

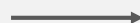
Overview of the CE-Marking Process for Plant Biostimulants Under the EU Fertilizer Products Regulation

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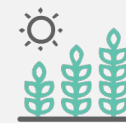
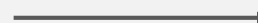




BIOSTIMULANTS
optimize natural
processes in plants



This results in



Improved plant
establishment
& vigor



Enhanced
uptake of
nutrients



Improved plant
tolerance to
abiotic stresses

Acadian Plant Health At A Glance

40 years of
experience
founded in 1981

Acadian products are used in
soil & foliar inputs on:



70+ crops



80 countries
worldwide



400
employees
worldwide



5 manufacturing and
production facilities
focused around key
harvesting areas,
including Canada,
Scotland and Ireland.



Sustainable processing
– harvesting and
extracting

Research & Development

40 years of R&D to be the
leader in biostimulants



CANADA

For R&D we have the Dr.
James Craigie R&D Centre,
Cornwallis, Canada 30,000 ft²
(2,790 m²) facility comprised
of laboratories, greenhouses
and experimental field trials



UNITED KINGDOM

The Formulation Centre of
Excellence, Malvern, UK which
expands on existing formulation
capabilities to support new business
growth, including novel and
proprietary formulations for global
business partners.

ORGANICALLY CERTIFIED



RESEARCH

We have a highly skilled
team of research scientists
for Proof-of-Concept
screening and Mode of
Action validation



DEVELOPMENT

A team of Technical
Managers dedicated to
Global Field
Development



FORMULATION

Formulation scientists located in
Canada & Europe for
formulation development
alliance with local experts



REGISTRATION

We have a team of
scientists supporting
global registration
along with dedicated
IP focus

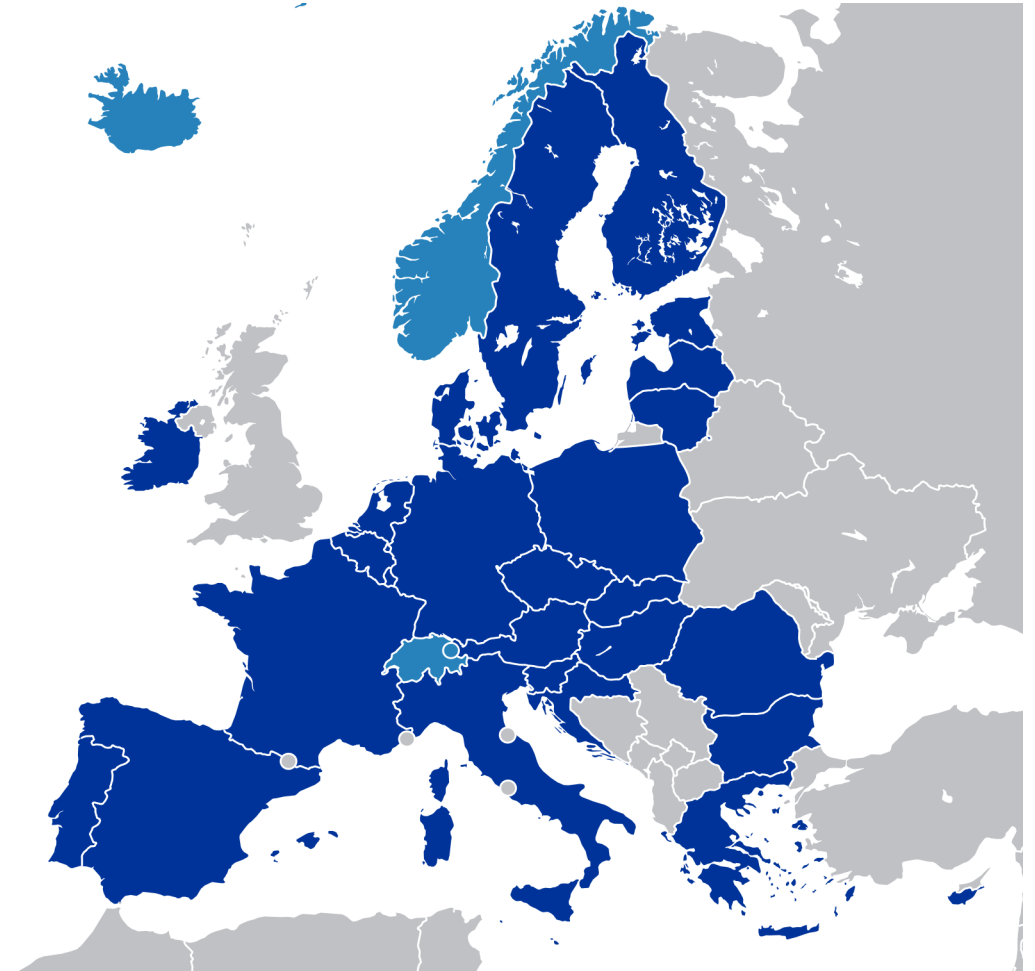
MEMBER OF:





The EU Fertilizing Products Regulation (FPR) 2019/1009

- Replaces the EC 2003 Regulation for Fertilizers
- Adopted on 25 June 2019
- Entered Into Force on 16 July 2022
- ✓ **Optional harmonization:** manufacturers can choose EU wide FPR or National rules
- ✓ Regulates **placement on the market** (not use)
- ✓ **Leads to CE-marking:** free movement in the EU single market
- ✓ Valid for up to 5 years (product changes must be reported)





What Products are Covered By The New FPR Regulation?



An EU fertilising product:

- * meets the requirements for a **PRODUCT FUNCTION CATEGORY**
- * meets the requirement for a **COMPONENT MATERIAL CATEGORY** or categories
- * is **LABELLED** according to the requirements in FPR
- * passes the **CONFORMITY ASSESSMENT PROCEDURE**

Product Function Categories (PFC)

- PCF 1: Fertiliser
- PCF 2: Liming material
- PCF 3: Soil improver
- PCF 4: Growing medium
- PCF 5: Inhibitor
- **PFC 6: Plant biostimulant**
- PCF 7: Fertilizing product blends

Component Material Categories (CMCs) most relevant for Plant Biostimulants:

- CMC 1: Virgin material substances and mixtures
- CMC 2: Plants, plant parts or plant extracts
- CMC 6: Food industry by-products
- CMC 7: Micro-organisms
- CMC 10: Animal by-products
- CMC 11: Industrial by-products
- CMC 12: Strubias (Struvite, biochar, and ashes)





Product Function Category 6: Plant Biostimulants

“Plant biostimulant means a product **stimulating plant nutrition processes** independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

- **nutrient use efficiency;**
- **tolerance to abiotic stress;**
- **quality traits;**
- **availability of confined nutrients in soil or rhizosphere.”**

Regulation (EU) 2019/1009, Annex I, Part II. <http://data.europa.eu/eli/reg/2019/1009/oj>

PFC 6 (A): Microbial plant biostimulants

Microorganism or consortium of microorganisms as referred to in CMC 7

PFC 6 (B): Non-microbial plant biostimulant

Substances and materials derived from the other CMC categories





How Are Fertilizing Products Evaluated for CE-Marking?

- The FPR creates a pathway for many new novel types of fertilizing materials to gain access to the EU Market
- Some of the PFC categories under the FPR can be self-certified; there is no need to engage with a Regulatory Authority or Notifying Body prior to going to market
- Notifying Bodies are organizations designated by EU Member States to conduct conformity assessment and provide certificates authorizing CE Marking
- PFC 6 (Plant Biostimulants) DO require review by a Notifying Body to evaluate the composition, safety and efficacy data of the product
- For PB's, there are two possible types of Reviews
 - Module B + C – Reviews individual product dossiers to check for compliance
 - Module D1 – “ISO type” site assessment of a company's quality management systems

10 Notified Bodies Are Accredited for Conformity Assessment of PBs

- [Cer Trust kft.](#), notified by Hungary. Both Module B+C and Module D1 CA for PFC 6 PBs.
- [POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.](#), notified by Poland. Both Module B+C and Module D1 CA for PFC 6 PBs.
- [Kiwa VERIN B.V.](#), notified by the Netherlands. Only for Module D1 for PFC 6 PBs (not Module B+C) .
- [EFCI Register](#), notified by the Netherlands. Only Module B+C for PFC 6 PBs (not Module D1).
- [TUV AUSTRIA HELLAS LTD](#), notified by Greece. Both Module B+C and Module D1 CA for PFC 6 PBs.
- [Eurofins Certification](#), notified by France. Both Module B+C and Module D1 CA for PFC 6 PBs.
- [AGES](#), notified by Austria. Only Module B+C for PFC 6 PBs (not Module D1).
- [CAAEE](#), notified by Spain. Both Module B+C and Module D1 CA for PFC 6 PBs.
- [LATSERT](#), notified by Latvia. Only Module B+C for PFC 6 PBs (not Module D1).
- [NEVEX Institute](#), notified by Hungary. Only Module B+C for PFC 6 PBs (not Module D1).

- Source: EU Commission NANDO Database, 25-Mar-2024



Under FPR Regulations PBs Must Meet Technical Standards

- WG1 Sampling
- WG2 Claims
- WG3 Pathogenic and non-pathogenic microorganisms
- WG4 Other safety parameters
- WG5 Labelling and denominations

- FPR CEN/TS 1770-1: General principles
- FPR CEN/TS 1770-2: Nutrient use efficiency
- FPR CEN/TS 1770-3: Tolerance to abiotic stress
- FPR CEN/TS 1770-4: Determination of quality traits
- FPR CEN/TS 1770-5: Availability of confined nutrients

- ✓ 33 Technical specifications published by CEN/TC 455 in March 2022
- ✓ Purchase through the national standardization bodies of CEN members
- ✓ Now being transformed into European Harmonized Standards (end of 2024)





General Requirements for the Demonstration of Efficacy

Table 1 — Crop groupings

Broadacre: Combinable and Processing Products	Woody Perennials	Vegetables, ornamental and AMP ^a crops
BARLEY	ALMOND	ANGELICA
BEAN	APPLE	ANISE
BEEF	APRICOT	ASPARAGUS
BORAGE	AVOCADO	AUBERGINE
BUCKWHEAT	BAY	BALM
CHICKPEA	BILBERRY	BANANA
CLOVER	BLACK CURRANT	BASIL
COTTON	BLACKBERRY	BROCCOLI and CALABRESE
DURUM WHEAT	BLUEBERRY	BRUSSELS SPROUT
EVENING PRIMROSE	CAPERS	BULB ONION
GRASSLAND	CHERIMOYA	CABBAGE
HEMP	CHERRY	CARDOON
LENTIL	CHESTNUT	CARROT
LINSEED	CITRUS FRUITS	CAULIFLOWER
LUCERNE	COCOA TREE	CELERIAC
LUPIN	COFFEE TREE	CELERY
MAIZE	CRANBERRY	CELERY LEAVES (Caraway and Salad Burnet)
MUSTARD (for seed)	CURRY LEAVES	CHERVIL
OAT	DATE	CHICORY (Witloof)
PEA	ELDERBERRY	CHILLI

Table 2 — Minimum number of trials carried out with plant based on the claim to be justified

Claim that may credibly be made on this basis	Minimum number of trials
Effect claimed for <u>a specific crop</u>	3 trials on the crop Claim is successfully demonstrated on the crop chosen during the same year or different years.
Effect claimed for <u>the entire crop group</u>	6 trials with minimum of 2 different crops Claim is successfully demonstrated on two crops chosen during the same year or different years. When the claim is demonstrated for two crops within a group, this is regarded as valid for the entire crop group
Effect claimed for <u>two entire crop groups</u> later	8 trials in total from 2 different groups = 4 trials per group (with min of 2 different crops per group) Claim is successfully demonstrated on crops chosen during the same year or different year.
Effect claimed <u>without being required to limit it to any specific crop grouping</u>	9 trials in total from 3 different groups = 3 trials per group (with min of 2 different crops per group) Claim is successfully demonstrated on crops chosen during the same year or different years.

- Under controlled conditions (meaning that the environment parameters are controlled), a minimum confidence level of 90 % (P-value < 0,1) has to be applied in comparison to untreated (non-plant biostimulant) treatment groups.
- Under Field and/or protected crop conditions, a minimum confidence level of 85 % (P-value < 0,15) shall be applied in comparison to untreated (non-plant biostimulant) treatment groups.

Full Details available in CEN/TS 17700-1:2023 - Plant biostimulants - Claims - Part 1: General principles



Acadian's CE Mark Biostimulant Label For Asco Extract


EU type examination certificate

STICHTING EFCI Register, appointed Notified Body FFR 2019/1009, registered under NANDO number 2832, registered with the Dutch Chamber of Commerce under number 72523665, statutory address Kruisplein 328, 3012CC, Rotterdam, Netherlands, hereinafter: EFCI.

-- The following product has been assessed according to the FFR 2019/1009 using the relevant FFR guidelines and the applicable (harmonized) standards and meets all applicable essential safety requirements as documented in the FFR 2019/1009. Assessment was done in accordance with Annex 1 of this certificate. --

Product	APH-1011-01
Manufacturer	Acadian Seaplants Ltd
Manufacturer address	30 Drown Avenue, B3B 1X8, Dartmouth, Canada
Certification module	B
Examination scope	Full product Assessment of the adequacy of technical design dossiers
PFC	6. Plant biostimulant (Non-microbial plant biostimulant)

Contained material: CMC1: CMC 1

PFC 6 Claims: See claims in Annex 1

Specifications: APH-1011-01 is the internal product code.

Certificate number & issue date: EFCI Register - FFR 2019/1009 - B-APH-1011-01-25/09/2023-25/09/2023

Certificate expires on: 25/09/2028

On behalf of stichting EFCI Register: G.M.C. Tebbelou, Chairman Mrs M.L. Lagemaat, secretary

signature:  

EliteSea™

PFC 6 (B) Bioestimulante de planta no microbiano

Bioestimulante de planta a base de extracto de alga (*Ascophyllum nodosum*)

SAMPLE ONLY

INGREDIENTES:
Extracto *Ascophyllum nodosum*
(CMC 1: Sustancias y mezclas de materiales vírgenes)

Contiene 1,2-benzisothiazol-3(2H)-one (2634-33-5).
Puede provocar una reacción alérgica.
Puede solicitarse la ficha de datos de seguridad.

El producto ha sido certificado por el registro EFCI (NANDO 2832)

Número de lote:
Fecha de fabricación:
Validez del producto: 3 años.



Producto apto para su uso en Agricultura Ecológica conforme al Reglamento (UE) No. 2018/848 y al Reglamento (UE) No. 2021/1165. Inspeccionado por ECOCERT SA F - 32600

Fabricado por:
Acadian Seaplants Limited
30 Avenida Brown
Dartmouth Nueva Escocia
Canadá, B3B 1X8
Tel: +1 902 468 2840, Fax: +1 902 468 3474
PRODUCTO DE CANADÁ

Importado y distribuido por:

Enjuague energicamente tres veces cada envase que utilice, vertiendo el agua de lavado al depósito (del pulverizador).
Deposite los residuos de envases en los puntos de recogida establecidos por los sistemas de responsabilidad ampliada del productor SIGFITO.

TM = Trademark
ES_PL32370-L_0224

Contenido neto: **5L**

Peso neto: **5,8Kg**

CE

Conclusion? CE-Marked Biostimulants Are Here to Stay!

- The EU FPR is a defining movement for plant biostimulants, however it has flaws
 - Microbial biostimulants are severely restricted (only four strains approved)
 - Products derived from animal byproducts (protein hydrolysates) are prohibited
 - REACH + requirements cause issues with co-formulants used at low levels
- The Conformity Assessment Process was quite positive and a collaborative process
 - The process is relatively quick (a few months) and reasonably priced (2500E)
 - Dossiers can be amended to address identified deficiencies, no strict deadlines
 - Once certified, formulations can be licensed to distributors via a letter of access
- The market is becoming educated on the value of CE marked fertilizing products
- Efforts focusing on integrating PB's into policies on food sustainability and security

Thank you

