



SLOVENSKI STANDARD
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Alge in izdelki iz alg - Vzorčenje - Smernice za opredelitev programov in protokolov vzorčenja

Algae and algae products - Sampling - Guidelines for the definition of sampling programs and sampling protocols

Algen und Algenprodukte - Probenahme - Leitlinien für die Festlegung von Probenahmeprogrammen und Probenahmeprotokollen

Algues et produits d'algues - Échantillonnage - Lignes directrices pour la définition des programmes et des protocoles d'échantillonnage

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Algae and algae products - Sampling - Guidelines for the definition of sampling programs and sampling protocols

Algen und Algenprodukte - Probenahme - Leitlinien für die Festlegung von Probenahmeprogrammen und Probenahmeprotokollen

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

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 17980:2023) 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 CEN Enquiry.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association.

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<https://standards.iteh.ai/catalog/standards/sist/50a7a645-88ef-47cb-92d9-acc132825747/osist-pren-17980-2023>

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 products.

This request, presented as Mandate M/547, 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 products 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 and algae products and will promote and support commercialization of the European algae industry.

This document has been developed with the aim to help algae producers and algae products industries to establish a sound sampling program and a correct sampling protocol. The sampling program will define the strategy for sampling, when, where and how much, and the sampling protocol will define how the samples will be collected, packaged, labelled, preserved and transported until the final destination: laboratory, long term storage, customer, health safety authority, etc.

[oSIST prEN 17980:2023](https://standards.iteh.ai/catalog/standards/sist/50a7a645-88ef-47cb-92d9-acc132825747/osist-pren-17980-2023)

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1 Scope

This document specifies a set of principles and rules that algae producers, algae products industries, laboratories or other entities that collect algae and algae products samples can follow for the definition of their own sampling programs and sampling protocols.

In the context of this document, algae are a functional group that include microalgae, macroalgae, cyanobacteria and *Labyrinthulomycetes*.

As algae and their production processes are so diverse, this document does not define a specific sampling program and/or a specific sampling protocol. Instead, this document specifies the aspects that can be considered when defining one's own sampling program and protocol.

This document describes when, where and how to draw a representative sample. For guidance on sample preparation of dry and wet samples of micro- and macroalgae, and algae products, please refer to EN 17605.

This document is intended to be used for the collection of samples for lot characterization for commercial or legal/regulatory purposes. However, this document can also be used for any type of sampling of algae, including samples for quality control during production.

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.

EN 17399:2020, *Algae and algae products - Terms and definitions*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 17399:2020 and the following apply.

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

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

3.1

lot

quantity of material that is assumed to be of the same production process and represented by specified sampling rules

[SOURCE: EN 17605:2022, 3.1]

prEN 17980:2023 (E)**3.2****sample**

quantity of material, from a larger amount for which the quality is to be determined

Note 1 to entry: A sample is intended to provide information on a given characteristic of the studied lot, and to form a basis for a decision concerning the lot.

Note 2 to entry: A sample can be a laboratory sample, a test sample, a test portion, an incremental sample, or a reserve sample.

[SOURCE: ISO 21637:2020, 3.63 — Notes to entry have been removed]

3.3**increment****incremental sample**

quantity of material taken from a single place in the *lot* (3.1)

[SOURCE: COMMISSION REGULATION (EC) No 333/2007 of 28 March 2007]

3.4**aggregate sample**

combined total of all the incremental *samples* (3.3) taken from the *lot* (3.1)

[SOURCE: COMMISSION REGULATION (EC) No 333/2007 of 28 March 2007]

3.5**representative sample**

sample (3.2) in which the characteristics of the *lot* (3.1) from which it is drawn are maintained

Note 1 to entry: It is the case of a simple random sample where each of the items of the lot has been given the same probability of entering the sample.

[SOURCE: CODEX ALIMENTARIUS, General Guidelines on Sampling CAC/GL 50-2004]

3.6**sampling**

process of drawing or constituting a *sample* (3.2)

[SOURCE: ISO 21637:2020, 3.68]

3.7**sampling program**

predetermined procedure for the definition of the amount, the number of *increments* (3.3), the timing of the *sample* (3.2) and the sample collection point, to obtain *representative samples* (3.5)

3.8**sampling protocol**

predetermined procedure for the definition of the steps to prepare, collect, package and label for shipping, and deliver the *sample* (3.2) until the transfer of responsibility at final destination

4 Principles of sampling

4.1 General

Sampling is an activity that is a common practice in almost any industrial, commercial or service area. It is done due to economic or time constraints to characterize a collection (a lot) of heterogeneous items, as it is not feasible to analyse the entire collection because the analysis is destructive, or too expensive.

The quality or confidence on the results of the sampling is related to two aspects: the representativeness of the sample, and the relation between the number of items sampled and the number of items of the entire collection.

The representativeness of the sample is based on the definition of a representative sample: the probability of being present on the sample is the same for any item in the collection.

To ensure that this probability is verified is not a trivial issue. If the production line has in some place a conveyor belt where the entire production passes in sequence, it is possible to ensure representativeness if samples are collected in the entire width of the belt, and at random intervals. However, the most common situation is the collection of samples from a pile, a tank or other three-dimensional stock of production.

There are many aspects that can skew the results of sampling, such as;

- material segregation by size, form, density, etc.;
- production process variation due to raw material differences, parameter deviation, human error, etc.

To minimize the impact of those anomalies different strategies can be chosen, such as;

- mixing;
- agitating;
- have samples made of different increments collected in different/random periods, locations, depths, etc.;
- take a larger sample or collect a larger number of increments to obtain a higher confidence interval.

A sampling program should define clearly the “when” to sample and “how much” sample material should be collected. The “when” can be time or production (at which stage of production) dependent. The “how much” should be a function of the lot size and should also be destination dependent. The “how much” may be dependent of the confidence interval that is required for the destination.

A sampling protocol should consider 4 stages:

- a) initial preparation, which defines the set of knowledge, expertise, experience needed for a correct collection, and the safety procedures and PPE (personal protective equipment) required, and the set of tools, packaging, labelling, preservation and transport equipment needed to be available for collection;
- b) before collection, which defines the checklist and the verification of tools, PPE, and other equipment;
- c) collection, which defines the procedure of collection;
- d) after collection, which defines the procedure for sample packaging, labelling, preservation, storage and delivery to the destination, until its responsibility is transferred to other entity.

prEN 17980:2023 (E)**4.2 Basic rules to obtain a representative sample**

To obtain a representative sample the following rules should be in place:

- a) ensure that the probability of any item being in the sample, is equal for all items: randomize the place, time and depth of the sample collection according to the specific situation, and stick to it;
- b) ensure that the items are not segregated by any means, and mix, agitate or scramble the entire collection before sample collection if possible;
- c) take as many increments as possible to complete the sample, at random locations, periods and depths, and homogenize the collected material. If too large, this sample can be divided into subsamples without losing representativeness;
- d) if samples or increments are collected at different time intervals, be sure that they are not synchronous with normal production cycles or other aspects of the production: avoid collection at personnel changing, at same time in the day, etc.

4.3 Good practices of sampling

Besides specific aspects of sampling algae or algae products, there are many other aspects that are common to sampling. This list is a reminder of those aspects that anyone collecting samples should keep in mind for the success of their task:

- a) be sure of the objective of sampling;
- b) ensure that you have available all items needed to collect the sample, and following steps;
- c) take all safety measures required to collect the sample;
- d) ensure that the sample collected is representative of the collection;
- e) take all the steps to close the container, label and preserve the sample;
- f) deliver the sample as soon as possible.

It is good practice of sampling to keep a counter sample under the control for any future reference or dispute that can arise from final destination (external lab, customer, H&S authority, etc.). This counter sample shall be collected following the same protocol and at the same conditions (location, time and amount) as the normal sample.

5 Development of a sampling program**5.1 General**

A sampling program shall be defined based on both the internal and external context of production of algae and algae products.

The internal context includes information on:

- production conditions, e.g. wild stock or controlled conditions;
- the production facility and unit;
- algae species;

- lot size;
- final product.

The external context includes information on:

- the local, national or regional legal, regulatory and commercial framework;
- objective of the sampling, e.g. microbiology, contamination, physical and chemical characterization, genetic analysis;
- final use of the sample.

When it is requested to keep a counter sample in house for future reference, then a duplicate sample shall be collected following the protocol and at the same conditions (location, time and amount) as the normal sample, and appropriately stored in-house.

Considering the diversity of algae production processes, the sampling program shall be defined for each type of production unit. The sampling program shall define the amount, the number of increments, the timing of the sample and the sample collection point, to fulfil the basic sampling principle of representativeness.

For algae products, the production process is not so much relevant for sample collection, except what refers to packaging: before, e.g. in bulk, or after packaging, e.g. units in warehouse. The basic sampling principle of representativeness shall be fulfilled as well.

The lot size is relevant to determine the amount of the sample, and/or the number of increments to be collected to obtain each sample.

Examples of a sampling program for different type of productions or collections are given in Annex A, B and C.

5.2 Identification of a lot

For each production unit, the internally defined lot size shall be defined in terms of weight, volume or number of packages. An example of how to physically divide into identifiable sublots is given below.

EXAMPLE If the lot size is larger than 1 000 kg or 1 m³, it could be physically divided into identifiable sublots of maximum 1 000 Kg or 1 m³, so that samples can be collected and identified.

The identification of a lot shall include at least:

- production unit;
- algae species and/or algae product;
- harvesting/production date;
- lot size (kg, l) or number of units/packages.

5.3 How to define a sample: where and when to collect, dimension and increments

5.3.1 General

Samples shall be collected during harvesting, or after the operations of preparation (washing, cleaning, concentration, etc.), or for packaged products, before packaging or after packaging and before storage at the warehouse.