec.europa.eu</u> is 30 May 2022.



## Thank you for your attention

