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Alge in izdelki iz alg - Uporaba hrane in krme: Splošni pregled omejitev, postopkov in analitskih metod

Algae and algae products - Food and feed applications: General overview of limits, procedures and analytical methods

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Algae and algae products - Food and feed applications: General overview of limits, procedures and analytical methods

This draft Technical Report is submitted to CEN members for Vote. It has been drawn up by the Technical Committee CEN/TC 454.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (FprCEN/TR 17559:2020) has been prepared by Technical Committee CEN/TC 454 “Algae and algae products”, the secretariat of which is held by NEN.

This document is currently submitted to the vote.

Introduction

This document has been prepared by the experts of CEN/TC 454 'Algae and algae products'.

The European Committee for Standardization (CEN) was requested by the European Commission (EC) to draft European standards or European standardization deliverables to support the implementation of Article 3 of Directive 2009/28/EC for algae and algae-based products or intermediates.

This request, presented as Mandate M/547[1], also contributes to the Communication on “Innovating for Sustainable Growth: A Bio economy for Europe”.

The former working group CEN Technical Board Working Group 218 “Algae”, was created in 2016 to develop a work programme as part of this Mandate. The technical committee CEN/TC 454 'Algae and algae products' was established to carry out the work programme that will prepare a series of standards.

The interest in algae and algae-based products or intermediates has increased significantly in Europe as a valuable source including but not limited to, carbohydrates, proteins, lipids, and several pigments. These materials are suitable for use in a wide range of applications from food and feed purposes to other sectors, such as textile, cosmetics, biopolymers, biofuel and fertilizer/biostimulants. Standardization was identified as having an important role in order to promote the use of algae and algae products.

The work of CEN/TC 454 should improve the reliability of the supply chain, thereby improving the confidence of industry and consumers in algae, which include macroalgae, microalgae, cyanobacteria, Labyrinthulomycetes, algae-based products or intermediates and will promote and support commercialisation of the European algae industry.

This document has been prepared in close collaboration with the CEN/TC 454 working groups. The European standards and technical reports developed in this mandate include:

CEN/TC 454/WG 1 Terminology

- EN 17399 'Algae and algae products – Terms and Definitions'

CEN/TC 454/WG 2 Identification

- EN xxx 'Algae and algae products – Identification'

CEN/TC 454/WG 3 Productivity

- EN xxx 'Algae and algae products - Determination of productivity'

CEN/TC 454/WG 5 Specifications for non-food/feed sector applications

- CEN/TR 17611 – Specifications for cosmetics applications

- CEN/TR xxx – Specifications for chemical and biofuel applications

- CEN/TR 17612 – Specifications for pharmaceutical applications

CEN/TC 454/WG 6 Product test methods

- EN xxx 'Algae and algae products - Determination of total lipids - Ryckebosch Foubert method'

- EN 17605 'Algae and algae products - Sample treatment'

- EN xxx' Algae and algae products – Chlorophyll'

The available EU directives and other ISO and CEN standards which are of relevance for algae and algae products for food and feed applications are listed in the bibliography.

[1] http://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=refSearch.search

1 Scope

This document describes product specifications, product characteristics and other relevant information for algae and algae products for food, nutraceutical and animal feed applications. This document is a general overview of available limits, procedures and analytical methods applicable to algae and algae products used for food and feed applications.

This document does not apply to pharmaceutical, cosmetics, fertilizer/biostimulants, chemical and biofuel applications.

2 Normative references

EN 17399, Algae and algae products - Terms and definitions.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 17399 and the following apply:

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
algae and algae products
functional group of organisms consisting of microalgae, macroalgae, cyanobacteria, Labyrinthulomycetes and products derived thereof

Note 1 to entry: examples of products are biomass, extracts or derivatives from algae, including a.o. algal oil and algal powder.

4 Product specifications

4.1 General

The interest in algae and algae products has increased significantly in Europe as a source of carbohydrates, proteins, lipids, minerals, several pigments etc. These materials are suitable for use in a wide range of applications for food and feed purposes and to other sectors, such as textile, cosmetics, biopolymers, biofuel and fertilizers and biostimulants.

Depending on the application different information on product characteristics (Clause 5) are required as product specification by the applicable regulation.

4.2 Food

All algae and algae products intended for food or food ingredients are accompanied by basic information on the product in line with applicable EU regulation for food labelling as well as specific directives from some EU countries. Some are mandatory and other optional and are dependent on the target market. These product specifications for food contain information that includes but is not limited to [21]:

- energy
- content of fat, saturates, carbohydrate, sugars, protein, and salt (sodium)
- other nutrients (e.g. vitamins, minerals, fibre, polyols) [26]

- total sulphites
- moisture
- ingredients and presence of allergens
- shelf-life, including requirements for storage and shipping
- contaminants as defined as critical in the risk assessment of the food safety management system (e.g. heavy metals)

4.3 Feed

All algae and algae products intended for feed or feed ingredients are be accompanied by basic information on the product. These product specification for feed contain information, where applicable, that includes but is not limited to [44]:

- type of feed and intended use
- energy
- crude protein
- crude oils and fats
- crude fibre
- crude ash
- amino acids (lysine and methionine)
- minerals (calcium, sodium, phosphorus, magnesium)
- moisture
- feed additives
- minimum storage life
- contaminants as defined as critical in the risk assessment of the feed safety management system (e.g. heavy metals)

4.4 Type of product specification documents

4.4.1 General

Different product specification documents with information on algae and algae products should be used by organisations. These documents are not mandatory and are used for information exchange.

4.4.2 Technical Data Sheet (TDS)

The technical data sheet is a technical document containing the technical parameters adopted to characterize the product and therefore being the equivalent of the Certificate of Analysis (4.3.2). The TDS includes the typical ranges of different parameters used to define the product characteristics or applicable regulatory limits. Examples of a TDS for some algae are attached as Annex A.

4.4.3 Certificate of Analysis (CoA)

The certificate of analysis is a document issued by the organization based on actual laboratory results to report test results of the sample. It includes references to the analytical method and quality standard(s) used. It may or may not have legal value.

4.4.4 Product data sheet (PDS)

The product data sheet is a document issued by the manufacturer for marketing purposes and usually used to provide product approval information to the customer.

4.4.5 Raw Material Specification (RMS)

The raw material specification is a technical document about the product, usually prepared by manufacturer, directed to provide all product approval information to the customer and usually attached to a commercial contract.

4.4.6 Material Safety Data Sheet (MSDS)

The material safety data sheet is a document issued according to EC Regulation [33] with the aim of providing product compliance information in respect of human health and safety at the workplace and protection of the environment.

This document is issued by the manufacturer for hazardous substances and mixtures and is not required for all materials or products. In general a MSDS is not necessary for food and feed applications.

NOTE Some customers ask for an MSDS even if it is not mandatory. It is the algae and algae product manufacturer's responsibility to check the applicable regulation case by case. Algae and algae products may or may not fall under the MSDS obligation.

5 Product characteristics

5.1 Purity

5.1.1 General

The product purity is defined as the percentage of a specific component in the total amount of a product. Any other substances are specified in the technical data sheet.

Purity is affected by the accidental presence or the fraudulent addition of any organism, part or product of an organism, other than named in the product specification and description of the concerned algae; or any extraneous substances with the same composition as dry algae, even in the absence of contamination. The minimum purity required for a food product will depend on the application of the algae or algae product and is agreed with the customer. The minimum requirement of purity for feed is regulated by legislation and customer contracts. Purity is not related to contamination since contamination will not affect the amount of required substance.

The following substances affecting the purity of a product can be addressed [46]:

1. Physical foreign matter (i.e. (micro) plastic fragments, wires from fishing nets and ropes, feathers from birds, shells, etc.);

2. Other algae (including toxin-producing cyanobacteria), bacteria or organic materials (i.e. grass, proteins or oils from other species);

3. Algae from other origin or location than stated (i.e. from Asia instead of Europe).

NOTE 1 The percentage is specified by mass fraction (kg/kg), volume fraction (m3/m3) or cell fraction (cell counts/all cell counts) or their corresponding concentrations if more appropriate.

NOTE 2 Foreign matter related to the use of genetically modified species or non-organic produced products are regulated by EU Regulation.

Methods of analysis to determine the purity of algae and algae products include qualitative and quantitative methods. If a qualitative method shows substances that affect the product purity, a quantitative method may be necessary. Various methods are suitable for fresh materials and dry materials or powders.

Available methods include visual inspection, microscopy, nuclear acid identification (DNA barcoding, PCR techniques, DNA microarrays, NGS, Q-PCR), molecular and chemical fingerprinting (fatty acid profile, pigment analysis) and isotopic analysis.

5.1.2 Physical foreign matter

Macroscopic examination is suitable for determining the presence of particles of foreign matter in whole or cut (macro)algae. Foreign matter are all materials which are not part of the (macro)algal biomass. Additional aids (like UV-light, sieving, centrifugation) might be helpful to find the foreign matter.

Microscopy is a suitable tool for microalgae, cyanobacteria, Labyrinthulomycetes and powdered materials and small particles of physical foreign matter for which macroscopic examination is not suitable. Reduction of particle size or powdering materials can hide the presence of foreign matter and make it more difficult to detect. Also diluted samples cannot be qualified and need a quantification step.

5.1.3 Other algae, bacteria or organic materials

Visual inspection is suitable for freshly harvested macroalgae as the intact cells can be recognized as a whole. When the holdfast is removed, epiphytic organisms may be present on the surface and visual inspection is not sufficient to identify the species after harvesting. Macroalgae need to be crushed and mixed and the mixture needs to be plated to identify which colonies are present in the sample. For ground algae, cells are disrupted and the algae species can no longer be recognized nor be quantified. Rehydration might help here. Specifically for cyanobacteria, some guidance for the numeration of phytoplankton can provide the degree of purity on fresh samples [28].

Macroscopical and microscopical characterization includes features, which distinguish the algae material from potential non-specified substances. Identification tests need to be specifically validated for algae and are usually a combination of methods depending on the algae species. Identification tests include macroscopical characters, microscopical characters, chromatographic procedures and physicochemical analysis. Automated tools might help like cell counters or cell flow cytometers.

The development of methods based on nuclear acids characteristics (microsatellites, NGS, barcoding, RAPD, AFLP, etc.) to be sequenced and/or quantified (qPCR) from product samples would provide simple and fast tools for the identification of multiple targeted species and would help to indicate the presence of other nuclear acids than those of the algal material. Other horizontal analytical methods useful for purity detection (molecular or chemical fingerprinting like fatty acid analysis, etc) will be developed in CEN/TC 460 'Food and feed authenticity'. Currently, there is a lack of databases for the identification of foreign matter.

5.1.4 Algae from other location

The most promising test to detect the presence of algae from other regions then stated, is the use of stable isotopes. However, first databases with the characterization of isotopes from different regions needs to be established. Another method is the use of lipidomics tools, although these tools also require the establishment of databases [60].

Currently these methods are not yet standardized and available for routine testing. In addition, essential databases are not complete to identify all different species. Therefore, good farming practices (GFP), good manufacturing practices (GMP), traceability and Chain of Custody systems are essential to monitor the purity for algae and algae products.

An overview of the currently available types of foreign matter and respective detection methods including qualitative and quantitative determination are shown in Annex B [46]. The reliability of these different methods depends on the complexity of the species and foreign matter and are not necessarily sufficient for each case.

5.1.5 Methods of analysis

The inventory of available methods and recommendation for prioritizing future method development on purity of algae and algae products are listed in Annex B.

Specific gaps to use these methods are lack of respectively [46]:

- sampling strategies for visual inspection and microscopy;
- quantification method for microscopy;
- databases, algae selective primers and protocols for nuclear acid identification, and
- databases for molecular and chemical fingerprinting and isotope analysis (see Annex B).

In addition to the gap per analysis methodology, methods are lacking for the quantification of the found foreign matter. Furthermore, protocols describing what to do with the product if the presence of a foreign matter is detected, are lacking.

It is recommended to further develop and standardize the following protocols [46]:

- Sample strategies for quality control of fresh materials and of dry/powdered materials;
- Quality control protocols describing which other checks have to be done when foreign matter is found;

- Visual inspection protocols for fresh materials and for dry/powdered materials;
- Microscopical inspection protocols for fresh materials and for dry/powdered materials;
- Protocol for molecular biological quality control taking into account the most important criteria;
- Study the applicability of isotope analysis for specification of the region of origin.

5.2 Contamination

5.2.1 General

A contaminant is defined as any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability of algae and algae products in the food or feed application [40]. Several types of contaminants exist including chemical, microbiological and physical contamination. Chemical contamination of algae and algae products can occur in the open waters (macroalgae) or in a closed or semi-closed cultivation system (micro- and macroalgae), e.g. when water sources for algae cultivation have been in contact with human or industrial activities or outlets. Most algae tend to accumulate minerals and other compounds if present in the surrounding environment. Therefore, this form of contamination is important to monitor. Processes to reduce contaminants to acceptable levels are available, like rinsing.

5.2.2 Food

The contaminants for algae that have been identified as potential hazards for food safety include: heavy metals (including uranium), toxins, pesticides, dioxins, PAH's, allergens, pheophorbides and

microorganisms. The potential presence of these hazards depends on the algae species and its cultivation and processing conditions.

Several gaps in legislation for macroalgae have been identified [3], [5]. Inorganic arsenic (iAs) and other potential toxic arsenic compounds, cadmium (Cd), lead (Pb), mercury (Hg), iodine (I), selenium (Se) and uranium (U) are of particular concern since these can be found in algae. There is a need for a clear overview of the regulation for algae used as food. The algae market is growing and there is a need for EU legislation on e.g. iodine and inorganic arsenic. The specific threshold values should be set by the European Commission and EFSA (European Food Safety Authority) taking maximum levels of daily intake, quantity of intake and the effects of processing into consideration.

The current available EU regulation [5] is not clear in the description whether the threshold levels are based on dry or wet material. The threshold levels being set by EFSA should be based on dry material as the algae or algae product. Research shows that some contaminant concentrations (e.g. iodine and inorganic arsenic) can be decreased considerably by processing, e.g. boiling, rinsing, drying etc [62][63]. Each product has to comply with the legislation, but some national food authorities demand that the packaging should mention specific processing to be done by the consumer before consumption. This should be harmonized in EU legislation regarding consumer processing on the packaging and if part of the population should be warned.

Algae grown in semi-closed or open systems as well as wild-harvested macroalgae can be cross-contaminated by allergens (such as shellfish and crustaceans). If there is a possibility that such contaminants and/or traces/spores hereof are present in the macroalgae, this should be reported on the product packaging [21].

Pheophorbides are breakdown compounds of chlorophyll and are not regulated. Japanese legislation sets maximum limits. Therefore, it should be considered if these compounds are a hazard for algae and algae products in food applications.

Although the EC Regulation sets no maximum levels for microorganisms in algae or algae products in food, all food products have to be microbiologically safe to consume. These products have to be stable during storage and processing, at least as long as the shelf life is indicated on the label. Specific threshold values for microorganisms in microalgae and macroalgae and their microbial stability should be evaluated and harmonized in the various national guidelines.

Regarding food quality management, a guidance for good hygiene practices is being validated for the production of spirulina as food [47].

The EFSA working group for industrial contaminants is currently in the progress of updating this legislation on contaminants, and looks at including macroalgae as food in the legislation (working document on contaminants in macroalgae [4]). If there are not already recognized methods from EU reference laboratories etc. in place, then standards on methods for extracting, identifying and quantifying contaminants should be established.

Algae and algae products, elements and their chemical species to be considered in food safety control are listed in Annex C together with the different legislations that cover the microalgae and macroalgae used for food and food applications and food supplements in the European Union.

5.2.3 Feed

The contaminants for algae and algae products that have been identified as potential hazard for feed applications include: heavy metals (including uranium), inorganic arsenic, toxins, pesticides, dioxins, PAH’s, fluorine, nitrate, allergens, pheophorbides and microorganisms.

Feed legislation sets different threshold levels of contaminants in different animal species. Several gaps in legislation for algae have been identified. Inorganic arsenic (iAs) and other potential toxic arsenic compounds, cadmium (Cd), lead (Pb), mercury (Hg), iodine (I) and uranium (U) are of particular concern since these can be found in algae that are cultivated in uncontrolled or contaminated conditions.