AGRO4AGRI

Deliverable 2.2 Report on the agrochemical products regulatory framework and market uptake potential barriers

Plant Biostimulant,

Controlled Delivery Fertilizer

Bio-nematicide

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EXECUTIVE SUMMARY

AGRO4AGRI's details

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Project name	FOSTERING THE ADVANCED USE OF AGROCHEMICALS FOR A SUSTAINABLE AGRICULTURE
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Official project website	TBU (M6)

The AGRO4AGRI consortium

Nº	NAME	ROLE	COUNTRY
1	AINIA (AINIA)	Coordinator	Spain
2	FUNDACION CENTRO TECNOLOGICO DE COMPONENTES (CTC)	Beneficiary	Spain
3	SYDDANSK UNIVERSITET (SDU)	Beneficiary	Denmark
4	DANMARKS TEKNISKE UNIVERSITET (DTU)	Beneficiary	Denmark
5	FUNDACION GRUPO CAJAMAR (FGC)	Beneficiary	Spain
6	PROEFCENTRUM HOOGSTRATEN (PCH)	Beneficiary	Belgium
7	F. INICIATIVAS, CONSULTADORIA E GESTAO, UNIPESSOAL, LDA (FIG)	Beneficiary	Portugal
7.1	F. INICIATIVAS ESPANA I MAS D MAS I SLU (FI GROUP)	Affiliated Entity	Spain
8	SIPCAM OXON SPA (SIPCAM)	Beneficiary	Italy
9	INSTITUT FUR HOHERE STUDIEN - INSTITUTE FOR ADVANCED STUDIES (HIS)	Beneficiary	Austria
10	SYSPRO AUTOMATION SL (SYSPRO)	Beneficiary	Spain
11	MIRAT FERTILIZANTES SL (MIRAT)	Beneficiary	Spain
12	OPTIMAT LIMITED (OPTIMAT)	Associated partner	United Kingdom

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Project's summary

Agrochemicals are chemical products used in agriculture such as fertilizers, plant-biostimulants or pesticides. The application of fertilizers in synergistic combination with biostimulants provides the nutrients required for enhancing the crops yield, while pesticides are used to reduce the risk of loss from plant diseases and weeds on agricultural production. Today, the agricultural sector faces several challenges, namely the loss and leaching of fertilisers, the large amounts of pesticides used, the bioaccumulation and bioconcentration of them and the high dependency on water availability.

In this context, nano and biotechnology strategies have recently gained more interest in the agricultural sector compared to conventional agricultural techniques.

AGRO4AGRI seeks to provide ground-breaking and Safe and Sustainable by Design solutions for plant nutrition and protection consisting of nano and biobased controlled delivery fertilisers and plant biostimulants, and target-specific biopesticides based on RNAi technology, both for enhanced agrochemicals use efficiency. AGRO4AGRI involves R&D and validation stages, aiming to minimize in the long term the use of agrochemicals in agriculture in more than 50% to be aligned with the Farm to Fork Strategy, among other EU initiatives. Further project developments include the evaluation of safety, social and economic impacts, activities to promote society and policy makers engagement to bring wider impacts and better fulfil EU targets and position Europe at the forefront of the agroindustry.

Document details

Deliverable type	(Document, report / Demonstrator, pilot, prototype / Websites, patent filings, ideas, etc / Data Management Plan / Other)
Deliverable nº	D2.2
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Lead beneficiary	SIPCAM
Work package and task	WP2 – Task 2.1
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Contractual delivery date	M2
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Dissemination Level	Public
Purpose	Description of the market and regulatory framework needed for the registration of a controlled delivery fertilizer, plant biostimulant and double strained RNA based bionematicide.

Main author for the "Plant Biostimulant" and "Bio-nematicide" sections is Sipcam, whereas for the "Controlled Delivery Fertilizer" is Mirat and CTC.

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Document's abstract

The Deliverable D2.2 "Report on the agrochemical products regulatory framework and market uptake potential barriers" reported the general market description and Regulatory framework for Plant Biostimulants (PBs), controlled delivery fertilizers and bionematicides. For all three product categories, the overall market is growing significantly due to demand of greener products, from naturally origin, that can optimize the crop efficiency as well as finding alternative to conventional pesticides obtained from chemical synthesis.

PBs are specific compounds that increase plant absorption and use efficiency of main nutrients, increase yield quality, and improve the capability to withstand abiotic stresses such as high temperature, drought and physical damage to the crop. The D2.2 focused on the evaluation of PBs that can implement the Nitrogen use efficiency of crops, thus reducing nutrient losses. These features can be then exploited in a synergistic way with the slow release fertilizer, which by using new compounds, will be able to prevent nitrogen leaching in to the soil, and with the PB that will increase root system expansion and nitrogen uptake, PBs and the fertilizer are regulated by the new EU Regulation EU 2019/1009 on Fertilising Products (FPR) in force since 16th July 2022.

Controlled release fertilizers will enable the efficient use of essential crop nutrients and mitigate damage and losses to the environment. For marketing with proven effectiveness and use as fertilisers, the EU regulation 2019/1009 on Fertilising Products (FPR) must be complied with. This regulation does not currently include some of the components of Controlled release fertilizers in the categories of component materials (CMC), but the legislation (FPR) allows them to be added to it. This is not an insurmountable problem. In view of this, and in order to market a fertiliser release with CE marking, other European legislation (REACH, CLP) must be complied across the board, as described in the report.

Soil pest nematodes are microscopic worms that can affect and damage the root system of plants, compromising their nutrient and water uptake capability, causing a detrimental effect on the crop final yield. Different methods are available for constraining their spread and development in the field, however in areas where the infestation is high, a nematicide treatment is recommended. It is estimated to be one of the Plant Protection Product segment with the greater expansion in the next decade. Moreover, due to the ban and phase out of several conventional active ingredients occuring in the European market, the use of greener compounds is significantly increasing.

The Registration of a new bio-nematicide, as well as other Plant Protection Products, either natural or Chemical, follow the EU Regulation 1107 from 2009. The Registration process follows mainly two steps: registration of the new active ingredient and registration of the formulation. Among the EU countries, a Rapporteur Member State is nominated which evaluates the Dossier submitted for granting the Registration. The dossier contains all studies needed related to environmental, operator and consumers safety as well as efficacy data for final product approval and label definition.

The solutions under evaluation during the AGRO4AGRI project aim to provide new tools for farmers that will allow to guarantee an effective and efficient crop production system in a more sustainable way. They aim to rely on new technologies obtained possibly for circular economic systems that reduce waste and nutrient loss and implement nutrient use efficiency. The bio-nematicide product, based on a microencapsulated RNA sequence, it's designed to be very specific and belongs to a completely new generation of Crop Protection Products that should be easily degraded in the environment and being harmless to non-target organisms.

Document's revision history

The following table describes the main changes done in the document since it was created.

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REVISION	DATE	DESCRIPTION	AUTHOR (PARTNER)
V.0.1	20/06/24	first draft	SIPCAM, MIRAT, CTC
V.0.2	23/06/24	revision from partners and final layout	AINIA, MIRAT
V.0.3	26/06/24	Final version	SIPCAM

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Terminology and acronyms

TERM/ACRONYM	EXPLANATION
ASAR	Active substance adsorption ratio
BRL	Business Readiness Level
dsRNA	Double-stranded RNA
EC	European Commission
FAIR	Findable, Accessible, Interoperable and Reusable
HDES	Hydrophobic Deep Eutectic Solvent
IP	Intellectual Property
KER	Key Exploitable Results
KPI	Key Performance Indicator
LCA	Life Cycle Assessment
MSN	Mesoporous Silica Nanoparticle
NC	Nanocellulose derivative
NCH	Nanocellulose hydrogel
NCL	Nanoclay
NF	Nanocellulose foam
NFC	Nanofiber of cellulose
NUE	Nitrogen Use Efficiency
ORE	Open Research Europe
PB	Plant Biostimulant
PPP	Plant Protection Product
RNAi	RNA interference
SAP	Super Absorbing Polymer
SEIA	Social, economic and sustainability impact assessment
SO	Specific objective

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SSH	Social Science and Humanities
SSbD	Safe and Sustainable by Design
TRL	Technology Readiness Level
USP	Unique Selling Proposition

Disclaimer

1. PLANT BIOSTIMULANT

1.1. Market overview

Among plant nutrients, Nitrogen (N) is the most important both for the strongest effect on crop productivity and for the impact on environmental pollution, due to losses through volatilization and leaching.

Many international studies have demonstrated that Nitrogen Use Efficiency (NiUE) of traditional fertilizers, as previously defined, reaches around 50 %, so about 50% of the nitrogen applied is lost and not available for crop growth. This is, on one hand, a threat for the environment, on the other reduces profitability of the crop.

So NiUE enhancement is a key target to improve sustainability of cropping systems, mainly in extensive crops which are responsible of the highest application of nitrogen fertilizers worldwide.

The global Plant Biostimulants (PBs) market, according to DunhamTrimmer®'s Global Biostimulant Report, will reach about 4000 M USD turnover in 2025 (Figure 1)

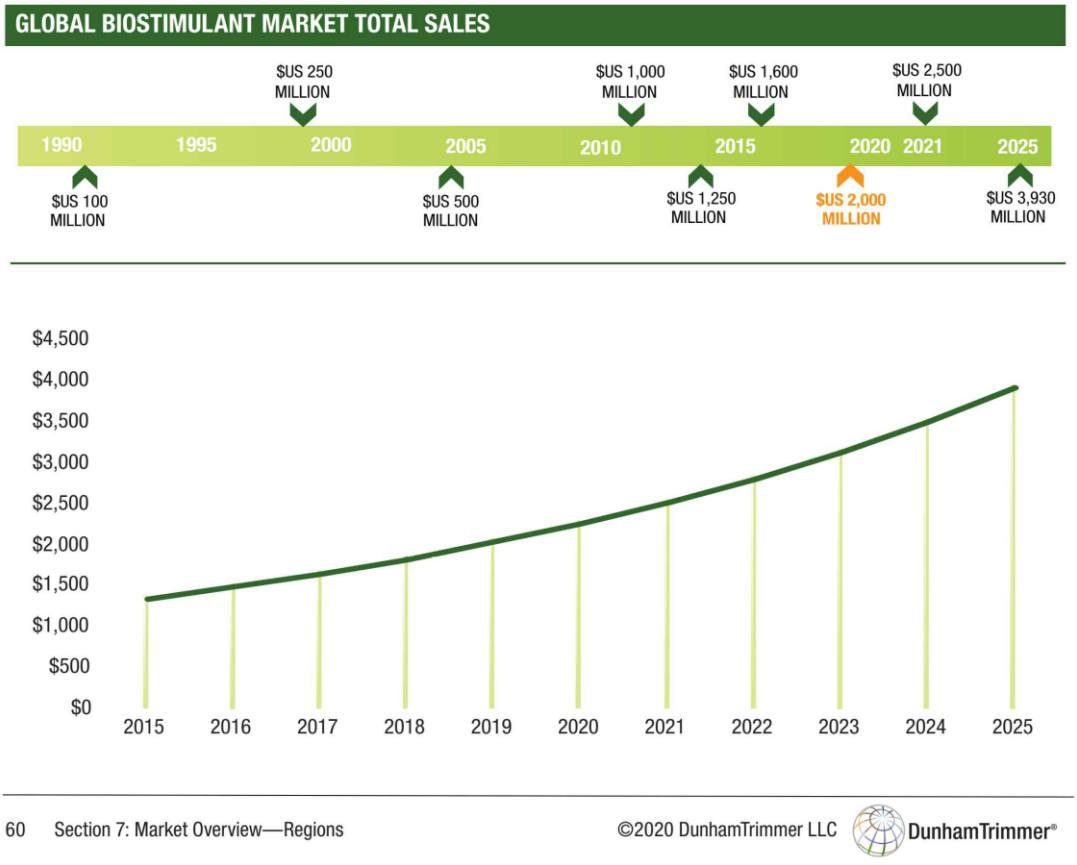

Figure 1: Global Biostimulant Market Total Sales

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About 30% of total turnover (1.200 M USD) in 2025 will be generated in row crops and cereals (Figure 2) where the main application type is foliar.

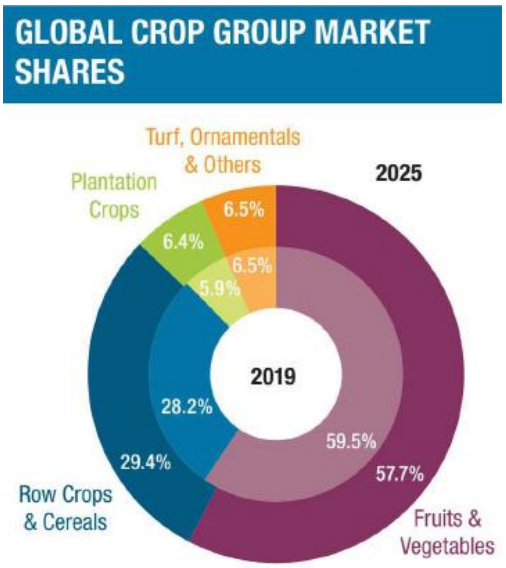

Figure 2: Global Crop Group Market Shares

About 25 % of total turnover (1.000 M USD) in 2025 will be generated in Europe.

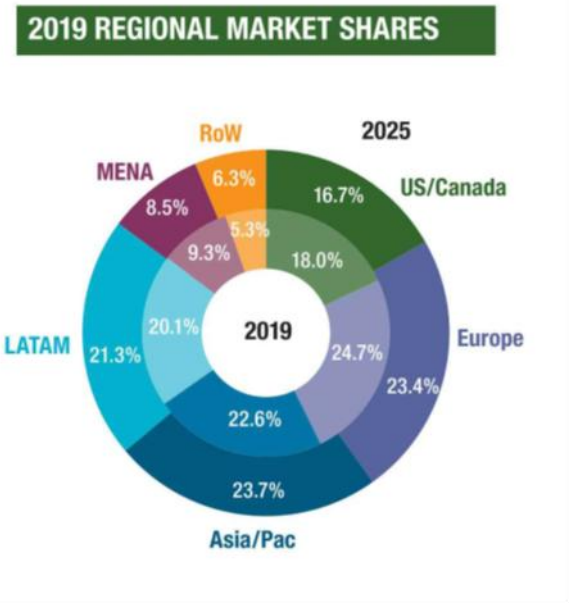

Figure 3: Regional Market Shares

In PBs market studies there is no market estimate split for the claim for which the PBs are used.

We think to be quite prudent affirming that in 2025, the market for PBs improving NiUE should be at least 100 M USD at global level, and around 25 M USD at EU level.

Plant Biostimulants (PBs) can improve NiUE by means of:

- direct nitrogen fixation (microbial PBs)
- crop root system expansion
- better nitrogen uptake

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- yield enhancement

The introduction of PBs use as common practice by the farmers in extensive crops, is linked to many factors:

- general perception of PBs: not consistent efficacy, not strategic for crop performance
- PBs are utilized just in mixture with PPPs, so not always in the best moment for exploiting their biological activity
- Cost/ha and ROI are the main drivers for adoption by the farmers, particularly in extensive crops
- The maximum application rate is 3 l/ha, more often 1-2 l/ha
- Good compatibility and no interference with PPPs is mandatory

Concerning PBs for NiUE improvement other specific factors should be considered:

- Price of nitrogen fertilizers
- Price of commodities (grains, seeds, tubers, sugar…)
- Legal thresholds or restrictions to nitrogen amount applied per crop and season
- Sustainability improvement requested by agroindustry and customers

1.2. Legislative Framework

1.2.1. General introduction

Plant biostimulants can be brought to the market in the EU by complying to either:

- the national regulation of the EU countries, or
- the new EU Regulation EU 2019/1009 on Fertilising Products (FPR) in force since 16th July 2022.

The FPR replaced Regulation (EC) No 2003/2003 relating to EC Fertilisers, which applied mainly to traditional inorganic fertilisers and limes out of various raw materials. The FPR has extended the scope of the EU rules to include fertilising products out of waste recovered materials or by-products, has introduced new recognised categories of products such as biostimulants and new safety criteria for the environmental effects and risks to human and animal health.

Another novel element of FPR has been the introduction of detailed conformity assessment procedure that ensure the conformity of the EU fertilising products with CE marking to the requirements of the FPR. The stakeholders identified as responsible for the conformity assessment procedure are the Notified Bodies (NoBo), which have the scope of assessing:

- product compliance with the requirements of Annexes I to II,
- the technical documentation (TD) compiled by the producer,
- other requirements following relevant modules from Annex IV.

The new FPR has also given manufacturers of fertilisers and plant biostimulants the option to bring their products on the internal EU market with a CE marking and market them in all countries of EU without any additional requirements or prerequisites imposed at the national level. All these products can be placed on the EU market with an CE marking just if they comply with the prerequisites of the Regulation (EU) 2019/1009 on fertilising products (FPR).

The FPR is optional: manufacturers may also opt to continue to bring their plant biostimulants to the national market following national regulations on biostimulants. These biostimulants may be brought to the market of other EU countries by applying to the Mutual recognition principle. In that case, EU countries can restrict the market entry by placing additional requirements or prerequisites **(L. van Schöll, 2023).**

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Within the EU, plant biostimulants are defined (**EU FPR 2019/1009,** art. 47.2) as:

"a product for the purpose of stimulating plant nutrition processes with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

nutrient use efficiency, (measure of a plant's ability to acquire and utilise nutrients from the environment for a desired outcome based on (a) nutrient availability (b) uptake efficiency and/or (c) utilisation efficiency)

tolerance to abiotic stress (the ability to endure abiotic stress, meaning the negative impact of non-living factors on the plant in a specific crop environment) such as chemical stress, light stress, mechanical stress, osmotic stress, oxidative stress, thermal tress, water stress.

quality traits, (desired attribute(s) of a crop regarding agronomical and marketable traits), or

a*vailability of confined nutrients in the soil or rhizosphere* (moving soil nutrients from the pool of confined nutrients to the pool of available nutrients)."

The stimulation is independent of the product's nutrient content.

Plant biostimulants are therefore distinguished from fertilisers, which are defined as products the function of which is to provide nutrients to plants or mushrooms, and from PPPs (PPP), which have the function to influence the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant.

Some products can have dual functions, when they act as both a biostimulant and a PPP. In that case the product is regulated under the scope of the PPP regulation EC Regulation 1107/2009.

According to FPR, fertilizer and biostimulants products must be classified according to two their specific functions defined as *Product Function Categories (PFCs)* and raw materials used, named *Component Material Categories (CMCs*), and must respect the requisites of both these categories. PFCs and CMCs requirements are defined respectively in Annex I and Annex II of the FPR.

1.2.2. Product Function Categories (PFCs)

Within the FPR, plant biostimulants are classified under the category **PFC 6 plant biostimulants** and further under two subcategories: **PFC 6(A) microbial plant biostimulants** or **PFC 6(B) non microbial biostimulants**.

Independently from the subcategory, the definition of plant biostimulant used in the regulation is claim-based and all biostimulant claims indicated on the label must be demonstrated during the conformity assessment procedure.

The type of information that can be used to demonstrate the efficacy of the claim are the following:

- field and/or protected crop experimental data;
- controlled condition data (e.g.: laboratory data, greenhouse, growth chamber);
- literature review (only peer reviewed, analytical methods used as given in the CEN-TS).

The general principles for justifying the product claims for plant biostimulants by experimental trials are specified in CEN/TS 17700-1 **(FprCEN/TS 17700-1)** norm. The norm specifies:

1) Quality criteria for trials, such as: trial design; the statistical analysis, crop groupings, minimum number of successful trials for effects claimed for a specific crop, entire crop group etc.
2) Quality criteria on the type or organization in charge of trial.
3) Specification of the information to be collected in individual trials, such as: experimental conditions, Trial conditions presentation of the results, including raw data, analysis data and conclusions from the trial observation.

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In addition to the general principles settled by CEN/TS 17700-1, specific CEB/TS norms exist for demonstration of each claims.

The NoBo and market surveyance authorities involved in the conformity assessment accept the experimental data or literature reviews performed according to the CEN technical specifications however the use of these CEN-TS is not compulsory. Manufacturers may use other methods or assessment criteria and markers in case of need.

Apart from the agronomical performance, plant biostimulants must demonstrate to be compliant with the content of heavy metals defined by the EU FPR 2019/1009, in accordance with the table here below (Table 1) (**EU FPR 2019/1009)**.

Table 1: Heavy metals limits in plant biostimulants

Metal	Limit (mg/kg dry matter)
Cadmium (Cd)	1.5
Hexavalent chromium (Cr IV)	2
Lead (pb)	120
Mercury (Hg)	1
Nickel (Ni)	50
Inorganic arsenic (As)	40
Copper (Cu)	600
Zinc (Zn)	1500

1.2.3. Component Material Categories (CMCs)

Plant biostimulants are categorised in microbial and non-microbial plant biostimulants. The main difference between these categories is that they contain different CMC materials and differ in the pathogen risks and specification.

Within the FPR, 15 categories have been identified **(EU FPR 2019/1009, 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: Digestate other than fresh crop digestate

CMC 6: Food industry by-products

CMC 7: Micro-organisms

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CMC 8: Nutrient polymers

CMC 9: Polymers other than nutrient polymers

CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009

CMC 11: By-products within the meaning of Directive 2008/98/EC

CMC 12: Precipitated phosphate salts and derivates

CMC 13: Thermal oxidation materials and derivates

CMC 14: Pyrolysis and gasification materials

CMC 15: Recovered high purity materials

CMCs for PFC 6A Microbial Plant Biostimulants

A Microbial Plant Biostimulant can exclusively consist of a micro-organism or a consortium of the following micro-organisms, defined in CMC 7 Micro-organisms **(EU FPR 2019/1009, Annex II)**, reported here below:

Azotobacter spp.

Mycorrhizal fungi

Rhizobium spp.

Azospirillum spp:

These may include the dead or empty-cell micro-organisms and non-harmful residual elements of the media on which they were produced, which have undergone no other processing than drying or freeze-drying.

When the microbial plant biostimulant is in liquid form, the plant biostimulant shall have a pH optimal for contained micro-organisms and for plants.

In terms of pathogens, a microbial plant biostimulant must respect the limits showed in the following table (Table 2) (**EU FPR 2019/1009, Annex I)**

Table 2: Pathogens limits in Microbial Plant Biostimulants

Micro-organism	Sampling plans		Results
	n	c	
Salmonella spp.	5	0	Absence in 25 g or 25 ml
Escherichia coli	5	0	Absence in 1 g or 1 ml
Listeria monocytogenes	5	0	Absence in 25 g or 25 ml
Vibrio spp.	5	0	Absence in 25 g or 25 ml
Shigella spp.	5	0	Absence in 25 g or 25 ml
Staphylococcus aureus	5	0	Absence in 25 g or 25 ml
Enterococcaceae	5	2	10 CFU/g
Anaerobic plate count unless the microbial plant biostimulant is an aerobic bacterium	5	2	10^5 CFU/g or ml

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Yeast and mould count unless the microbial plant biostimulant is a fungus	5	2	1 000 CFU/g or ml

Where:

n = number of units comprising the sample,

c = number of sample units giving values over the defined limit.

CMCs for PFC 6B Non-Microbial Plant Biostimulants

Plants biostimulants that do not belong to PFC 6A are considered Non-microbial plant biostimulants. They may solely consist of component materials that belong to one or more of the CMCs of Annex II, except CMC 7 which is limited to the PFC 6A Microbial biostimulants.

The component materials must meet the definition and prerequisites of the CMC that they belong to and for PFC 6B Non-Microbial biostimulants one or more component materials can be identified:

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: Digestate other than fresh crop digestate
CMC 6: Food industry by-products
CMC 8: Nutrient polymers
CMC 9: Polymers other than nutrient polymers
CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009
CMC 11: By-products within the meaning of Directive 2008/98/EC
CMC 12: Precipitated phosphate salts and derivates
CMC 13: Thermal oxidation materials and derivates
CMC 14: Pyrolysis and gasification materials
CMC 15: Recovered high purity materials

The CMC prerequisites can include requirements on REACH registration, certain treatment processes, specification of processing conditions (including time-temperature trajectory and feedstock materials) and are further specified in Annex II of the FPR **(L. van Schöll, 2023)**.

Currently no ingredients that are derived of animal by-products are allowed as component material. These ingredients will have to obtain an '*end point in the manufacturing chain*' under the regulation (EC) 1069/2009 (**EC Regulation 1069/2029**) on Animal By-Products (ABP) before they can be included in the relevant CMCs of the FPR (including as feedstocks for the compost and digestates CMCs, or as a component material for CMC 10 Derived products within the meaning of ABP Regulation.

Pathogens in a non-microbial plant biostimulant must not exceed the limits set out in the following table (Table 3) (**EU FPR 2019/1009, Annex I**).

Table 3: Pathogens limits in Non-Microbial Plant Biostimulants

Micro-organism	Sampling plans			Limit
	n	c	m	M

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Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
Escherichia coli	5	0	0	Absence in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU

1.2.4. Conformity assessment procedure

Different conformity assessment procedures exist in the meaning of FPR with different data requirements. Which procedure can be followed depends on PFC and CMC. Based on different fertilizer product categories and raw material categories, fertilizer manufacturers need to complete different conformity assessment procedures.

The conformity assessment procedures are divided into 4 categories: **Module A**, **Module A1**, **Module B+C** and **Module D1**. The applicability and requirements for each module in the FPR are described in Annex IV to the FPR. The modules A1, B, and D1 require the involvement of notified bodies as shown in Figure 1 (L. van Schöll, 2023).

No Notified Body		Need Notified Body	
Module A	**Module A1**	**Modules B +C*** **	**Module D1**
PFC 1*- 4, if composed exclusively of one or more of CMC 1 (excl. Inhibiting compounds), CMC 4, 6, 8, and/or 11	PFC 1 I(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content)	**PFC 1*- 6**, if composed exclusively of one or more of CMC 1 (incl. inhibiting compounds), 2, 4, 6, 7, 8, 9, 10, and/or 11	**PFC 1*- 6**, if composed of one or more of CMC 1 (incl. inhibiting compounds), 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, and/or 15
PFC 7**	PFC 7 with 28% or more of nitrogen from such a fertiliser	**PFC 7****	**PFC 7****

* Except PFI©(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory

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

*** Module is always followed by Module C, which is performed by the manufacturer without involvement of notified body

Figure 4 Overview of which conformity assessment procedure modules are available depending on the product function category (PFC) of a product and the component material categories (CMC) of its components.

The first step for determining to which criteria the product must comply and which assessment procedure can be followed, is determining the PFC to which the product belongs. A flow chart to determine the applicable conformity assessment module is shown in Figure 5. When several conformity assessment modules are applicable, it is up to the manufacturer to decide which module to use **(L. van Schöll, 2023)**.

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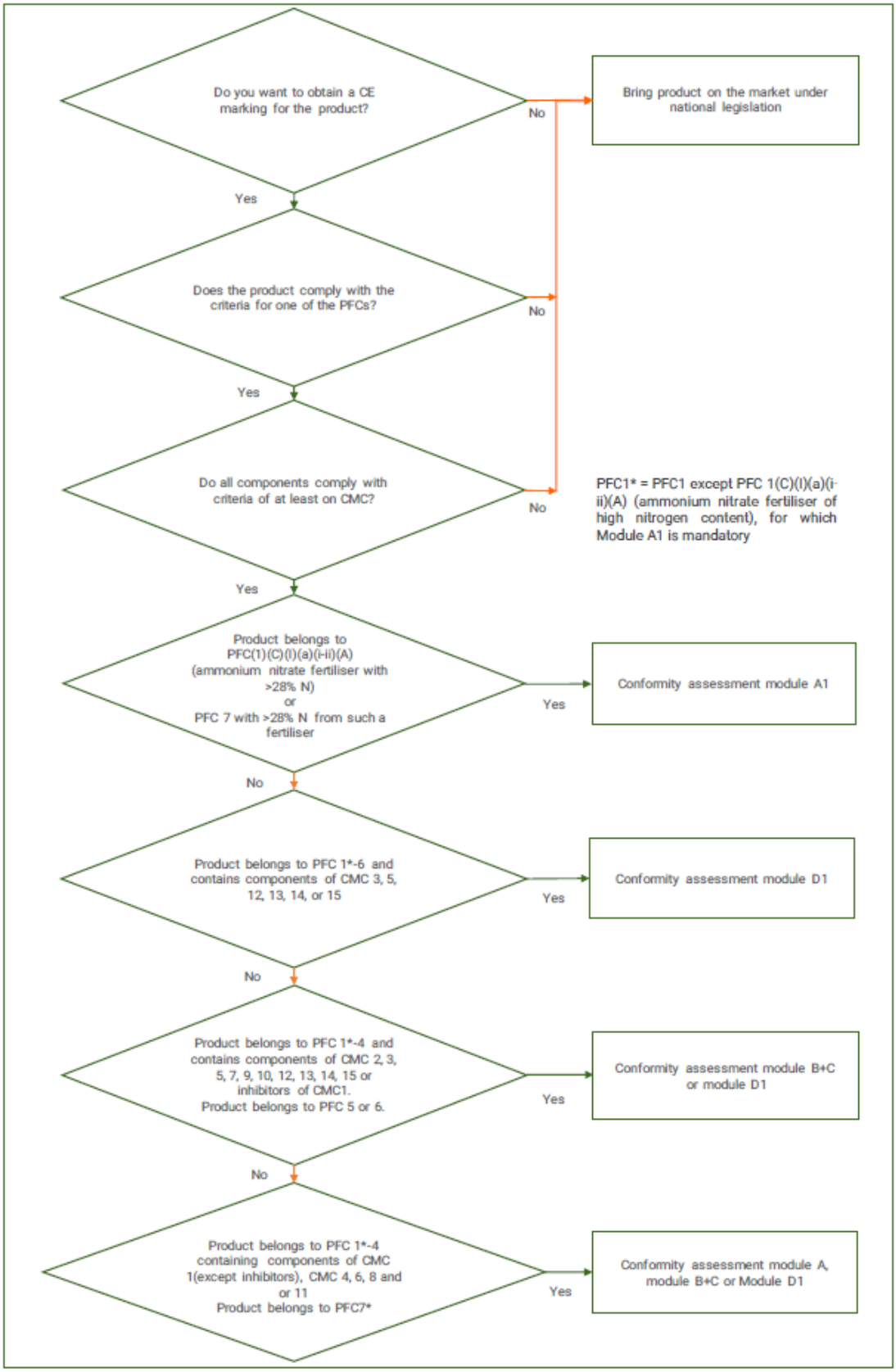

Figure 5: Flow chart determining the applicable conformity assessment modules (Annex IV to the FPR).

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For a biostimulants two conformity assessment can be chosen: Conformity assessment under module B + C or Conformity assessment under module D1.

Where compliance of the plant biostimulant with the FPR is certified by a NoBo, the producer shall draw up an EU declaration of conformity (EU FPR 2019/1009, Annex V).

Manufacturers shall keep the technical documentation and the EU declaration of conformity for 5 years after the EU fertilising product covered by those documents has been placed on the market (L. van Schöll, 2023).

Module B+C EU-type examination

The Module B+C EU-type examination is the conformity assessment procedure in which the producer provides to NoBo the technical documentation and product samples. The NoBo examines the information and verifies and attests that the technical design of the EU fertilising product meets the requirements of the FPR. No auditing on the production location is required.

Module B covers only the design phase. The notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the FPR by issuing an EC-type examination certificate.

Module C covers only the production phase and follows module B. The manufacturer ensures himself the conformity of the products to the type described in the EC-type examination certificate and to the requirements of FPR. Its common point with module A is that the manufacturer ensures himself the conformity of its products; however, under module C this conformity is evaluated against an approved EC-type resulted under module B.

When MODULE B+C is used as the conformity assessment procedure, the manufacturer will apply documentation to a NoBo of their choice for EU-type examination. The NoBo will examine the technical documentation to assess the adequacy of the technical design of the fertilising product. The NoBo will further verify that samples of the product have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant standards and specifications (Figure 6).

When a manufacturer modifies a product which has an EU-type examination certificate held by a NoBo in such a way that it may affect the conformity, the manufacturer shall then inform the NoBo. Such modifications require additional approval in the form of an addition to the original EU-type examination certificate.

This procedure can be chosen for products containing one or more of the following CMCs 1, 2, 4, 6, 7, 8, 9, 10, and/or 11 (L. van Schöll, 2023).

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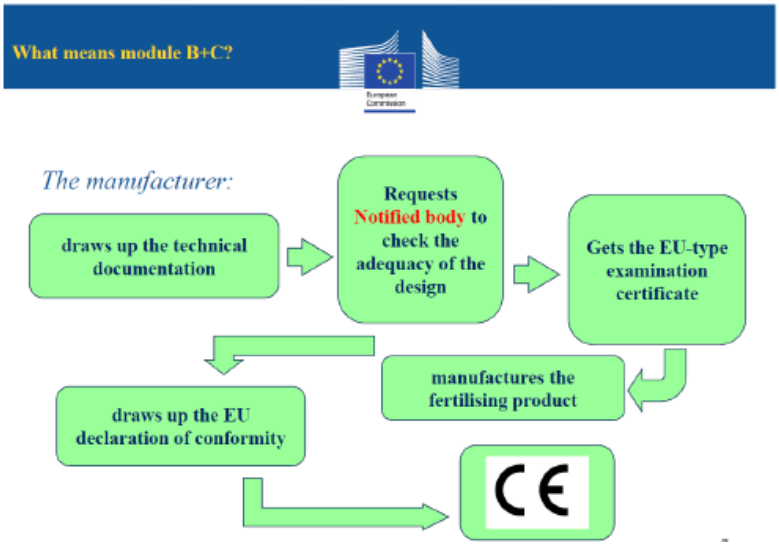

Figure 6: Module B+C EU-type examination schema

Module D1 EU-type examination

Module D1 Quality assurance of the production process is the conformity assessment procedure where the producer fulfils the obligations on the technical documentation, the manufacturing and quality system (Figure 7). The producer ensures and declares on his or her sole responsibility that the products concerned, satisfy the requirements of the FPR. The notified body shall assess the quality system to determine whether it satisfies the requirements. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

Module D1 is more comprehensive and is required when the plant biostimulant product contains material from either one of the CMCs 3, 5, 12, 13, 14 or 15 (L. van Schöll, 2023).

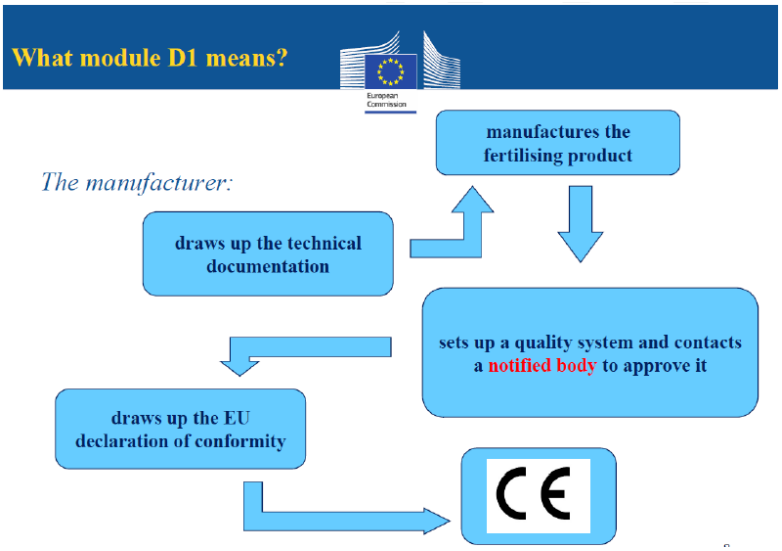

Figure 7: Module D1 EU-type examination schema

1.2.5. Technical documentation

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When a manufacturer intends to bring a product on the market as EU fertilising product with CE marking, the manufacturer must prove the compliance of the product with the specifications in the FPR. All documents that prove compliance criteria or otherwise support or clarify the proof, are compiled in a dossier. This dossier is referred to as the "technical documentation". The obligation for the technical documentation applies to every EU fertilising product that is placed on the EU market, whatever its geographical origin is. It is the responsibility of the manufacturer to draw up the required technical documentation. Generally, manufacturers shall prepare a technical documentation, CE marking and EU declaration of conformity.

The technical documentation must be kept for 5 years after the EU fertilising product has been placed on the market. This is the responsibility of the manufacturer, or the authorised representative established within the EU while importers shall ensure that the manufacturer has drawn up the technical documentation. As a rule, the technical documentation shall contain all relevant data or details that are necessary to ensure that EU fertilising products comply with the requirements of the FPR. The details included in the documentation depend on the nature of the EU fertilising product.

Technical documents usually contain test reports, manufacturing processes, product descriptions, list of component materials, etc. The technical documentation shall make it possible to assess the conformity, cover the design, manufacture and intended use of the product, and specify the applicable requirements of EU and national law and it enables conformity assessment of an EU fertilising product with the relevant requirements.

Part II of Annex IV to the FPR gives a description of conformity assessment procedures and Part I of the Annex IV specifies the applicable modules depending on the function and the component materials of a product. The technical documentation shall specify the applicable requirements and when relevant for the assessment also the design, manufacture and intended use of the EU fertilising product. General requirements on the technical documentation are described below (L. van Schöll, 2023).

1.2.6. Common elements for all modules

General description and designated PFC.

The general description should clearly state the claimed function of the EU fertilising product and a description of the intended use. Typically, the function claim of the products is described in the first point under the PFC description while the intended use of the product should include application rates, timing, and frequency (L. van Schöll, 2023).

Component materials.

A list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process. This list shall include all materials that are present in the product, including those that are present in quantities <5%. The list does not include the precursors of the materials that were used to produce the component materials. When the product concerns a fertiliser blend (PFC 7), the EU declarations of conformity for the component EU fertilising products of the blend. For components that contain or consist of substances that require a REACH registration, the technical documentation should include the documentation that the substance is registered pursuant to Regulation (EC) No 1907/2006 and Annex II of the FPR. The documentation shall include the material safety data sheet covering the use as a fertilising product. Substances for which a REACH registration is required belongs to: CMC 1, 3, C4, 5, 6, 8, 11, 12, 13, CMC 14 and CMC 15 (L. van Schöll, 2023).

Information on the manufacturing process.

Drawings, schemes, descriptions, and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. For products with materials belonging to CMCs 3, 5, 12, 13, 14 or 15 (Module D1) a

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written description and a diagram of the production or recovery process, where each treatment, storage vessel and area is clearly identified. For products containing or consisting of CMC 13 material, hazardous waste calculations should be included (L. van Schöll, 2023).

Specimen of the label or the leaflet

More information on the labelling can be found in the *Guidance on the labelling of EU fertilising products* **(EU Communication 2021/C 119/01)**. This guidance also contains clear examples of labels for all PFCs.

List of standards or specifications

A list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, manufacturer shall clearly state which part was used. Generally harmonised standards (hEN) or CEN technical specifications are mainly used but they are not mandatory and other relevant specifications or standards can be applied. In that case, the manufacturer must show that these standards or tests are reliable and reproducible and in conformity with the harmonised standards or parts thereof (L. van Schöll, 2023).

Results of calculations made, examinations carried out

Any results of calculations, studies or examinations carried out on the product to demonstrate the compliance with requirements of Annexes I, II and III should be given. For products containing or consisting of CMC 13 materials (Module D1), the technical document must include the calculation on the removal of the hazardous property during the production process (L. van Schöll, 2023).

Test reports

The results of the calculations made and examinations carried out should be supported by the test reports of the analyses, trials, or reviews carried out on the product and its components to demonstrate conformity with the requirements of Annex I (PFC) and Annex II (CMCs), sing the standards or specifications in the list of standards or specifications (L. van Schöll, 2023).

1.2.7. Specific elements under MODULE B+C and D1

Chromium content

Where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr).

By-products of CMC 11

Where the EU fertilising product contains or consists of by- products within the meaning of Directive 2008/98/EC, prove that the component complies with the agronomic efficiency and safety criteria established for the CMC 11 (L. van Schöll, 2023).

End-point for ABP-derived component materials

For any product that consist of or contains components that are derived of Animal by-products: (1) the commercial documents or health certificates as required under the EU regulations on ABP and (2) the evidence for the 'end-point in the manufacturing chain' for that regulation (L. van Schöll, 2023).

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1.2.8. Labelling

Plant biostimulants that are brought to the market as an EU fertilising product can be recognised by the CE marking. The CE mark has to be affixed to the label and its location on the label is free to choose.

For Plant Biostimulants, the following information has to be provided on the label:

- The PFC designation, either as microbial plant biostimulant or non-microbial plant biostimulant,
- A list of all ingredients above 5 % by product weight or volume (in the case of products in liquid form by dry weight), in descending order of amont, including the designations of the relevant CMCs as referred to in Part I of Annex II to this Regulation.
- Instructions for use, including application method(s), growth stage and number of applications for the claimed function for each target crop or crop group (with reference to the terminology in the CEN technical specifications).
- Any other relevant instructions related to the efficacy of the product, including soil management practices, chemical fertilisation, incompatibility with PPPs, recommended spraying nozzles size, sprayer pressure and other anti-drift measures.
- Recommended storage conditions.
- Relevant information to control risks to human, animal or plant health, safety or the environment should be included.Pictograms (except CLP hazard pictograms if the product is not classified) may be used as long as they are clear and not misleading.
- Physical form of the product.
- Quantity by mass or volume.
- Production and expiry dates.
- A type number, batch number or other means of identification.
- Contact details of the producer or distributor.
- The certification number as issued by the NoBo after conformity assessment module D1.

For microbial plant biostimulants, the following additional information should be given on the label.

- All intentionally added micro-organisms shall be indicated.
- Where the micro- organism has several strains, the intentionally added strains shall be indicated. Their concentration shall be expressed as the number of active units per volume or weight, or in any other manner that is relevant to the micro-organism, e.g., colony forming unitsper gram (cfu/g).

If the product is authorised for use in organic farming according to EU legislation (Implementing Regulation EU 2021/1165), this may be stated on the label.

Detailed examples of labels can be found in the Guidance document on EU fertilising product labelling (EU Communication 2021/C 119/01). Examples of a label according to this guidance are reported here below.

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[NAME OF THE PRODUCT]

CE

Notified body n°: xx xx xx xx (if applicable)

PFC 6 (A) – Microbial Plant biostimulant

Ingredients:

CMC 7 – Azotobacter vinelandii AS 80

Micro-organism concentration: 1×10^7 CFU/ml

Instructions for use:

Crops	Application rates (L/ha)	Application method	Application stage	Application number	Claims
Refer to the terminology specified in harmonised standards or other technical specifications	1 to 4	Soil applied nutrition or via irrigation water	Pre-plant, planting, or top dress stage	High value crops may receive repeat applications every 1-3 weeks. There are no restrictions on the number of applications per crop	Refer to the terminology specified in harmonised standards or other technical specifications
	1 to 4	Soil applied nutrition or via irrigation water	Pre-plant, planting, or top dress stage	The product can be applied weekly. There are no restrictions on the number of applications per crop or crop cycle.	
	1 to 4	with standard nutrition or via irrigation	Pre-plant, planting, or top dress stage	The product can be applied weekly. There are no restrictions on the number of applications per crop or crop cycle.	
	1 to 4	Applied in-furrow or with soil nutrition as well as side-dress/top-dress. The product may also be applied via irrigation	From the pre-planting through to mid-vegetative stage	There are no restrictions on the number of applications per crop or crop cycle.	

The product can be mixed with the majority of liquid fertilisers, plant nutrition products or plant protection products but must not be mixed with any bactericide. The product may also be applied with all transplant solutions, dips and watering solutions.

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<table>
<tr><td colspan="2">It is recommended to perform a compatibility test before applying this product as a mixture.
SHAKE/AGITATE WELL BEFORE USING.
Contact company or company's distributor for more specific recommendations. www.website.com</td></tr>
<tr><td colspan="2">Recommended Storage conditions:
Keep the product in its original packaging. Store in a cool, dry place between 2 °C and 48 °C. Do not expose to direct sunlight. Protect from freezing.</td></tr>
<tr><td colspan="2">Information on Safety and Environment (*):
EUH 208: Contains Azotobacter vinelandii, micro-organisms may have the potential to provoke sensitising reactions
P102: Keep out of reach of children
P270: Do not eat, drink or smoke when using this product
P280: Wear protective gloves/protective clothing/eye protection/face protection type FFP3</td></tr>
<tr><td colspan="2">Emergency contact:
In case of emergency contact: XX: tel. XX-XX-XX-XX, (24/24, 7/7)</td></tr>
<tr><td>Production date: see on the packaging
Expiry date: 3 years from production date</td><td>Type number/Batch number
+ notified body number (if applicable)</td></tr>
<tr><td>5 L LIQUID</td><td>ENTERPRISE S.A.S – Address.
Tel: XX XX XX XX XX – Fax: XX XX XX XX XX</td></tr>
<tr><td colspan="2">(*) CLP pictograms may be added only if the product is covered by the CLP Regulation.</td></tr>
</table>

Figure 8 Label Example for PFC 6(A) Microbial Plant Biostimulant

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[name of the product]

CE Notified body n°: XX XX XX XX (if applicable)

PFC 6 (B) NON-MICROBIAL PLANT BIOSTIMULANT

Ingredients: Derived products within the meaning of Regulation (EC) No 1069/2009 (Animal protein hydrolysate)

Virgin material substances and mixtures (Urea – Diammonium phosphate)

Instructions for use:

Crops	Application rates (L/ha)	Application method	Application stage	Application number	Claims
Refer to the terminology specified in harmonised standards or other technical specifications	2 to 4	Foliar pulverization	From 2-4 leaves stage	1 to 3	Refer to the terminology specified in harmonised standards or other technical specifications
	4 to 6	Foliar pulverization	From vegetative growth	1 to 4	
	5 to 10	Foliar pulverization	Regrowth vegetation	2 to 5	

The product is compatible with many plant protection products. In case of mixture, it is the user responsibility to test the mixture before application. Pour last in the tank.
Farmed animal must not be fed with herbage, either directly or by grazing, with herbage, from land to which this product has been applied unless the cutting or grazing takes place after the expiry of a waiting period which is at least 21 days. Contact company or company's distributor for more specific recommendations. www.website.com

Recommended storage conditions:
Store in a dry place (see pictures).

Information on Safety and Environment (1):

Wash the hands after use. Do not breathe dusts.

In case of emergency contact: XX: tel:XX-XX-XX-XX, (24/24, 7/7)

Additional Information

Poor in chloride

This fertiliser contains urea, which can release ammonia and have an impact on air quality. Depending on local conditions, appropriate remediation measures must be taken.

Production date: see on the packaging Expiry date: 3 years from production date	Type number/Batch number + notified body number (if applicable)
5 L LIQUID	ENTERPRISE S.A.S – Address. Tel: XX XX XX XX XX – Fax: XX XX XX XX XX

(1) CLP pictograms, may be added only if the product is covered by the CLP Regulation.

Figure 9 Label Example for PFC 6(B) Non-Microbial Plant Biostimulant

Concerning Nutrient Use Efficiency (NUE) the "operative" reference at this moment is:

CEN/TS 17700-2 Plant biostimulants - Claims - Part 2: Nutrient use efficiency resulting from the use of a plant biostimulant (Annex 1).

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2. CONTROLLED DELIVERY FERTILIZERS

2.1. Market overview

The agricultural industry is one of the fastest-growing sectors globally. Traditional chemical fertilizers cause leaching, eutrophication, pollution, and have lasting negative impacts on crops. In this context, nanofertilizers have a significant advantage in nutrient management because they enhance nutrient utilization efficiency and reduce environmental toxicity. Additionally, nanofertilizers can be used to increase resistance to abiotic stress, and when combined with microorganisms, these nano biofertilizers offer further benefits. Consequently, the demand for nano fertilizers is rising worldwide. The shift from chemical fertilizers to nano fertilizers is driving the growth of the global market.

Nano Fertilizers Market size was valued at USD 400 million in 2022 and is expected to grow from USD 3.1 billion in 2022 to USD 1675 million by 2032, growing at a CAGR of 14% in the forecast period (2023-2032) (Precedenceresearch, 2024).

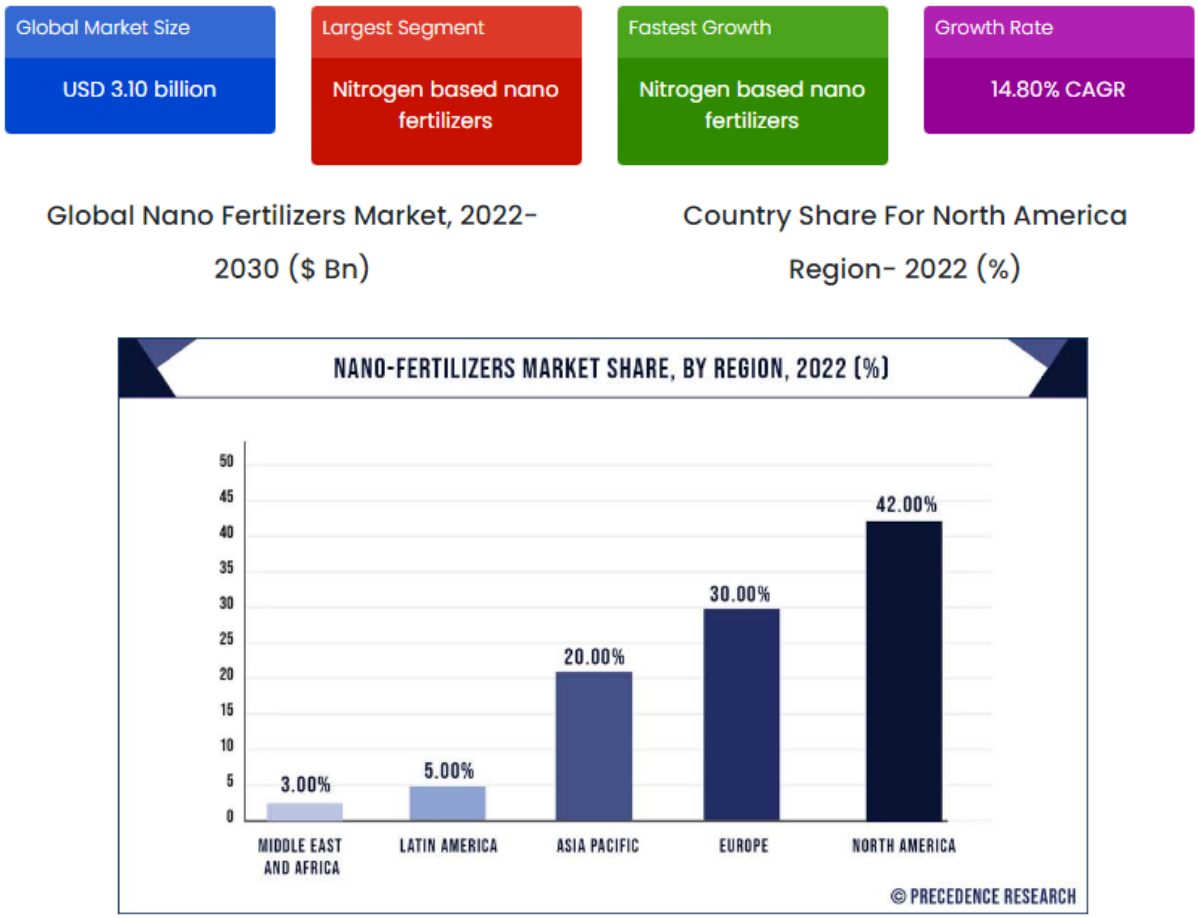

Figure 10: Nanofertilizers market overview (Precedenceresearch, 2024 and Skyquestt, 2024)

However, sometimes, the nanofertilizers efficacy is less than expected, and the yield required for fertilization is unable to complete the nitrogen fixation process, which limits the nanofertilizers market expansion and growth.

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The urgent need for a more efficient use of nutritional elements in agriculture for a sustainable and profitable management, minimising negative environmental impacts, ensuring food security, among other priorities, make the biotechnological development of controlled release of nutrients a priority for precision agriculture.

The European Green Deal's 2030 target of reducing nutrient losses by 50%, while ensuring no deterioration in soil fertility, needs new fertilization strategies and more sustainable and efficient formulations. Growing concerns over agricultural sector pollution and water contamination have led farmers to adopt sustainable agricultural practices and environmentally friendly fertilizers. CRFs reduce nutrient leaching and volatilization and release nutrients based on crop requirements, which will provide necessary nutrients to the crops when required and decrease the risk of nutrient losses, reducing also the need for multiple fertilizer applications.

Nanofertilizers are nutrients that are encapsulated or coated within nanomaterial in order to enable controlled release, and its subsequent slow diffusion into the soil.

We can classify Nanofertilizers within the so-called **CRF** (Controlled Release Fertilizers), according to the definition that IFA (International Fertilizer Association) establishes for them: Fertilizer product that releases nutrients at a controlled rate relative to a "reference soluble" product. The controlled rate of nutrient release is achieved by modifying readily available nutrient forms with recognized physical mechanisms such as coatings, occlusions or other similar means.

The consumption of the so-called Nanofertilizers is very scarce in Europe, establishing the focus of development in India and China. Nanofertilizers remain at a small base in terms of Nutrient Content. (Source: FAI, IFA).

IFA is tracking the emerging role of nano fertilizers in India. Production of nano urea in 2022/23 was estimated at 24% of the installed capacity (Figure 11). Sales were reported at 16.2 million liters, a 50% increase year-on-year. Comparing nano urea (liters) to urea (tonnes) consumption of the former accounted for 0.05% of the total urea consumed in the country in 2022/23.
Nano DAP production has also begun in India, with installed capacity of 30 million liters.
Nano urea has been introduced to other markets, namely Argentina, Brazil, and Nepal.

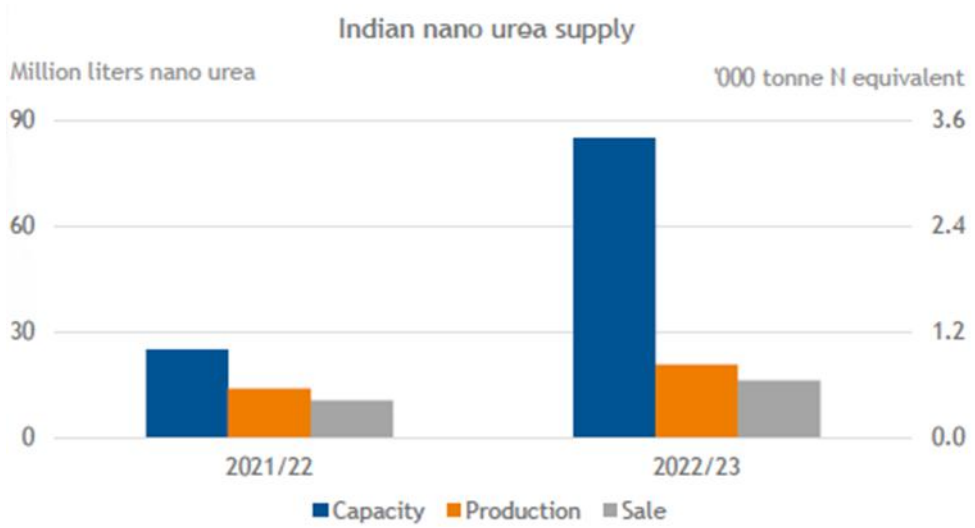

Figure 11: Evolution of production of nanourea in India.

According to IFA, the demand for CRF in Western and Central Europe has remained constant since 2016 at around 78,000 tonnes/year; it has even suffered a 2% decline in 2022. Demand from North America and East Asia is about 550,000 tonnes/year and 650,000 tonnes/year, respectively.

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Figure 12: Controlled release fertilisers consumption around the world.

As we can see in Figure 12, the demand for CRF remains stable over the last 5 years, although it is expected to rebound in 2024. For the year 2028 IFA forecasts strong increases in demand for WSF (Soluble Fertilizers), CRF and SNF (Stabilized Nitrogen Fertilizers), having not provided specific figures in its study.

The Europe Controlled Release Fertilizer Market size is estimated at USD 385.11 million in 2024, and is expected to reach USD 602.87 million by 2030, growing at a CAGR of 7.76% during the forecast period (2024-2030). (Source: Research and Markets).

In Figure 13 CAGR% of CRF Fertiliser Market depending by coating type is shown. Biodegradable and polymer-based ones has the highest market potential.

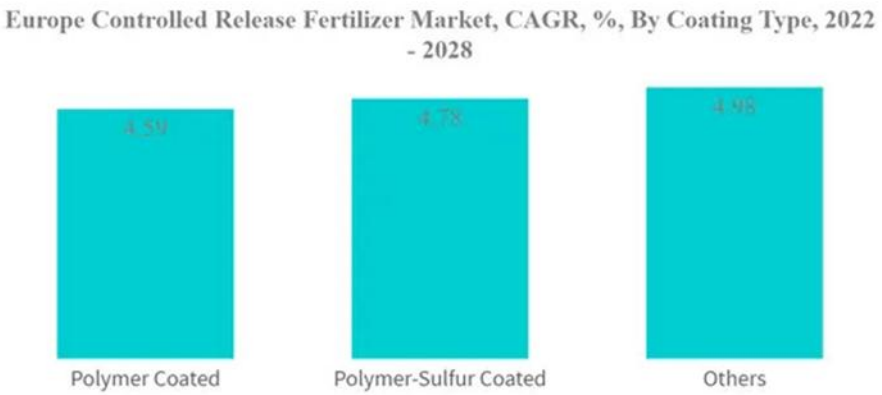

Figure 13: Evolution of Europe Controlled Release Fertilizer Market

The European Union has set rules and regulations for controlled-release fertilizers, including polymer encapsulation systems, which are currently under the scope of future restrictions until they are developed to be biodegradable. From 2026 onwards, only polymers meeting the biodegradability requirements laid down in the new Fertilizing Products Regulation will be allowed on the market.

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2.2. Regulatory framework for fertilizer products

2.2.1. General Introduction

The new Fertilising Products Regulation (FPR) EU/2019/1009 applies since 16 July 2022, this regulation was created with the aim of covering the lack of harmonisation, it also aims to promote the use of recycled materials from the internal market, contributing to the development of the concept of circular economy within a clear idea of sustainable agriculture, emphasising the quality criteria of the raw materials used, preventing the use of those whose quality standards are outside the criteria of Safety for users and the environment.

This harmonised regulation covers all products whose function is related to fertilisation and soil improvement: fertilisers, amendments, biostimulants and growing media. This regulation establishes the requirements for each type of function and component that make up the product, which must be assessed before declaring its compliance with the regulation. If the product complies, it will be an "EU fertiliser product" and must bear the "CE marking".

However, we must not lose sight of the fact that this is a standard whose compliance is absolutely voluntary, as the current national fertiliser standards will continue to be valid, ensuring the Principle of Mutual Recognition contained in EU Regulation 2019/515 the free movement of fertilisers.

Main legislation to place fertilisers in the European Market and horizontal legislations to be taken in account are listed in Table 4.

Table 4 Legislation regulating the marketing of fertiliser products in Europe

RELEVANT LEGISLATION	OTHER LEGISLATION TO BE CONSIDERED
Regulation (EU) 2019/1009 (RPF)	Regulation (EC) No 1069/2009 (SANDACH)
Regulation (EU) 2019/1020 (RVM)	Regulation (EC) No 1272/2008 (CLP)
	Regulation (EC) No 1907/2006 (REACH)
	Directive 2008/98/EC and Law 7/2022 of 8 April (WASTE)

The Fertilising Products Regulation (FPR) EU/2019/1009 in article 2 sets out definitions, '**fertilizing product'** means a substance, mixture, microorganism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency; and **'EU fertilizing product'** means a fertilising product which is CE marked when made available on the market.

In order to place a fertiliser product on the market with CE marking, it must comply with the requirements set out in Regulation 1009/2019 (Figure 12).

1. Comply with the requirements of the **Product Function Categories** (PFC) set out in Annex I.
2. The raw materials used must comply with the requirements of the **Component Material Categories** (CMC) set out in Annex II.
3. The labelling of the products must comply with the requirements set out in Annex III.
4. The product should go through the applicable conformity assessment procedure according to Annex IV and issue the conformity assessment.

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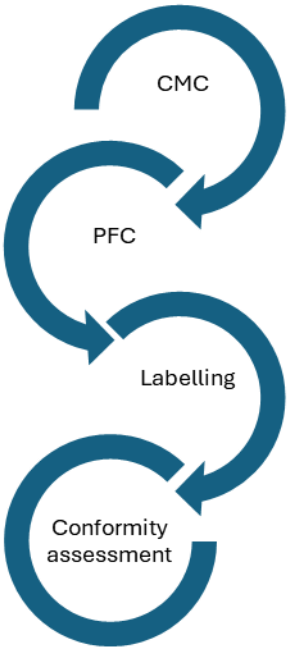

Figure 12. Compliance phases for CE marking

The Commission is empowered to adopt delegated acts amending Annexes for the purposes of adapting them to technical progress and of facilitating internal market access and free movement for EU fertilising products. Some Delegated Regulations have been already published but Regulation establishing the criteria for polimer biodegradability is still pending.

2.2.2. Product Function Categories

The classification of fertiliser products follows two criteria, the first one is PFC (Product Function Categories), described in Annex I.

The claim that an EU fertilising product complies with the function set out in this Annex for the relevant PFC shall be supported by the product's mode of action, the relative content of its various components, or any other relevant parameter.

PFC1 . Fertiliser
A. Organic fertiliser
- I. Solid organic fertiliser
- II. Liquid organic fertiliser

B. Organo-mineral fertiliser
- I. Solid organo-mineral fertiliser
- II. Liquid organo-mineral fertiliser

C. Inorganic fertiliser
- I. Inorganic macronutrient fertiliser
  - (a) Solid inorganic macronutrient fertiliser
    - (i) Straight solid inorganic macronutrient fertiliser
      - (A) Straight solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
    - (ii) Compound solid inorganic macronutrient fertiliser

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(A) Compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content
(b) Liquid inorganic macronutrient fertiliser
(i) Straight liquid inorganic macronutrient fertiliser
(ii) Compound liquid inorganic macronutrient fertiliser
II. Inorganic micronutrient fertiliser
(a) Straight inorganic micronutrient fertiliser
(b) Compound inorganic micronutrient fertiliser
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. Denitrification inhibitor
C. Urease inhibitor
PFC 6. Plant biostimulant
A. Microbial plant biostimulant
B. Non-microbial plant biostimulant
PFC 7. Fertilising product blend

Requirements related to nutrient content, contaminants, pathogens are defined for each PFC.

Controlled release fertilisers products developed during the project will fall under the scope of PFC 1 or PFC 7.

2.2.3. Component Material Categories

The raw materials used must comply with the requirements of the Component Material Categories (CMC) set out in Annex II. A product may be placed on the market as an EU fertiliser composed of different materials from different Component Material Categories (CMCs), provided that each material meets the requirements of the category to which it belongs. Therefore, an EU fertiliser product shall consist only of component materials that meet the requirements for one or more of the CMCs.

The component materials and the raw materials used to produce them shall not contain any of the substances for which maximum limit values are indicated in quantities that compromise the compliance of the EU fertiliser product with any of the applicable requirements. The component material categories (CMCs) listed in Annex II, are as follows;

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: Digestate other than fresh crop digestate
CMC 6: Food industry by-products
CMC 7: Micro-organisms
CMC 8: Nutrient polymers
CMC 9: Polymers other than nutrient polymers
CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009
CMC 11: By-products within the meaning of Directive 2008/98/EC.
CMC 12: Precipitated phosphate salts and derivates.
CMC13: Thermal oxidation materials and derivates.

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CMC14: Pyrolysis and gasification materials.
CMC15: Recovered high purity materials.

Therefore, the requirements for each type of material to be used in the formulation of a fertiliser product would be:

- REACH registration: All substances must be registered under REACH unless exempted, except for CMC 2, 7, 9 and 10. It is important to point out that for the FPR, the REACH registration obligation also applies to substances produced in quantities less than a metric ton per year.
- Declaration of Conformity according to the EU fertiliser regulation.
- Safety data sheet according to Annex II of Regulation (EU) 2015/830 together with exposure scenarios for relevant use, if applicable.
- If the substance classified as a health hazard according to the CLP Regulation, is a mixture, UFI (unique formula identifier) No. that it is notified to ECHA.
- Declaration as by-product according to Directive 2008/98/EC.
- SANDACH certificate if it concerns animal by-products, and the end point of the manufacturing chain has not been determined.
- Certificate as organic input, if considered as such.

In AGRO4AGRI project the preselected nutrients to be used in controlled release fertilisers correspond to CMC 1, and the materials used in delivery systems could be included in the Component Material Categories (CMCs) 1, 2, 6, 9 and 14.

Below we describe the requirements for these specific CMCs according to FPR. These may include requirements on the origin, production or recovery process and parameters, treatment, feedstocks, criteria on contaminants and pathogens and sanitary requirements.

CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES

1. An EU fertilising product may contain substances and mixtures, except: wastes, by-products, polymers other than

- polymers that are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted and that have not been chemically modified within the meaning of Article 3(40) of Regulation (EC) No 1907/2006,
- biodegradable polymers, or
- polymers with a water-solubility higher than 2 g/L in the following conditions:
    - temperature 20º C
    - pH 7
    - loading: 10 g/1 000 mL
    - test time: 24h,

compost, digestate, precipitated phosphate salts or derivates, thermal oxidation materials or derivates, pyrolysis and gasification materials, ammonium salts, sulphate salts, phosphate salts, elemental sulphur, calcium carbonate or calcium oxide, recovered from waste.

2. All substances incorporated into the EU fertilising product, on their own or in a mixture, except polymers, shall have been registered pursuant to Regulation (EC) No 1907/2006.

3. If the substance is intended to enhance the long term availability to plants of micronutrients, chelating agent or a complexing agent, description and stability.

4. For nitrification, denitrification or a urease inhibiting compound, description and experimental evidence of the required reduction in corresponding rates.

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The exclusion of a material from CMC 1 does not prevent it from being an eligible component material by virtue of another CMC stipulating different requirements, for example polymers CMC 9, biochar CMC 14, ...

CMC 2: PLANTS, PLANT PARTS OR PLANT EXTRACTS

Components, origin and process, considering that an EU fertilising product may contain plants, plant parts or plant extracts having undergone no processing other than cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze-drying, extraction with water, supercritical CO 2 extraction, or fiberisation at a temperature not higher than 100 °C and without any additives except water.

For the purpose of this point, plants include mushrooms and algae and exclude blue-green algae (cyanobacteria).

CMC 6: FOOD INDUSTRY BY-PRODUCTS

Material and treatments allowed: food industry factory lime, molasses, vinasse, distiller grains, plants, plant parts or plant extracts having undergone only heat treatment or heat treatment in addition to processing methods referred to in CMC 2; or lime from drinking water production.

CMC 9: POLYMERS OTHER THAN NUTRIENT POLYMERS

Components and purpose: may contain polymers other than nutrient polymers only in cases where the purpose of the polymer is:

(a) to control the water penetration into nutrient particles and thus the release of nutrients (in which case the polymer is commonly referred to as a 'coating agent'),
(b) to increase the water retention capacity or wettability of the EU fertilising product, or
(c) to bind material in an EU fertilising product belonging to PFC 4.

Restrictions related to biodegradation: From 16 July 2026, the polymers referred to in point 1(a) and (b) shall comply with the biodegradability criteria established by delegated acts referred to in Article 42(6). In the absence of such criteria, an EU fertilising product placed on the market after that date shall not contain such polymers.

By 16 July 2024 The Commission shall assess biodegradability criteria for polymers, as stated in Article 42 (6) that shall ensure that:
(a) the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments, so that it ultimately decomposes only into carbon dioxide, biomass and water;
(b) the polymer has at least 90 % of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period of the EU fertilising product indicated on the label, and
(c) the use of polymers does not lead to accumulation of plastics in the environment.

Adverse effects: For the polymers referred to in point 1(a) and (b), neither the polymer, nor its degradation by-products, shall show any overall adverse effect on animal or plant health, or on the environment. The polymer shall pass a plant growth acute toxicity test, an earthworm acute toxicity test and a nitrification inhibition test with soil microorganisms.

CMC 14: PYROLYSIS AND GASIFICATION MATERIALS

Material and processing: pyrolysis or gasification materials obtained through the thermochemical conversion under oxygen-limiting conditions of determined input materials, listed in section 1 of the CMC 14 in Annex II.

The thermochemical conversion process shall take place under oxygen- limiting conditions in such a way that a temperature of at least 180 °C for at least two seconds is reached in the reactor. The input and output materials must be kept separated from each other.

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The pyrolysis and gasification materials shall have a molar ratio of hydrogen (H) to organic carbon (H/C org) of less than 0,7, in the dry and ash-free fraction for materials that have an organic carbon (C org) content of less than 50 %. They shall have no more than: 6 mg/kg dry matter of PAH 16, 20 ng WHO toxicity equivalents of PCDD/F/kg dry matter.

In the final fertiliser product the chlorine (Cl -) content shall not be higher than 30 g/kg dry matter and the thallium (Tl) content shall not be higher than 2 mg/kg dry matter.

2.2.4. Labelling

The labelling of the products must comply with the requirements set out in Annex III.

The Regulation sets out the rules for labelling EU fertiliser products, including general (part I) and specific requirements (part II) associated with the PFC:

The following information as general requirements shall be provided:
(a) for EU fertilising products in PFC 1 to PFC 6, the designation as indicated in Part I of Annex I of the PFC corresponding to the product's claimed function.
(b) for EU fertilising products in PFC 7, the designations as indicated in Part I of Annex I of all the PFCs corresponding to the claimed functions of the component EU fertilising products.
(c) the quantity of the EU fertilising product, indicated by mass or volume.
(d) instructions for intended use, including application rates, timing and frequency, and target plants or mushrooms.
(e) recommended storage conditions.
(f) for products containing a polymer belonging to CMC 9 in Part II of Annex II, the time period following use during which the nutrient release is being controlled or the water retention capacity is being increased (the 'functionality period'), which shall not be longer than the period between two applications in accordance with the use instructions referred to in point (d);
(g) any relevant information on measures recommended to manage risks to human, animal or plant health, to safety or to the environment; and
(h) a list of all ingredients above 5 % by product weight in descending order of magnitude by dry weight, including the designations of the relevant CMCs as referred to in Part I of Annex II to this Regulation; where the ingredient is a substance or a mixture, it shall be identified as specified in Article 18 of Regulation (EC) No 1272/2008.

More details and specific labelling requirements can be consulted in Annex III and the Guidance document on EU fertilising product labelling **(EU Communication 2021/C 119/01)**.

2.2.5. Conformity assessment

The product should go through the applicable conformity assessment procedure according to Annex IV and issue the conformity assessment to get CE marking.

The declaration of conformity is a document by which compliance with the requirements laid down in the EU fertiliser regulation has been demonstrated for a finished product.

Four different conformity assessment modules (Figure 14) or procedures have been established for EU fertilisers based on the categories of component materials (CMC) used in their manufacture and the functional categories of products (PFC) where they are found (annex IV of the regulation (EU) 1009/2019.

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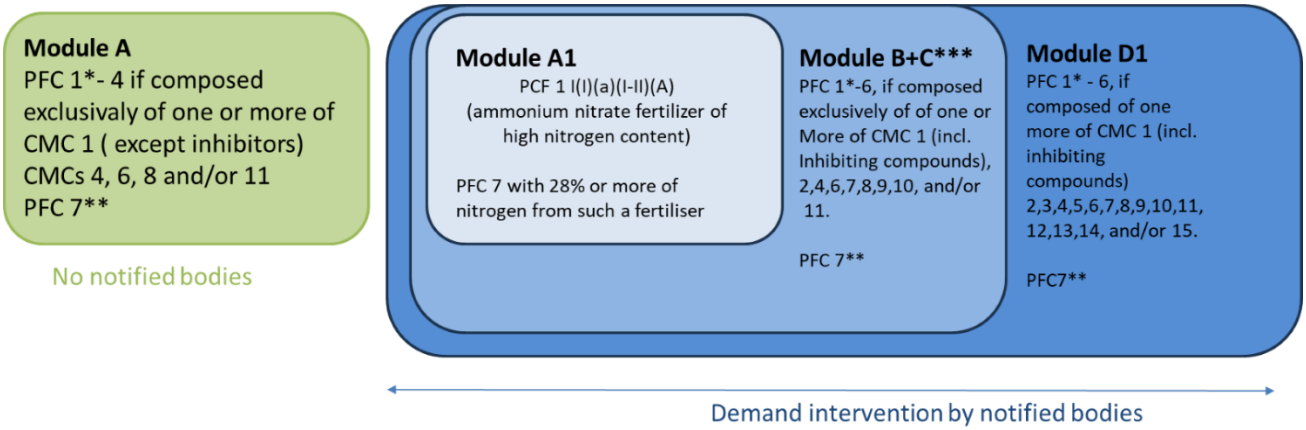

* Except PFC 1(C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory ** except PFC 7 with 28% or more of nitrogen from a fertiliser belonging to PFC 1 (C)(I)(a)(i-ii)(A) (ammonium nitrate fertiliser of high nitrogen content), for which Module A1 is mandatory. ***. Module is always followed by module C, wich is performed by the manufacturer without involvement of notified body.

Figure 14 Overview of which conformity assessment procedure modules are available depending on the product function category (PFC) of a product and the component material categories (CMC) of its components (Modified L. van Schöll 2023).

A notified body is an organization that has been designated by the European Commission at the proposal of an EU Member State, to carry out the conformity assessment procedures established by the regulation for its placing on the market.

Module A. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.

Module A1: Internal production control plus supervised product testing.
To be applied: inorganic solid inorganic fertilisers or compound fertilisers based on ammonium nitrate macronutrients with high nitrogen content (PFC 1), and for a mixture of fertiliser products (PFC 7) containing at least 28% by mass of nitrogen of EU fertiliser products belonging to PFC 1.

The test reports from product checks for oil retention and detonation resistance.

Module B+C: The conformity assessment procedure is structured in two distinct phases, firstly for compliance with Module B and then Module C.

Module B: The manufacturer prepares a technical dossier and the notified body attests that it complies with all the requirements set out in Regulation (EU) 1009/2019 for the PFC in question and for the CMCs used in the formulation and an EU certificate is issued, valid for 5 years, with annual controls and re-evaluations every two years.

Module C: must be carried out by the manufacturer himself who, on the basis of the EU type-certificate, ensures and declares that his fertiliser product is manufactured and placed on the market in compliance with the technical design that has been approved by the notified body. The manufacturer shall include in the EU declaration of conformity of the product the indication of the notified body that has carried out the conformity assessment according to Module B.

Module D1: quality assurance of the production process must be carried out by a notified body and implies that the manufacturer must establish a documented quality system that ensures compliance with the requirements of the regulation applicable to its fertiliser products, as well as the quality of the fertiliser products.

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When several conformity assessment modules are applicable, it is up to the manufacturer to decide which module to use.
Flow chart determining the applicable conformity assessment modules can be seen in Figure 5.

2.3. Market authorizations required for delivery system materials

Three different materials classifications will be tested in AGRO4AGRI as fertilizer delivery systems: nanoparticles, biochar and cellulose. These materials are subject to specific regulations, certifications or guidance in order to place them on the market which have been summarized in the following sections.

2.3.1. Nanoparticles

Nanotechnology is increasingly utilized in agriculture for various applications, including boosting crop growth, enhancing soil quality, and creating more effective and precise pesticide delivery systems (Prasad et al., 2014; Prasad et al., 2017; Hassani et al., 2020). Nonetheless, the integration of nanotechnology in agricultural products raises significant concerns regarding potential environmental and health risks (Khot et al., 2020; Mishra et al., 2021). In the present project **nanoclays** and **mesoporous silica nanoparticles** will be used like nanocarriers for fertilisers in a slow and controlled delivery system.

To mitigate these concerns, regulatory authorities globally have established **guidelines and regulations to ensure the safe application of nanotechnology in agriculture**. There are efforts worldwide to address and regulate the production and safe handling/use of nanomaterials (NMs) and nanotechnology either by legislation or by (non-binding) recommendations and guidances. Below some of the principal regulations and guidelines pertaining to nanotechnology-based agricultural products are described.

Different countries have established various regulations and guidelines to ensure the safe use and development of nanotechnology-based agri-products (Kumari et al., 2023). Table 5 is a summary of the regulation and guides of different countries and regions.

Table 5 The regulatory framework on Regulation and Safety Measures for Nanotechnology-based Agri-Products of different countries (from Kumari et al. 2023)

Country	Regulatory Framework	Regulatory Body	Safety Measures	Labelling Requirements	References
United States	Combination of existing regulations and guidelines from EPA, FDA, and USDA	EPA, FDA, USDA	Safety assessment and management, regulations on labelling of nanomaterials	No mandatory labelling requirements	EPA, 2017; FDA, 2018; USDA, 2016
European Union	Comprehensive regulatory framework, including REACH regulation and regulations governing labelling and pesticide residues	European Commission, European Chemicals Agency, European Food Safety Authority	Safety assessment and management, mandatory labelling requirements	Mandatory labelling of nanomaterials in food and cosmetics	EC, 2018; ECHA, 2021; EFSA, 2018

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China	Regulatory framework established by National Nanotechnology Standardization Technical Committee, guidelines for safety assessment and management, labelling, and traceability	Ministry of Agriculture and Rural Affairs	Safety assessment and management, guidelines for labelling and traceability	Guidelines for labelling and traceability	NNSC, 2017; MARA, 2017; SAMR, 2018
India	Limited regulatory framework, voluntary guidelines for safety assessment and management, guidelines for use of nanomaterials in food	Ministry of Environment, Forest and Climate Change, Food Safety and Standards Authority of India	Voluntary guidelines for safety assessment and management, guidelines for use of nanomaterials in food	No mandatory labelling requirements	MoEFCC, 2014; FSSAI, 2018; DST, 2018

Focusing on the European level, the main general regulations related with nanotechnology/nanoparticles are:

- Regulation (EU) 2015/2283: Definition of engineered nanomaterial
- REACH Regulation (1907/2006): The Regulation on Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) applies to all chemical substances. A specific revision of this regulation in 2020 included and regulated the nanoforms of substances.

ECHA also has a range of guidance documents specifically developed for nanomaterials (Nielsen et al., 2021).

The World Health Organization (WHO) has developed guidelines with recommendations on how to best protect workers from the potential risks of MNMs (World Health Organization, 2017). These recommendations are designed to assist policy-makers and professionals in the field of occupational health and safety in making informed decisions about the optimal protection against the specific risks posed by MNMs in workplaces. Additionally, these guidelines aim to support both workers and employers.

Several international organizations are active in the area of nanomaterial safety. The most active and influential are the Organisation for Economic Co-operation and Development (OECD) and the International Organization for Standardization (ISO):

- The OECD Working Party on Manufactured Nanomaterials (WPMN) has four steering groups. The first steering group on testing and assessment is in the process of publishing dossiers with data on toxicity testing and physicochemical characterization for 11 nanomaterials. It is also responsible for updating safety testing guidelines to make them suitable for nanomaterials. The second steering group on risk assessment and regulatory programmes reviews approaches for risk assessment of nanomaterials. The third steering group on exposure measurement and mitigation focuses on developing guidance for exposure assessment and mitigation of exposure to nanomaterials in the workplace, during consumer use of nano-enabled products and for the environment. Finally, the fourth steering group is looking at environmentally sustainable use of nanomaterials. As of 31 May 2016, the OECD working party had published 58 reports in total.

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- The ISO Technical Committee 229 (TC229) Nanotechnologies has five working groups. Of these, Working Group 3 (WG3) is tasked with developing standards related to the safety of nanomaterials and nanotechnology. As of 22 March 2017, this technical committee had published a total of 55 standards of which 18 were prepared by WG3; they deal directly with the health and safety issues of nanomaterials including specific standards on safe handling of nanomaterials in the workplace aimed at industrial hygienists.

There is no specific regulation for the use of nanoparticles in agriculture, but there are guidelines (not legally binding) (Food.ec.europa, 2024) such as the Guidance on the Risk assessment (EFSA, 2021a) ,and the Guidance on technical requirements (EFSA, 2021b).

The ***Guidance on the Risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health*** provides an overview of complementary information to Regulation 2015/2283 and how to perform risk assessments of nanomaterials in the food and feed area, by proposing a structured pathway for carrying out safety assessment of nanomaterials in food/feed and related applications. The Guide is cross-sectoral and contains sector-specific information (e.g. for feed additives and pesticides). Moreover:

- This Guidance is applicable to materials used in food and feed that meet the criteria of the definition of engineered nanomaterials as outlined in Regulation (EU) No 2015/2283, FCM substances in nanoform as outlined in Commission Regulation (EU) 10/2011, or deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale as outlined in Commission Regulation (EC) No 450/2009; and pesticide active substances and PPPs consisting of or containing nanoforms as outlined in Regulation (EU) 2018/1881.
- This Guidance should be used also for the assessment of conventional materials requiring assessment in the nanoscale, identified according to the Guidance on Particle-TR, setting out information requirements for applications in the regulated food and feed product areas, and establishing criteria for assessing the presence of a fraction of small particles.
- Furthermore, the Guidance should be used for nanostructured materials and materials which could retain properties that are characteristic of the nanoscale, e.g. related to the large specific surface area of nanomaterials or different toxicokinetic behaviour (i.e. significant changes in absorption, distribution and/or metabolism) as compared to its corresponding conventional material.
- When a material falls under the scope of this Guidance, its degradation products in the form of nanomaterial and materials with the same elemental composition but different particle morphology, e.g. shapes, sizes, crystalline forms and/or surface properties also must be assessed.
- This Guidance is complementary to the EFSA Guidance documents on conventional materials. This means that applicants and risk assessors have to follow the relevant guidance for conventional material and to apply also the additional information requirements in this present Guidance when the evaluation concerns a nanomaterial.

On the other hand, the ***Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles*** defines the criteria for assessing the presence of a fraction of small particles and setting out information requirements for applications in the regulated food and feed product areas.

This Guidance on Particle-TR is applicable to all chemical materials, marketed or to be marketed as substances or mixtures, to be assessed by EFSA, including mixtures and products marketed as liquid formulations unless the information confirms that they are true liquids and do not contain small particles in suspension. The

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characterisation of the fraction of small particles, including the particle size distribution, is needed in all cases unless the applicant demonstrates that the material will be fully dissolved under the intended use conditions and consumers will not be exposed to particles. For multiconstituent substances and mixtures, the information to be submitted should cover each single constituent or each component in the mixture, as well as the multi-component material. The document guides the applicant on different ways for confirming when a conventional risk assessment is sufficient. The applicants may select, according to their knowledge and available information, the best appraisal route or combination of appraisal routes to justify: (a) the absence of a fraction of small particles, or (b) that the material contains a fraction of small particles, but it is covered by the conventional risk assessment and does not require a separate assessment regarding nanoscale properties.

2.3.2. Biochar

Pyrolysis technology and the production of biochar for soil use (among its many applications) are becoming increasingly important as they allow for the reuse of waste and provide it with utility. Due to its recent development, regulations on the use of biochar in soils are still being formulated. However, there are already binding European regulations included in **Commission Delegated Regulation (EU) 2021/2088 of 7 July 2021 amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding pyrolysis and gasification materials as a component material category in EU fertilising products** (Regulation (EU) 2019/1009). Regulation (EU) 2021/2088 amending Annexes II, III and IV of Regulation (EU) 2019/1009 on fertiliser products. Thus, "CMC 14: Pyrolysis and gasification materials" is included in the ANNEX.

Additionally, it is necessary to register the biochar produced under The **Regulation (EC) No 1907/2006** (hereinafter referred to as **REACH**, acronym for Registration, Evaluation, Authorization and Restriction of Chemicals).

The REACH Regulation entered into force on June 1st, 2007, with the main objective of enhancing protection for human health and the environment against the risks associated with the manufacturing, marketing, and use of chemical substances and mixtures. In principle, REACH applies to all chemical substances present in daily life, whether as such, in the form of mixtures, or contained in articles, thus being applicable in various economic sectors.

To comply with the provisions of REACH, companies must identify and manage the risks associated with the substances they manufacture and market in the European Union. They must demonstrate how to use such substances safely and communicate all relevant information regarding risk management measures to stakeholders.

To achieve these objectives, the REACH Regulation includes the following processes:

- Registration (Title II): All substances manufactured/imported in quantities equal to or greater than 1 tonne/year must be registered.
- Evaluation (Title VI): The risks to health and the environment of any substance posing a risk according to the criteria established for priority assessment will be evaluated.
- Authorization (Title VII): Authorization for use must be requested for any substance considered of high concern according to the REACH Regulation.
- Restriction (Title VIII): Certain uses of substances will be prohibited or restricted when they pose an unacceptable risk to human health and the environment.

Another regulation applicable to biochar is **Regulation (EC) No 1272/2008** of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. CLP determines whether a substance or mixture exhibits properties that need to be classified as hazardous. Once these properties have been identified and the substance or mixture has been classified, the hazards identified must be

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communicated through labelling. Furthermore, packaging provisions are laid down for the safe supply of dangerous substances and mixtures. According to this regulation, they must be labelled and packing:

- The substance or mixture is classified as dangerous.
- The mixture contains one or more substances classified as dangerous beyond a certain threshold value.
- The article has explosive properties.

Biochar must be labelled as it may have explosive properties.

In addition to the binding regulations, there are certificates developed by **IBI** and the **Ithaka Institute**, which establish good industrial practices and ethical and environmental standards to support biochar systems that are safe and economically viable. IBI has developed the document **"Standardized Product Definition and Product Testing Guidelines for Biochar That Is Used in Soil"** (International Biochar Initiative (IBI), 2015). Ithaka Institute has developed two documents, "Guidelines for a Sustainable Production of Biochar," one for obtaining the **European Biochar Certificate (EBC, 2022)** and the other for obtaining the World **Biochar Certificate (WBC, 2022)**.

There is also **the Biochar Quality Mandate (BQM)** which is voluntary (Shackley et al., 2014). This document has been developed with standards similar to those of the IBI and EBC. However, the difference with the IBI and the EBC is that the BQM has focused on the specific regulatory requirements of developers, producers, users, and authorities in the United Kingdom.

Table 6. Biochar Legislative Framework at European, Spanish State and voluntary level.

European Regulation	National Regulation (Spain)	Voluntary Regulation
Commission Delegated Regulation (EU) 2021/2088 Regulation (EC) No 1907/2006 (REACH) Regulation (EC) No 1272/2008 (CLP) (Labelling and packing)	RD 506/2013 RD 865/2010	There are three main organizations: European Biochar Certificate (EBC); Biochar Quality Mandate (BQM); and International Biochar Initiative (IBI-BS).

2.3.3. Cellulose

According to (Mishra et al., 2022), currently there is no specific EU legislation regulating nanocellulose, and therefore the general legislation of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") must be applied (Foth and Hayes, 2008; Kautto and Valve, 2019). Therefore, REACH norms must be applied to any handling of nanocellulose from plants. In REACH, the European Commission has repeatedly defined nanomaterials as a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1–100 nm.

The Nanocellulose extracted from plants is a polymer already present nature in the nanoform. This substance falls in the category of Article 3 (1) of REACH and is subject to registration if more than 1 tonne per year is manufactured or imported into the EU. Because Nanocellulose meets the definition of nanoform in Annex VI of REACH, NC-based materials that have been obtained as a result of a chemical treatment must be registered. "Cellulose pulp" is

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exempted from registration in Annex IV of REACH; however, cellulose pulp is not nanocellulose. If they are naturally occurring substances and are not chemically modified, they shall also be exempted from registration under Annex V, provided it is not a dangerous substance. According to Article 9 of REACH, Nanocellulose may also be exempted from registration if it is for research and development. However, even in the case of an exemption, it is necessary to identify the substance and duly justify its use for research and development.

The general conditions of the registration for registration of a substance under REACH include: the identification of the manufacturer or importer, the identification of the substance according to the Annex to REACH and the provision of the technical record, which includes study summaries (Article 10 (a) (vi)).

2.3.4. Fertilizers

Depending of the combinations of materials of delivery systems and nutrients different conformity modules will be necessary to obtain the UE declaration of the conformity of the product to be placed in the European market, demanding or not (module A) intervention by notified bodies.

Considering that in the project the preselected nutrients to be used in controlled release fertilisers correspond to CMC 1, the materials used in delivery systems could be included in the CMCs 1, 2, 6, 9 and 14, and that final products will fall under the scope of PFC 1 or PFC 7, we could expect that intervention by notification bodies will be necessary to go through module A1 (if ammonium nitrate is one of the component), module B+C or module D1 (if we use biochar for example).

“CE marking” as stated in RPF means a marking by which the manufacturer indicates that the EU fertilising product is in conformity with the applicable requirements set out in Union harmonisation legislation. Therefore a fertiliser product with CE marking can be placed on all countries of EU market without any additional requirements at national level.

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3. BIONEMATICIDE

3.1. Market overview and potential barriers

Nematodes are small worms that lives in the soils, their size is typically around 1 mm long and only 50 microns in diameter. They generally feed on fungi, bacteria and other soil organisms, together with plant cells. While most of nematode species can have a beneficial role in the soil balance and fertility, some species on the other hand have a parasitic behavior and are considered pests that can significantly impact the agricultural production (AUSVEG, 2024).

Nematodes can be differentiated by their feeding type or mouth structure. For example, bacteria feeding nematodes have a tube-like sucking structure, nematodes feeding on fungi have a stylet needle which penetrates the fungal cells whereas the root feeding nematodes, have a piercing mouthpart.

Parasitic nematodes are those considered pests because they feed on plant roots thus disrupting and slowing plant growth. The most common pest nematodes living in the soil and targeting the crop root system are the potato cyst nematode (PCN – *Globodera rostochiensis*), the root know nematode (RKN – *Meloidogyne incognita*) and root lesion nematodes (RLN – Pratylenchus spp.). The PCN affects mainly vegetables crops belonging to the Solanaceae family such as potato, tomato and eggplant. The RKN affects a wide range of crops like carrots, potato, tomatoes, eggplant, pepper, cucumber, onion, lettuce, spinach and it causes typical root swellings or galls (knots), easy to recognize (Figure 15). The upper part of the plant affected by the nematodes shows generally symptoms related to a damaged root system: reduced growth, yellowing on leaves and wilting, lack of turgor, higher mortality (Figure 16).

Figure 15: Severely damaged cucumber roots showing swollen galls (or knots) in which the RKN nematode hatches the eggs.

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Figure 16: Cucumber plant aerial part showing RKN attach symptoms.

Nematodes can be spread by infected plant material and soil and they preferably infest sandy soils with medium high temperatures. The conditions can typically be present in the Mediterranean greenhouse growing condition of Spain, Italy, Greece; however, this type of plague is spreading also in new northern areas such as France, Germany and in open field conditions due to climate change that brings to the average raise of temperatures.

When the damage caused by nematodes to the crop root system is above a specific threshold that can vary among different species and varieties of cultivated plants, it brings to a significant reduction of yield, which on high infestation conditions can be even above 50% of total yield loss, causing indeed an economic damage to the farmer. The strategies for limiting nematodes are several and all related to the good agronomic practices: implementing crop rotation, avoid using infected plants and propagation material, choice of tolerant varieties, etc. The above-mentioned practices however are not sufficient to cope against the high nematodes pressure found in specific areas. Moreover, in growing conditions where a high specialization of the crop system is present, the farmer economic competitiveness is strictly linked to few crops, therefore the crop rotation cannot be an easy alternative for reducing the nematode pressure. It is estimated that the total surface significantly affected by nematodes in Europe is around 100.000 – 150.000 hectares (Sipcam Oxon, marketing data 2024).

Under these growing conditions, in order to guarantee the expected yield, the use of agrochemicals products is widely adopted. The total market of Plant Protection Products (PPP) in the above mentioned countries in Europe is estimated to 90-100 M€ (Sigma Kynetec, 2022). The PPP utilized for the protection against nematodes are mainly three types: fumigants, nematicides and seed treatments. Fumigants are a type of chemical compounds that applied to the soil release gases that disrupt most of the biological processes. A fumigation treatment has a wide spectrum of activity, and it is not selective among non-targets plants and organisms. The application needs high relatively high rate of product and high expertise to properly manage high volumes of harmful chemicals. Although fumigants are considered very effective products and today are still covering more than half of total market share, due to the raise of environmental concerns, many active ingredients are not renewed for their authorization as PPP and they are gradually phasing out from the market. This creates room and opportunities for newer active ingredients, with a greener profile, more selective toward non-target organisms, and safer for the operators and the environment. These products can be either chemical or from natural origin, some are applied directly to the seed as a seed treatment product or as final formulation to be diluted in water and applied through the drip

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irrigation system. The seed treatment method is typically used for extensive and row crops like cereals, maize, and others whereas the drip irrigation method is common on vegetable crops and in greenhouse conditions.

The natural origin nematicides, as previously mentioned, are also known with the term “bionematicides”. They are specific PPP which all compounds that they are made of, must be exclusively from natural origin, in other words, they should be available and found in Nature. This characteristic applies to the active ingredient as well as most of the coformulants that have to be compliant with the Organic farming regulation. Therefore, if the bionematicide, as any other CPP, apart from bio-herbicides, complies with these requirements, it can be certified as Organic Product and utilized in the Organic Farming production system.

Among the bionematicides, and regarding the type of active ingredient used, here are mainly two types present today in the market:

- Microbials bionematicides: they can be bacteria such as Bacillus spp or fungi such as *Myrothecium verrucaria, Pochonia chlamydosporia, Purpureocillium (or Paecilomyces) lilacinum.* They are also identified as biological control agents, which means living microorganisms, selected strains that are naturally parasites of target nematodes.
- Plant extracts or botanicals bionematicides: the active ingredients of these products are generally plant extracts or specific molecules contained in plant species. Some examples of active ingredient applied as bionematicide, but not only, are terpenes such as Geraniol and Thymol, saponins from Quillaja saponaria, azadirachtin from Neem plant oil, Garlic extract, etc.

At industrial level, microbials are produced through a fermentation process occurring in bioreactors. This process, once optimized, allows a quite responsive ramp-up of volumes and a stable production throughout the year guaranteeing a consistent supply. Plant extracts and purified molecules, on the other hand are obtained from vegetal biomasses specifically selected from plant species that can be grown for that purpose or can be obtained from biomass waste of previous industrial processes and thus in the latter case being part of a circular economic system. The nature of the source, however, makes the overall supply system keener to unpredictability, and linked to the season trend. For example, a severe drought can compromise the yield and quality of the raw material from which the active ingredient is obtained. Moreover, if the type of crop is used specifically for the purpose of extracting that specific compound needed for formulating the final PPP, the offer can be limited, therefore the raw material can be susceptible to a strict availability which in case of increased volumes of CPP requested, it brings to high price volatility. Some molecules originating from plants can be, on the other hand, obtained also by a synthetic or bio-synthetic process. The first one is a chemical synthesis that brings an identical molecule as though it was purified from a vegetal source. The biosynthesis operates with a modified microorganism which is able to produce the desired molecule as a metabolite. Both synthesis methods are accepted by the Authorities in Europe, even for the Organic Agriculture Certification and that helps to guarantee a more stable in terms of quantity and purity level and economically competitive active ingredient. The biosynthesis process is becoming more and more important in the latter years for allowing the development of also a new category of PPP which are starting to approach the market. Few examples exist of bio-insecticides and bio-fungicides commercialized in North America having Peptides or dsRNA as active ingredients.

The scheme reported in Figure 15, summarizes the 5 areas in which positive or negative contributions can be found that can significantly influence the adoption of the biological PPPs. The arrows standing upwards indicate the driving factors that increase the adoption of biological PPP, on the contrary the arrows pointing downwards indicate the elements that are restraining the process. The Social acceptance of biological PPP is well known, especially in developed countries as in EU and for high value crops such as vegetables and fruits. The perception of end user consumers, more than farmers, is that biological PPPP are very safe for the environment and the risk of potential residues on food is not perceived. This phenomenon brought to the development of new and parallel markets of food products that imply chemical-free, green products, belonging to the Organic Farming Certification, are supported in the Integrated Pest Management (IPM) and/or to positive lists of agrochemicals drafted by the Large-

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Scale Retail Distribution. Biopesticides have been developed and commercialized for decades, however for a long time they struggled to growth significantly and to be adopted in a wide range of conditions, in fact they remained mostly bound to few application niches. Two reasons that played an important role on this are (1) the lower overall efficacy compared to chemical benchmarks and (2) higher application costs. Very often, when an alternative is available, it is cheaper and effective; farmers, which their first task is to provide yield in a safe and consistent way, choose the most efficient option available. This method, however, is not possible today with the same extend. In fact, the technical and economic factors need to face with market trends and political decisions that are limiting the use of conventional chemical products. Consequently, this brought to a higher need of biological PPP, and among these also bionematicides (Dean, 2017). Moreover, chemical products often rely on few Modes of Actions for exerting their toxicological activity against the target pest. This aspect, after time, contributed to the development of resistance issues by target pests, which mean drastic reduction of control efficacy. Biological products, on the other hand, work on different and sometimes on multiple Modes of Actions, thus they can become a very important ally for an anti-resistant management strategy. This means that a farmer, nowadays is apt choosing biocontrol products for including it in a pest management program in combination with conventional agrochemicals in an integrated program. This strategy consists of tank mixes of the two different products or of a rotation of active ingredients applied during the spraying program planned across the season. The use of a Biological PPP in tank mix with a Conventional PPP partner, if a synergistic efficacy is observed, becomes then a great tool to help to wipe off potential disease strains that might develop resistance trait against a specific active ingredient. Moreover, a successful Biological + Conventional PPP tank mix, can help reducing the load of conventional active ingredient by lowering the application rate but at the same type keeping an efficacy in line with the expectations.

Another driver that contributes to the adoption of biorationals, is the Maximum Residual Level (MRL) and pre-harvest interval (PHI) exemptions. The MRL is the highest level of a PPP residue that is legally tolerated in or on food or feed (Food EC Europa, 2024) whereas the PHI consists of the minimum amount of time between the last application of a PPP and when the crop can be harvested (Canada.ca, 2024). Many biological PPP can benefit the exemption of MRL and PHI. In other words, this allows a more flexible spraying program to the farmer, that is allowed to carry out the treatment in a close to harvest timing. This is very important for some fungal diseases and pests which they can occur few days before harvest or develop their symptoms on fruits after harvest. Moreover, it can be very convenient in those crops, such as tomato, cucumber, strawberries, etc. where an overlapping of the crop phenological stages is present, which means that at the same time can be present in the field flowers, early developed fruits or full-grown fruits. The possibility to the farmer to be able to spray a product that protect the flower on plants that at the same time are bearing ripening fruits can be in some case crucial. This feature of low or lack of MRL and PHI thresholds applies mainly to insects and fungal disease applications, since for the control of nematodes the most effective application timings occur during the first and early crop stages. The first application targeting nematodes can occur even before transplanting, during transplanting or in the first weeks of crop establishment. Therefore, considering that the application timing of nematicides occurs at the starting of the season whereas, by definition, harvest occurs at the end of the season, the risk of potential residues in edible fruits is expected to be negligible.

As already described, the Regulation framework, influenced by the political and societal trends occurring especially in Europe, creates obstacles and limitation to the registration or renewal of conventional synthetic molecules and as a consequence their commercialization and use. On the other hand, the main Regulation concerning the registration and marketing of PPPs (EU Agrochemical Regulation 1107/2009) for chemical and biological products is the same. Therefore, for biological active ingredients and biological PPPs, for some extends, few specific guidelines are present indicating how to deal with natural products, such as plant extract, natural compounds, microbial strains, viruses and more advanced materials like peptides, RNA. The discovery and development activities carried out by private companies need to consider many uncertainties related to timing and development costs needed to bring the whole project of a new PPP to full registration and to the market.

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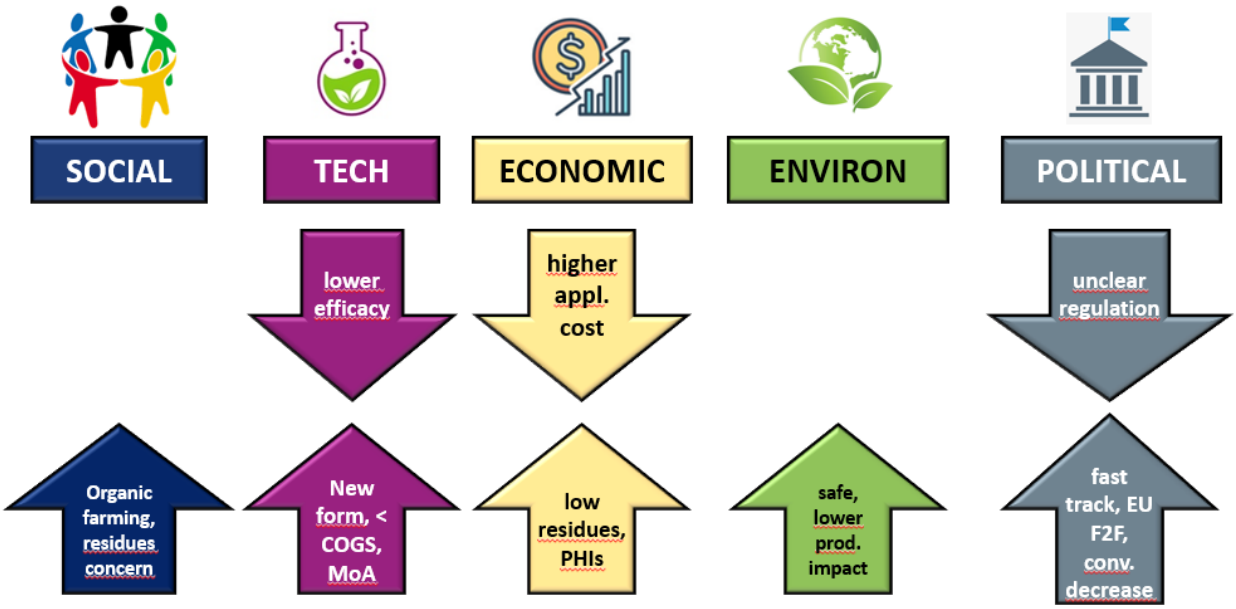

Figure 17: Factors stimulating, represented by upward facing arrows, and constraining, represented by downward facing arrows the growth and adoption of natural PPP considering 5 different contexts (S&P Global, 2022). MoA: Modes of Action, COGS: Cost of Goods, PHI, pre-harvest interval, F2F: Farm to Fork program.

The company Agbioinvestor (agbioinvestor.com), a leading consultancy and analytical firm in the Agrochemical market, biologicals market and the seeds & traits industries carried out in 2022 a market survey for collecting the opinion concerning the biological pesticides, drivers and growth potential. More than 120 interviews from Ag-chem industries, including biopesticide and agrochemical companies gave feedback. On Figure 16 is reported the ranking from least to most important aspect considered as drivers for the market adoption of biological PPPs. Efficacy and Regulation are considered to have one of the key factors holding back growth of biopesticides in recent years. Resistance management, as previously explained, is considered the third factor for the adoption of biological which are leading a strong potential in management of resistant pests. The market reach and organic cultivation practices were considered the least important drivers of growth of pesticides. In fact, it is estimated that only 10% of the total biocontrol market is applied exclusively to Organic farming (IHS Markit, 2021).

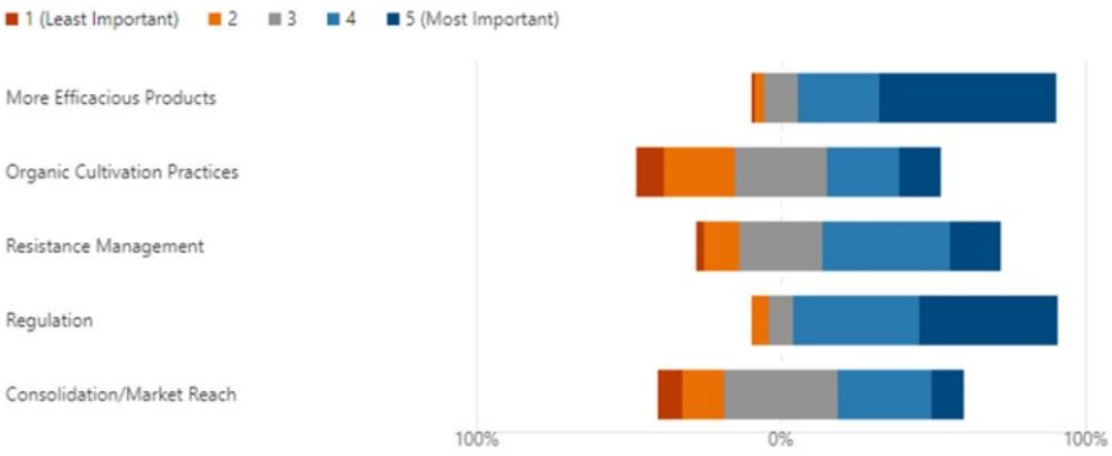

Figure 18: Key Drivers importance assessment by interviewed panel.

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One of the objectives of Agro4Agri project is to develop a novel RNA interference (RNAi) based bionematicide. The RNA regulates gene expression on target organisms by silencing or "turning off" specific genes on target pests. The Double Strained RNA (dsRNA) containing the specific genetic sequence that affects the target pest, is delivered through ingestion and then the silencing process is passed from cell to cell. The RNA applications don't lead to a change in the genome treated plants. Some of the advantages of RNAi applied for pest control are (Agropages, 2024):

1. Due to the high specificity of dsRNA, such a technology has a small effect on non-target organisms.
2. As RNAi naturally occurs in the environment or organisms, and is biodegradable, the toxicity potential of RNA pesticides is lower than that of chemical pesticides.
3. RNA pesticides can be developed to control all species of pests.

A great challenge for many manufacturers is in terms of RNA degradation. RNA may be easily degraded after being sprayed in the field. Therefore, its efficacy may not last long enough and frequent reapplication may be required. This might result in high costs for growers. The formulation can play a key role for finding the right balance between the product availability, delivery system and product shelf life, which should be on comparison with other benchmark around two years.

3.2. Regulatory Framework for PPPs

A PPP usually contains more than one component. The component that works against pests/plant diseases is the "active substance".

Active substances can only be approved for use in PPPs if they fulfil the approval criteria that are laid down in Regulation (EC) No 1107/2009.

Regulation 1107/2009 is the framework legislation setting out the rules and procedures for the placing on the market of PPPs and it covers the general process of the placing on the market of PPPs. Its scope is limited to the process of approval of active substances at Community level, and of authorisation of PPPs at Member State level.

The Regulation describes the general process for placing PPPs on the market. This process consists of two steps:

1. **Substance approval**. An active substance is approved at the European level. One or more applicants can submit an active substance dossier plus one or more product dossiers. The active substance dossier is used to establish the "endpoints": the commonly agreed intrinsic properties of the substance. The product dossier(s), presenting both product data and information on the proposed conditions of use for one or more "representative uses", allows to conduct risk assessments for human and environmental safety, using the endpoints from the substance dossier.

A substance is only approved if at least one safe use can be identified. An approval is not proprietary and does not allow the placing on the market of any products containing the active substance. It is a precondition for applying for a product authorisation at Member State level, in step 2.

2. **Product Authorisation**. PPPs must be authorised in each separate Member State before they can be placed on the market. An applicant must submit a complete dossier, consisting of an active substance dossier for each of the active substances contained within the product, plus a product dossier. Instead of submitting complete active substances dossiers, an applicant can submit a reference to (parts of) the dossier submitted for the approval if he is the owner of that dossier, or if studies from that dossier are no longer protected. For studies that are still protected, an applicant can provide either a Letter of Access from the dossier owner, or present his own studies.

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The Competent Authority of the Member State conducts a risk assessment based on the product and substance data, the proposed conditions of use, and the national or local environmental and climatological conditions.

The Member States, the European Food Safety Authority (EFSA) and the Commission evaluate every active substance before it can be placed on the market and used in a PPP.

The initial approval of an active substance is valid for a limited period and the approval of these substances need to be reviewed periodically. A renewal of approval is only granted after the substance is re-evaluated and at that occasion, at least one safe use of the substance is demonstrated.

All approved active substances are listed in Implementing Regulation (EU) No 540/2011 and included in the EU Pesticides Database.

Depending on their characteristics, some active substances can be approved as so-called low risk substances or as candidates for substitution.

Once active substances are approved companies can submit in the Member States applications for authorisation for placing on the market and use of PPPs containing them.

3.2.1. Procedural Steps

The approval process can be subdivided in a number of steps:

- An application for approval (or amendment of approval) is submitted in accordance with the applicable procedural rules to a Member State (the Rapporteur Member State (RMS), which may be supported by a co-rapporteur Member State(co-RMS).
- Prior to submission of the application, the applicant may request general pre-submission advice from EFSA and the RMS and must notify studies that it commissions or carries out. EFSA recommends submitting the request at least six months before the envisaged submission date of the application. Applicants (and laboratories) must notify information on studies commissioned or carried out to support a future application.
- In accordance with Implementing Regulation (EU) 2021/428 (for active substances) and Commission Regulation (EU) 2024/1487 (for safeners and synergists), applications (dossiers) have to be submitted via IUCLID format, which allows to share them with Member States, EFSA and the Commission. Dossiers must comply with the data requirements set out in Regulation EU 283/2013 and its associated Communication and Regulation 284/2013 and its associated Communication, as last amended.
- After submission, the RMS verifies if the application is admissible
- The RMS prepares a draft assessment report (DAR) and delivers it to the European Food Safety Authority (EFSA) for peer-review. If necessary, the RMS can request the applicant to provide additional information during the evaluation. According to the legislation, the RMS has to submit its assessment to the Commission and to EFSA 1-1.5 years after the admissibility of the application for a first approval or 13 months for a renewal of approval. There is a common structure for the DAR/RAR agreed by the EU and OECD;
- EFSA coordinates the peer-review process, which begins with a public consultation on the DAR prepared by the RMS. The applicant, EFSA and all Member States also comment on it;
- EFSA may organise expert discussion on aspects of the assessment and, if necessary, request the applicant to provide additional information in accordance with the rules laid down in the EU legislation;
- EFSA issues its conclusions on whether the active substance may expect to meet the approval criteria;
- Based on the conclusions of EFSA, the assessment of the RMS, and other legitimate factors the Commission puts forward a draft Regulation for approval or non-approval and an accompanying Review Report;

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- The Standing Committee on Plants, Animals, Food and Feed (ScoPAFF – made up of representatives from each EU Member State) delivers its opinion on the proposal put forward by the Commission;
- Following a favourable opinion of SCoPAFF, the Commission adopts the Regulation, which is published in the EU Offical Journal.
- For renewals of approval, applications must be submitted at the latest 3 years before the expiry of the current approval of the active substance.

3.2.2. Critical aspects for not approving a product

The cut-off criteria prevent the approval or re-approval of active substances for which particular types of danger are present. Substances that meet any of the cut-off criteria are rejected without considering the results of the risk assessment.

There are 4 toxicological and 3 environmental cut-off criteria. If the substance is classified one of these groups, the registration cannot be granted.

Toxicological cut-off criteria:

- Endocrine disruptor
- Mutagenic Category 1A or 1B
- Carcinogenic
- Toxic for reproduction

Environmental cut-off criteria:

- PBT substance (Persistent in the environment AND Bioaccumulative AND Toxic)
- vPvB substance (Very Persistent in the environment AND Very Bioaccumulative
- POP substance (Persistent in the environment AND Bioaccumulative AND Potential for long-range environmental transport)

3.2.3. Unacceptable co-formulants

Commission Implementing Regulation (EU) 2023/574 lays down detailed rules and criteria for the identification of co-formulants that will not be accepted in PPPs. The Regulation applies to applications for the authorisation of PPPs.

The new product composition should take into consideration these rules and exclude coformulants listed as unacceptable co-formulants in Regulation (EU) 2021/383 of 3 March 2021

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CONCLUSIONS

Plant Biostimulant

The Plant Biostimulant (PB) developed in this project must comply with the new EU Regulation EU 2019/1009 on Fertilising Products (FPR) in force since 16th July 2022.

In particular it should be included in the class PFC 6 (Plant Biostimulants) with the specific claim of "improvement of nitrogen use efficiency, claim that is included in the more general definition of "improvement of nutrient use efficiency" as defined in the FPR EU 2019/1009.

Concerning the raw material used for PB formulation, it must comply with one (or more) of the Component Material Categories (CMC) included in the list.

The product can be registered for one single crop, one single crop category, two or all three crop categories.

In this last case the crop categories will be:

- Broadacre crops (combinable and processing products): annual and non-annual crops usually characterized by being grown in large extensions, harvested via combiners or industrial harvesters, with the aim of obtaining vegetative organs, Roots, Tubers and/or seeds/grains,
- Woody perennials: non-annual crops with the ability to cover their stems with suberized cork,
- Vegetables, ornamental and AMP (Aromatic and Medicinal Plant) crops: annual and non-annual crops usually correlated with seasonality and not included in the broadacre and woody perennial crops

If we assume to register the new PB product in all the three crop categories, at least 9 positive trials in total (3 per crop category) are required. Some of these trials could be established in controlled conditions (growth chamber) other in open field conditions. To speed up the registration process, all the trials will be managed in one season and at least 12 trials will be run, for a total cost about 120.000 €. Time needed to obtain the registration according FPR EU 2019/1009, can be estimated in a range of 15-21 months, including the time needed for trials execution.

Controlled delivery fertilizer

The Controlled Release Fertilisers developed in this project must comply with the European Regulation EU 2019/1009 on Fertilising Products (FPR). This legislation states that the REACH registration obligation (Regulation EU 1907/2006) also applies to the components of the fertiliser, although substances are produced in quantities less than a metric ton per year.

There is no specific CMC (component material categories) for controlled release fertilisers, but every component in the final product must comply with requirements established for the corresponding CMC, and for some CMCs, related to ingredients susceptible to work with in this project, REACH Registration is obliged, as CMC 1 (virgin material substances and mixes), CMC 6 (Food industry by-products) and CMC 14 (pyrolysis or gasification materials). Biochar needs registration under REACH regulation.

Others CRFs related materials as polymers are included in CMC 1, natural polymers registered in REACH, biodegradables or very soluble in water, CMC 8 (nutrient polymers) and CMC 9 (other than nutrient polymers), exempted from REACH registration, and to which toxicity criteria for plants, human and environmental are defined in FPR, and whose biodegradability criteria will be established by delegated acts from 16 July 2026.

Regarding to proposed nanoparticles and nanocellulose materials to be used as delivery systems, we can look at different scenarios, if they are naturally occurring substances and are not chemically modified, they will also be

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exempted from REACH registration under Annex V, provided it is not a dangerous substance, but nanoparticles are not exempted from registration and specific regulation for nanoforms is under way. But if nanoparticles or nanoforms are chemically modified to be used as proper delivery system they are subject to registration.

Technical specifications of specific components for delivery systems as nanoparticles are not published but in the near future we can expect that Annex II of the Regulation EU 2019/1009 will extend with new CMC adapting to technical progress.

It is difficult to predict time and costs for these products to get CE marking and to reach European market, it depends on REACH registration where needed and the module of conformity evaluation, but they should not be more than one year.

Bio-nematicide

The RNA interference sequence that disrupts the metabolic system of the target pest nematode *Meloydogyne incognita* can become a very interesting technology for dealing with this pest. The crop territory affected by this pest is spreading steadily, affecting new areas. In the meantime, due to the increased concern of the risks caused by fumigants and conventional chemical nematicides, the number of effective solutions available is decreasing.

Approval of RNA interference sequence as a new active ingredient in EU would require going through the extensive set of testing and evaluation criteria as set by existing EU regulations. The main legislative reference is the EC Regulation 1107/2009. The whole process to discover, develop and finally register a new PPP comprising a new active substance is very long. Once an active substance is selected among several and the final formulation is finalized, at least two years of efficacy trials are needed to prove the product efficacy towards the selected target. In this phase, new minimum effective application rate has to be found and in the meanwhile the product needs to prove its selectivity towards the tested crop. Then the dossier for proving that the PPP responds to al legislative and safety requirements needs to be prepared. Generally, once a new active substance is discovered and selected it takes up to 10 years before the final PPP is finally registered commercialized. The investment needed, for the whole development process of a biological product can be between 4-8 M€.

The process for deciding whether a new active substance can be approved for use in plant protection products in the European Union (EU), involves all Member States, the European Food Safety Authority (EFSA) and the European Commission. Members of the public and other interested parties can also provide comments through the public consultation process of EFSA. After an active substance is approved, a national application for registration of a plant protection product containing the active substances can be submitted.

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ANNEXES

Annex 1: CEN/TS 17700-2 Plant biostimulants - Claims - Part 2: Nutrient use efficiency resulting from the use of a plant biostimulant

1 Scope

This document provides guidance for justifying agronomic nutrient use efficiency claims of Plant biostimulants used in agriculture.

This document is aimed primarily at manufacturers, laboratories, researchers, technical centres, companies that will put the products on market, notifying authorities, notified bodies, and market surveillance authorities.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CEN/TS 17700-1:—1, *Plant biostimulants - Claims - Part 1: General Principles*

1 Under preparation. Current stage is: FprCEN/TS 17700-1:2021.

2 Under preparation. Current stage is: FprCEN/TS 17724:2021.

CEN/TS 17724:—2, *Plant biostimulants - Terminology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in CEN/TS 17724:—, CEN/TS 17701-1:— and the following apply.

3.1

nutrient use efficiency

measure of a plant's ability to acquire and utilize nutrients from the environment for a desired outcome based on (a) nutrient availability (b) uptake efficiency and/or (c) utilization efficiency

Note 1 to entry: Nutrient use efficiency is a complex trait: it depends on the ability to take up the nutrients from the soil, medium, fertilizers… but also on transport, storage, mobilization, usage within the plant.

3.2

nutrient availability

elements either present in the soil solution or exchangeable on soil colloids

3.3

uptake efficiency

measure of the plant capacity to acquire nutrients from the environment

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3.4

utilization efficiency

measure of the plant capacity to transform and valorise acquired nutrients into more complex substances (e.g. organic compounds, plant biomass)

3.5

plant nutrient

chemical element used by the plant for growth and development usually classified as a Primary Macronutrient, Secondary Macronutrient or Micronutrients per the quantity required by the plant

Note 1 to entry: Carbon, hydrogen and oxygen are also essential element for plant growth.

Note 2 to entry: Primary Macronutrients – Nitrogen, Phosphorus, Potassium,

Secondary Macronutrients – Sulphur, Calcium, Magnesium, Sodium,

Micronutrients – Iron, Molybdenum, Boron, Copper, Manganese, Zinc, Cobalt.

4 Terminology of the claim

The label shall clearly indicate the effect of the Plant biostimulant. For the case of the claim Nutrient Use Efficiency, the effect shall be written on the label like mentioned below:

• Improvement of the use efficiency of [Plant Nutrients]

The Plant Nutrients indicated shall be one of those demonstrated during the trials.

For terminology of the crops, refer to General Principles Technical Specification (CEN/TS 17700-1:—).

5 Assessment indices to validate the claims

Agronomic indices have been proposed for the short-term assessment of Nutrient Use Efficiency and its components.

These indices are reported in Table 1, adapted from Dobermann A. 2007 [1].

They can be used independently to justify the claim. These indices are based on the following measurements

F: Amount of nutrient made available to the plant

U: Amount of nutrient acquired by the plant biomass (total biomass or biomass in the part of interest.) Concentration of each nutrient measured in the plant.

Y: Crop yield. Could be interpreted in different manners: Harvested part or total biomass.

C: Concentration of the plant nutrient in the part of interest.

In order to justify the claims, these indices shall be calculated in presence and absence of plant biostimulants.

U and Y can also be measured for the control treatment without Fertilizers and noted Uo and Yo.

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Table 1

Index	Calculation	Interpretation
RE = Apparent crop recovery efficiency of supplied nutrient	RE = (U-Uo)/F	RE depends on the congruence between plant demand and nutrient made available to the plant by fertilizers and/or other environment resources. RE is affected by the application method (amount, timing, placement, N (*or nutrients)* form) and factors that determine the size of the crop nutrient sink (genotype climate, plant density, abiotic /biotic stresses)
PE = Physiological efficiency of acquired Nutrient(s) Kg yield increase per kg increase in Nutrient Uptake from fertilizer or/and environment	PE= (Y-Yo)/ (U- Uo) -	Ability of a plant to transform nutrients acquired from fertilizer or environment into economic yield.
IE=Internal utilisation efficiency of a nutrient (kg yield per kg nutrient uptake)	IE=(Y/U)	Ability of a plant to transform nutrients acquired from all sources (soil, fertilizer) into economic yield (grain). Depends on genotype, environment and management.
AE = Agronomic efficiency if supplied nutrient (kg yield increase per kg nutrient applied)	AE = (Y-Yo)/F or AE = RE x PE	Product of nutrient recovery from mineral or organic fertilizer (RE) and the efficiency with which the plan uses each additional unit of nutrient (PE). AE depends on management practices that affect RE and PE.
PFP = Partial factor productivity of supplied nutrient (kg Harvest product per kg nutrient applied)	PFP = Y/F or PFP = (Yo/F)+ AE	More important for farmers because it integrates the use efficiency of both indigenous and applied nutrients. High indigenous soil nutrient supply (Yo) and high AE are equally important for PFP.
NE = Nutrient export of a plant nutrient in a plant (plant part or total plant)	NE = Y*C	Calculates the quantity of nutrient exported in the part of interest, with same level of nutrition in all treatments (through fertilizers and/or environment) Evaluates how much nutrients are indeed recovered into the part of interest.

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Other indices or methods not listed in Table 1 and officially recognized by scientific community (peer review publications) could be used to justify the claim Nutrients Use Efficiency.

6 Specifications for the performance of the trials

6.1 General specifications

6.1.1 Control

Control is defined in Technical Specification CEN/TS 17700-1.

The different treatments in the test should be:

• Controls: substrate/soil with or without fertilizer,

• Treatments: substrate/soil with or without fertilizer + Plant Biostimulants.

The same substrate/soil should be used in each treatment and in case of field trials a characterization of the substrate/soil should be done.

6.1.2 Under controlled conditions

In the case that certain parameters or technical operations cannot be implemented in the open field, the conduction of the respective trials to prove the Plant Biostimulants claims should take place under controlled conditions.

EXAMPLE to have a measure of the total nutrient content in the substrate

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