



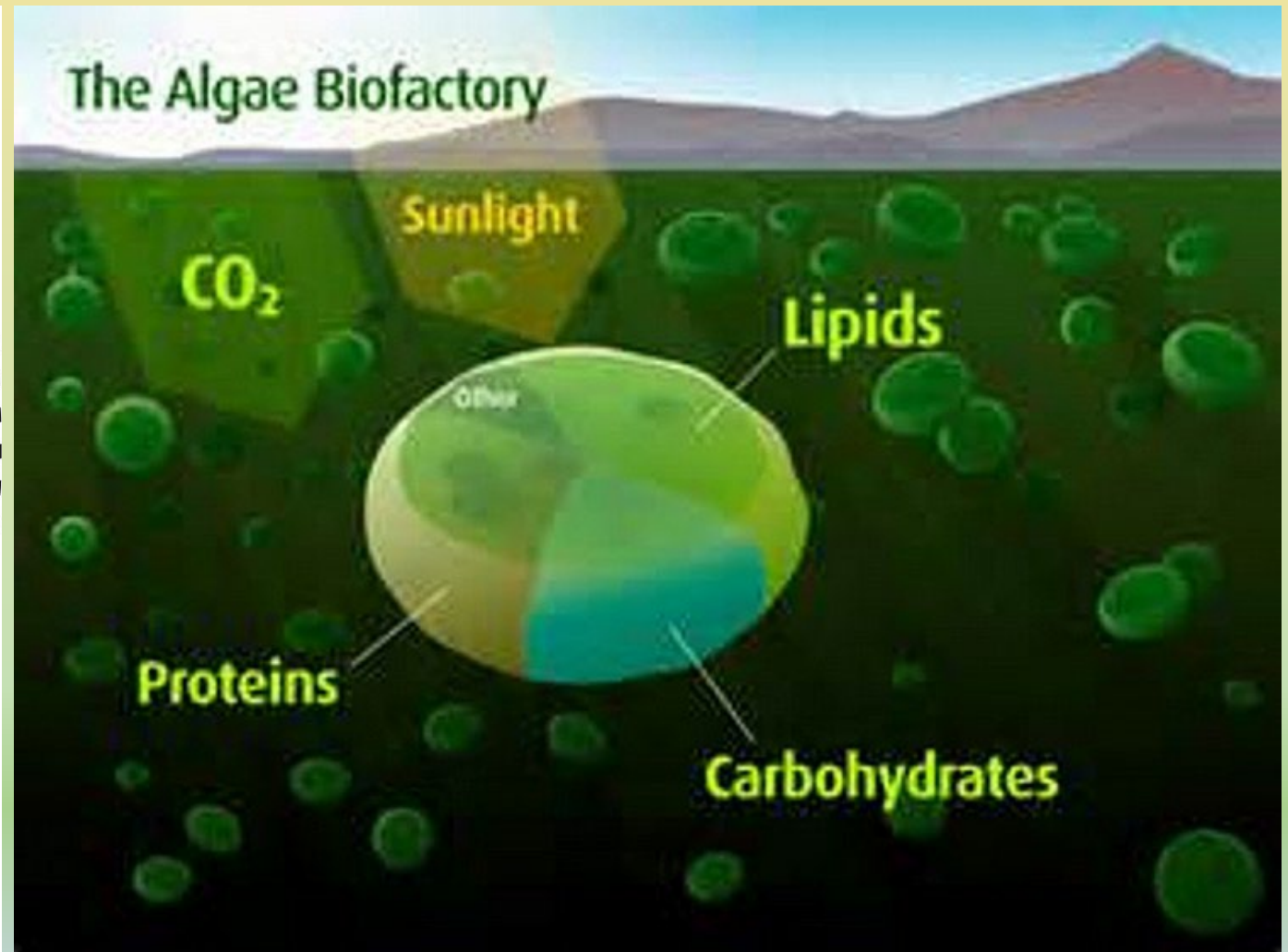
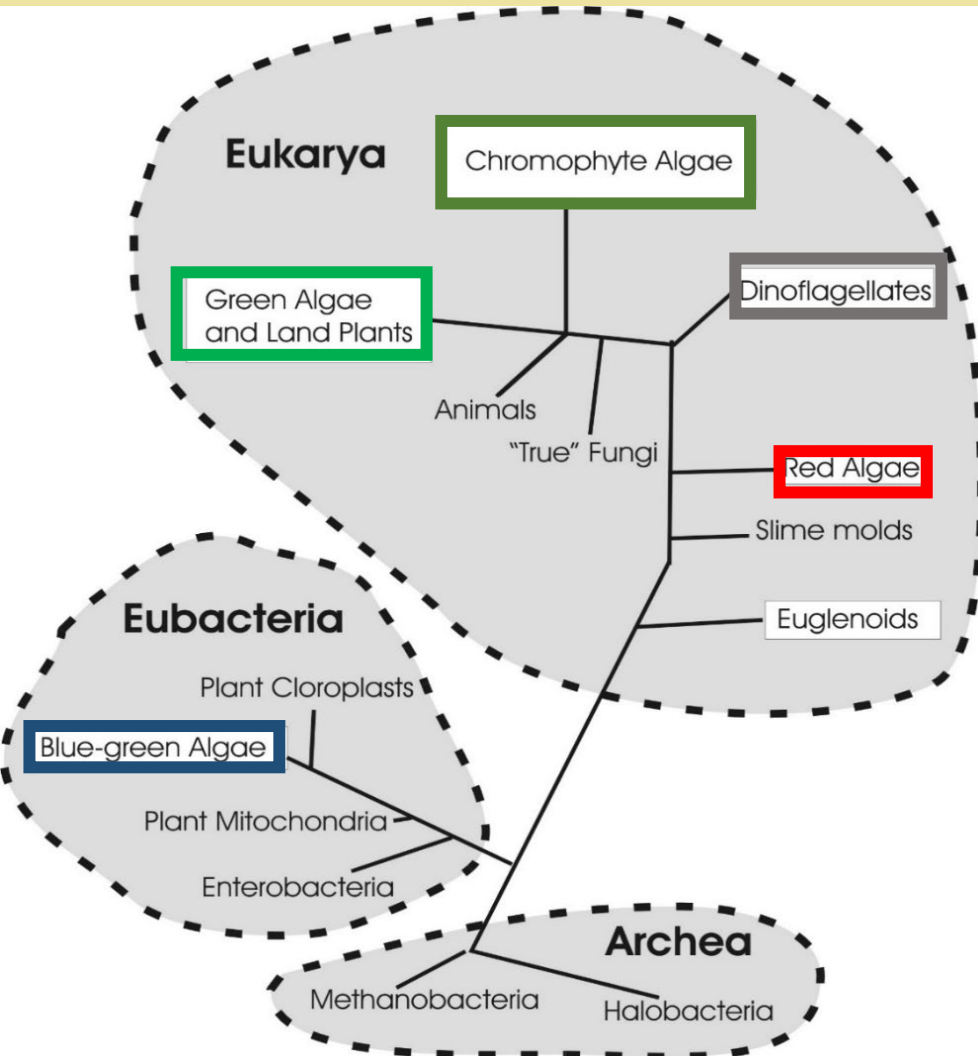
BioRural Knowledge-exchange Workshop:
Advancing the European Rural Bioeconomy
Aquatic systems

EU regulation and standardisation for the algal sector

Foreword

Distinguish taxonomy and functional classification

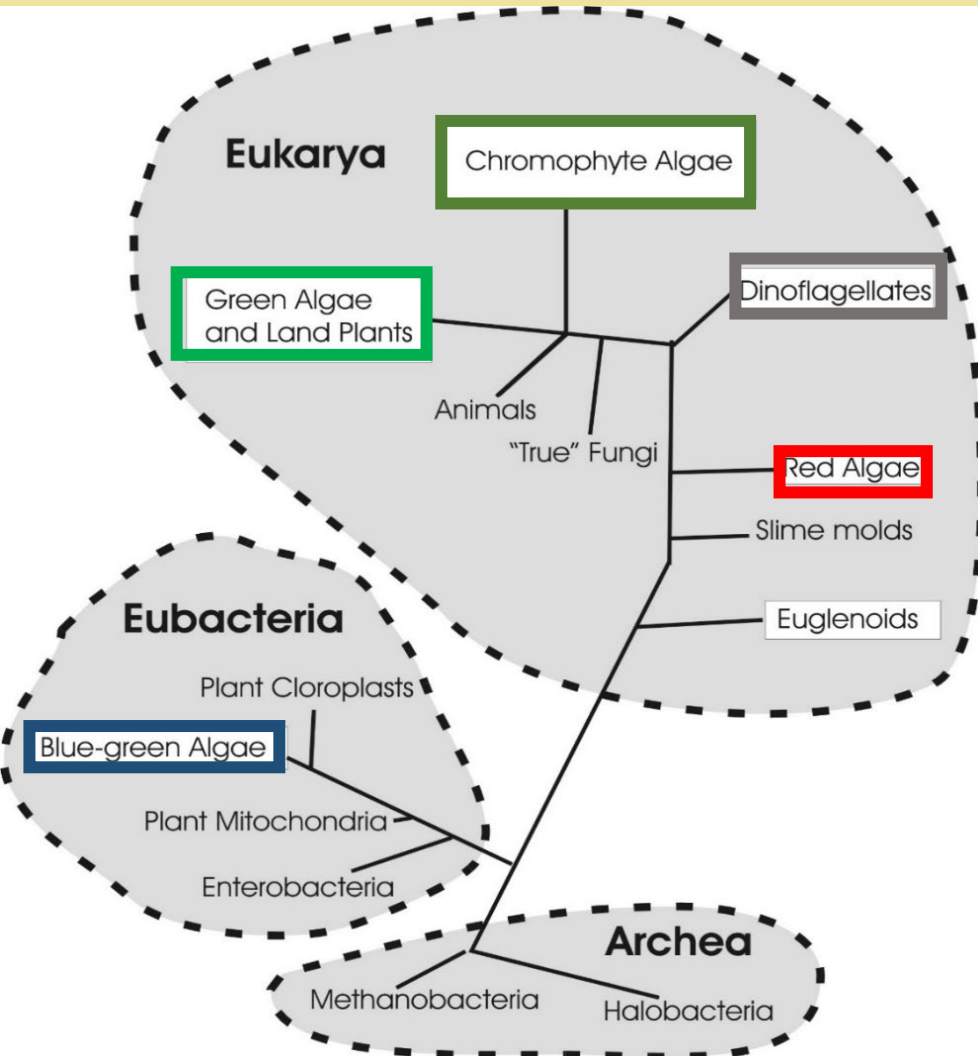
Classification
Regulation
Standardisation
Conclusions



Foreword

Distinguish taxonomy and functional classification

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CEN TC454: "algae are regarded as a functional group of organisms consisting of microalgae, macroalgae, cyanobacteria and Labyrinthulomycetes"

Algae: laws and technical norms

- Regulatory, scientific, commercial and product classification
- Algae in European Regulations
- Technical Standards for algae
- Conclusions

Product classification : NC 1212 21, 1212 29

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CUSTOMS CLASSIFICATION

Section II "vegetable products"	Chapter 12 "oil seeds and oleaginous fruits; miscellaneous grains, seeds and fruit; industrial or medicinal plants; straw and fodder"	Heading 1212 "Locust beans, seaweeds and other algae, sugar beet and sugar cane, fresh, chilled, frozen or dried, whether or not ground; fruit stones and kernels and other vegetable products (including unroasted chicory roots of the variety <i>Cichorium intybus sativum</i>) of a kind used primarily for human consumption, not elsewhere specified or included"	Subheading 1212 21 Seaweeds and other algae: Fit for human consumption	Subheading 1212 29 Seaweeds and other algae: Other
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Customs tariff TARIC is an integral part of the Harmonized System which came into force in 1988, introducing a standardized international system that allows all types of goods and tariffs to be classified [1].

Statistics classification: NACE A 03 21, A 03 22 ; ATECO 2025 (*) A 03 21 01, A03 22 01, C 10 20 01 The Eurostat [2] and Istat codes place the activities in the agriculture, aquaculture and fishing sectors, cultivation of algae in fresh and marine waters; the transformation of biomass into derivatives is an industrial activity (* Italy)

Affinare la ricerca

Per parola chiave

Nel titolo Nel testo

Per anno del documento

2023 (21)
2022 (146)
2021 (163)

Criteri di ricerca

Cerca: algh, Lingua della ricerca: Italiano

Salvare ne "Le mie ricerche" Crea in "I miei avvisi" (Feeds RSS) Salvare ne "I miei elementi"

Risultati 1 - 10 di 2454

Ordinare per

Rilevanza

Cancellare la selezione Modificare le informazioni visualizzate Esportare

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Algae farming has no specific legislation but occurs in 2454 EU acts

- Algae are aquatic organisms (Reg. 708/2007 EU)
«...any species living in water belonging to the animalia, plantae and protista kingdoms...»
- Algae farming is part of aquaculture (Reg. 1379/2013 EU Annex1)
«'aquaculture products' mean aquatic organisms at any stage of their life cycle resulting from any aquaculture activity»
- Algae products bear origin declaration obligation (Reg. 1379)
« ... may be offered for sale to the final consumer ... only if appropriate marking or labelling indicates ...the area where the product was caught or farmed »

Algae farming has no specific legislation **(fortunately)** but occurs in 2454 EU acts

- Algae are not **(yet? ...)** included in ANNEX I of EU Reg. 1151/2012 «Quality regimes for agricultural and food products» (PDO, PGI).
Consumers increasingly demand «Transparency»: agricultural or food products with specific identifiable characteristics, in particular those linked to their geographical origin.
- Algae may be «Organic» (Reg. 848/2018 EU)
 - i) Possibility of EU Organic certification
 - ii) Italy (AISAM) contributed to Reg 1165/2021 amendment
 - iii) as of 31/12/2025 the "Substantial Equivalence" of Organic certification according former Reg 834/2007 shall terminate
- Algae are under Novel Foods (Reg 2283/2015)
Marketing authorization mandatory, see below
- Algae are included in Fertilising Products Regulation (FPR, Reg. 1009/2019 EU)
but cyanobacteria currently **excluded** (*Spirulina based biostimulants!*)



ALGAE AND NOVEL FOODS

- 10 categories of novel foods
 - "... (vi) foods consisting of, isolated or produced from cell or tissue cultures derived from animals, plants, microorganisms, fungi or **algae** "
 - Biomass as such (bulk, powder, frozen paste, tablets, ...)
 - Algae extracts
 - Protein concentrates
- Not Novel Foods:
 - Food Enzymes
 - Additives
 - Flavourings
 - Extraction solvents
 - GMOs (genetically modified organisms)

Is my algal product Novel Food?

The responsibility for the decision lies with the Food Business Operator (FBO)

History of consumption before 1997 May 15 ?

Consumption outside EU (exotic food)?

Novel manufacturing process?

Which is the final product?

What is the intended use?

Novel food catalogue (EC website)
Novel food consultations (EC website)
Union list of novel foods (Commission Implementing Regulation (EU) 2017/2470)
Ongoing applications (EFSA open)
National lists (France, Italy, Belgium)

Example: "fortified" products

Some considerations on the NF

- NF authorization is "product-specific" (not alga-specific and no longer Company-specific)
- The scientific data supporting the application must not be used for the benefit of competition within five years from the date of authorization of the novel food without the consent of the initial applicant
- Before "applying" it is advisable to follow the Consultation procedure with your MS (Art.4).
- See also decision tree in CEN/TR 17559:2022 [3]

Some considerations on the NF

Food Safety

Home Food Animals Plants Horizontal topics

Home > Food > Novel Food > Consultation process on novel food status

Consultation process on novel food status

Name and description of the food concerned	Date of publication	Statement on the food concerned	Reasons justifying the statement	Where the food is novel, the most appropriate food category under which it falls in accordance with Article 3(2) of Regulation (EU) 2015/2283
A plant protein concentrate that is fermented with the mycelium of shiitake (<i>Lentinus edodes</i>).	25 February 2019	Novel when used as or in foods.	View document { EN *** }	Category 3(2) (a)(ii)
<i>Agaricus blazei</i> dehydrated mycelium powder	29 October 2019	Novel when used as or in foods.	View document { EN *** }	Category 3(2) (a)(ii)

Consultation request for the determination of the novel food status ARTICLE 4 of Regulation (EU) 2015/2283

Consultation request to determine the novel food status of the *Chlorella sp.* (*Auxenochlorella protothecoides*, *Auxenochlorella pyrenoidosa*, *Chlorella sorokiniana*, *Chlorella vulgaris*, *Jaagichlorella luteoviridis*, *Parachlorella kessleri*)

Recipient Member State: Czech Republic, Ministry of Agriculture, Food Safety Department

Date: 04/03/2022

Name and description of the novel food:

Chlorella sp. consists one or more species from this list of the species: *Auxenochlorella protothecoides*, *Auxenochlorella pyrenoidosa*, *Chlorella sorokiniana*, *Chlorella vulgaris*, *Jaagichlorella luteoviridis*, *Parachlorella kessleri*

Dried biomass of unicellular microscopic freshwater algae of the genus *Chlorella*, referred to as *Chlorella sp.* or *Chlorella*, obtained by cultivation in an autotrophic (with the presence of light), heterotrophic (without the presence of light in fermenters) or mixotrophic combination of the two previous modes) mode. The dried biomass is in the form of a fine powder which is used as a food supplement in form of capsules, tablets etc. or lyophilized *Chlorella* extract. The dried biomass can be used as a food material in food industry (as a food component), e.g. in bakery products, pasta, beverages. The food does not contain nanomaterials.

- See also decision tree in CEN/TR 17559:2022 [5]

NF Consultation

- Ask to the competent office of the Member State where you intend to place the product on the market according to Application Regulation 2018/456

Prepare mini-dossier (history of use, manufacturing process, specifications)

Submit to MS

MS evaluation* (ca. 4 months)

Outcome of the consultation published in EC website

Algae NF Regulatory : identification and nomenclature

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- "Typing" errors in the Novel Foods Catalog (NFC) ("Chlorella pyrenoidosa... the composition is quite similar to the other macroalgae")
- Chlorella case: not identified species, renamed, disappeared, etc.
- "Scientific" errors: *Odontella aurita* case, approved diatom (France) "because similar to other seaweed food"
- "Hystorical" errors: *Aphanizomenon Flos Aquae* case
- Union List: algae with molecular identification (*Tetraselmis chui*: "identified by means of nuclear marker rDNA 18 S (sequence analysed no less than 1 600 base pairs) in the National Centre for Biotechnology information (NCBI) database: Not less than 99,9 %), **and** algae without identification (*Euglena gracilis*)
- Microalgae (most relevant for market: omega-3 sources) which are not algae (according Academy ...) (*Schizochytrium*)
- ...

Standards

- What standards are
- The CEN/TC 454 and Codex
- Algae standards
- Coming soon



What is a standard?

- ▶ A document for a **common** and **repeated** use
- ▶ Produced by all **interested parties** through **a transparent, open and consensus-based process**
- ▶ A tool to underpin legislation
- ▶ **Voluntary** in use
- ▶ Automatically **transposed** into **national standards** and therefore **conflicting national standards** are to be **withdrawn**
- ▶ Integrated with **international** standardization work



Standards: official EU and from private sectors

- Algae Standards (Annex 2): support for regulations
- e.g. EHPM [] Quality Guide - Promoting Best Practice: see botanicals



CODEX ALIMENTARIUS

- Global food standards, guidelines and practice codes from FAO and WHO, since 1963
- Public domain documents, open, transparent and inclusive
- Recognized by many Jurisdictions and WTO's SPS (Sanitary and PhytoSanitary Agreement)
- Liaisons with CEN / ISO
- Comparison with "industrial" (private) "standards"
- Algae as NEW FOODS
- Other new foods: Insects, vegetable proteins, cultivated meat and seafood, fermentation-derived, 3-D printed

TAKE HOME MESSAGES

- Algae are well regulated and standardized! Let's go!
- General regulatory landscape is the same of other crops
- Food law applies to algae as well (contaminants, NF, etc)
- Algae specific rules should be sought only when necessary
- All regulatory constraints came when Algae were **missing** !
- Algae standards are available [4]
- Look at EU Algae Initiative COM/2022/592 [5]
- EABA [6] and national Associations (AISAM) [7] have Working Groups
- See also Annex 1

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ALGAE AND FOOD SUPPLEMENTS

Classification
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- “botanical”: plant material, including whole, fragmented or cut plants, plant parts, plant products (such as exudates), algae, fungi and lichens
- EHPM (European Health Products Manufacturers) botanical suppliers' questionnaire [8]
a guideline to assist suppliers and manufacturers in meeting plant raw material requirements for supplements.

Notes for microalgae



ALGAE AND FOOD SUPPLEMENTS

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ANNEX VIII - EHPM BOTANICAL SUPPLIERS' QUESTIONNAIRE

- Name: genus, species, (strain)
- Farming place (biomass origin)
- Microcystins
- Identification: morfological + molecular
- GACP : Good Agricultural and Collection Practice - lot file

1.1.1 - Scientific name (Latin name, family, genus).

Variety and chemotype, where necessary:

Common (vernacular) name:

Mycotoxins

(e.g. Aflatoxins B1, B2, G1, G2, Ochratoxin A)

4.1.2 - Identity (TLC, HPLC, ...)
Specify the analyses performed

Thank you!
Questions?



Annex 1

Background

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- Only algae products regulatory is dealt with here
- Environmental regulation (soil, water, air): Agriculture, Industry and/or both
- Regulation about input flows (mass, energy): generally not “Algae-specific” but:
 1. CO₂: food grade CO₂ is regulated only as additive (E290) or solvent, not as “Nutrient”
 2. Safety in algae facilities
 3. ... many other topics ... (permits, GMOs, ...)

- A. Total Infrastructure (Hectare)
- B. Total Energy Input (kWh/yr)
- C. Total Consumables Input (kg/yr)
- D. Total Required Labor (FTEs)
- E. Water Input (Liters/yr)
- F. Total Nutrient Input (kg/yr)
- G. Carbon Input (kg/yr)

‘Green Box’ Provides a Technical, Economic, & Environmental Boundary
-
Accounting for an Algae Operation’s Total Yearly Inputs & Outputs

- H. Algal Constituent Products (kg/yr)
e.g. Dry algal biomass, protein, oil etc.
- I. Indirect Algal Products (kg/yr)
e.g. Ethanol, butanol, fish etc.
- J. Un-captured Gas Emissions (kg/yr)
e.g. CO₂, NO_x, H₂O, Hydrocarbons etc.
- K. Liquid Waste Output (Liters/yr)
e.g. Saline or biologic discharge etc.
- L. Solid Waste Output (kg/yr)
e.g. Organics, salts, airborne dust etc.

Annex 2/1 CEN/TC454 Algae standards

- Terms and definitions: EN 17399 published in 2020, under revision for 2nd ed.
- Strain identification: EN 17477 published in 2021
- Productivity of algae growth sites: EN 17480 published in 2021
- Technical Reports: algae applications CEN/TRs
 - Food and feed - overview of limits, procedures and analytical methods - TR17559
 - Cosmetic applications - specifications - TR17611
 - Pharmaceutical applications - specifications - TR17612
 - Chemicals and biofuels applications - specifications - TR17739

- Analytical methods:
 - Total lipids (Ryckebosch)
 - Proteins (Kjeldahl, CHN)
 - Carbohydrates (for seaweeds)
 - Chlorophyll (HPLC)
 - Fatty acids (GC)
 - Amino Acids (HPLC)
 - Carotenoids (HPLC)
 - Phycocyanins (SF)
- Coming soon:
 - Standard on measurements for renewable algal raw material for energy and non-energy applications
 - Standard on sampling

REFERENCES

- [1] https://en.wikipedia.org/wiki/Harmonized_System
- [2] <https://ec.europa.eu/eurostat/web/nace/overview>
- [3] CEN/TR 17559:2022 Algae and algae products - Food and feed applications: General overview of limits, procedures and analytical methods
- [4] <https://standards.iteh.ai/catalog/standards/cen>
Standards can be purchased online or from NSB stores (National Standardisation Bodies, e.g. UNI, DIN, AFNOR, BSI etc)
- [5] <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM%3A2022%3A592%3AFIN>
- [6] <https://www.eaba-association.org/en>
- [7] <https://www.aisam-microalghe.it/>
- [8] <https://ehpm.org/>

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