



SLOVENSKI STANDARD SIST-TS CEN/TS 15568:2007

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Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Sampling strategies

Lebensmittel - Verfahren zum Nachweis von gentechnisch modifizierten Organismen und ihren Produkten - Probenahmestrategien

Produits alimentaires - Méthodes d'analyse pour la détection des organismes génétiquement modifiés et des produits dérivés - Stratégies d'échantillonnage

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ICS 67.050

English Version

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Lebensmittel - Verfahren zum Nachweis von gentechnisch
modifizierten Organismen und ihren Produkten -
Probenahmestrategien

This Technical Specification (CEN/TS) was approved by CEN on 7 November 2006 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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Contents

Page

Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 Principle.....	6
5 Apparatus and equipment	7
6 Sampling of non-packed food products.....	7
7 Sampling of pre-packed units	9
8 Preparation of the analytical sample and the test portion	10
9 Packaging and labelling of laboratory samples	10
10 Dispatch of laboratory samples	11
11 Sampling report	11
Annex A (informative) Laboratory sample sizes of different cereals and oilseeds.....	13
Annex B (informative) Sampling scheme for consignments of more than 100 bags according to ISO 13690.....	14
Annex C (informative) Estimation of the number of particles in 100 mg test portions after ultra-centrifugal milling.....	15
Bibliography.....	16

Foreword

This document (CEN/TS 15568:2006) has been prepared by Technical Committee CEN/TC 275 “Food analysis - Horizontal methods”, the secretariat of which is held by DIN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

NOTE This document has been submitted to the Enquiry under reference number prEN 21568.

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Introduction

Correct sampling is an operation that requires the most careful attention. Emphasis should be laid on the necessity of obtaining a representative sample of the goods under investigation.

If ad-hoc sampling of food products is undertaken without applying a sampling strategy and without considering the lot specific properties, the analytical result is only valid for the sample that has been analysed. It is not possible to extend the result to the rest of the lot.

By applying sampling strategies to assess the level of compliance of a given lot of products, a certain number of samples is taken, and the result of the analysis can be extended to the whole lot. The use of sampling strategies is the only effective way to make correct statements about the nature, in this case the GMO-content, of the product tested.

This Technical Specification has been established for food products, but could also be applied to other products, e.g. animal feed and plant samples from the environment.

NOTE In certain areas there are widely recognised trade associations which specify rules for the sampling strategies to be used in contracts under their auspices. In no case will this Technical Specification override the rules laid down in such contracts.

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1 Scope

This Technical Specification gives guidance for setting up valid sampling strategies for food products that are to be analysed for the presence of genetically modified organisms and derived products.

2 Normative references

The following referenced documents are indispensable for the application 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 ISO 21569, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods (ISO 21569:2005)*

EN ISO 21570, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods (ISO 21570:2005)*

EN ISO 21571, *Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction (ISO 21571:2005)*

EN ISO 21572, *Foodstuffs — Methods for the detection of genetically modified organisms and derived products — Protein based methods (ISO 21572:2004)*

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3 Terms and definitions (standards.iteh.ai)

For the purposes of this document, the following terms and definitions apply.

3.1 Consignment

quantity of some commodity delivered at one time and covered by one set of documents. The consignment may consist of one or more lots or part(s) of lots

[ISO 7002:1986]

3.2 Lot

stated portion of the consignment to be tested for presence of GMO

3.3 Increment

quantity of material taken at one time from a larger body of material

NOTE Increments may be tested individually aiming at estimation of the variation of any characteristic throughout a lot (or between lots).

[ISO 7002:1986]

3.4 Item

actual or conventional object (a defined quantity) on which a set of observations may be made

[ISO 7002:1986]

3.5 Sample

one or more items (or a portion of material) selected in a prescribed or systematic manner from a lot

NOTE It is intended to provide information representative of the lot, and, possibly, to serve as a basis for decision on the lot.

3.6 File increment sample

increment that is retained for a specific period of time for further analysis

3.7 Bulk sample

composite of the increments taken from a lot

3.8 Laboratory sample

sample as prepared for sending to the laboratory and intended for inspection or testing

[ISO 7002:1986]

3.9 Test portion

sample, as prepared for testing or analysis, the whole quantity being used for analysis or testing at one time

[ISO 3534-1:2006]

3.10 Lot size

number of items or quantity of material constituting the lot

[ISO 7002:1986]

3.11 Sample size

number of items or quantity of material constituting the sample

[ISO 7002:1986]

3.12 Sample division

process of selecting one or more representative sub-samples from a sample by such means as riffing or mechanical dividing

3.13 Sampling uncertainty

part of the total estimation uncertainty due to one or several of the following:

- the failing of a sample to accurately represent the lot;
- the random nature of sampling;
- the known and accepted characteristics of the sampling strategy

3.14 Sampling strategy

predetermined procedure for the selection, withdrawal and preparation of samples from a lot to yield the required information so that a decision can be made regarding the acceptance of the lot

[ISO 7002:1986]

4 Principle

In this Technical Specification sampling is considered to consist of the following steps:

- collection of a sufficient number of increments from a lot to form the bulk sample;
- reduction of the bulk sample to the laboratory sample;
- grinding the laboratory sample to the appropriate particle size and homogenisation.

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Samples shall be representative of the lots from which they are taken. Therefore, as the composition of a lot is seldom uniform, a sufficient number of increments shall be taken and carefully mixed, thus giving a bulk sample from which the laboratory sample is obtained by successive divisions or otherwise.

If it is necessary to determine the sampling uncertainty, file increment samples should be kept for further analysis.

Appropriate measures shall be taken to avoid any alteration in the composition of the samples.

5 Apparatus and equipment

Many different types of sampling instruments or equipment are available. Equipment should be chosen as appropriate for the food products to be sampled and the quantity and containers involved. Examples of sampling instruments are given in e.g. ISO 13690 and ISO 6644. Special care is necessary to ensure that all sampling apparatus is clean to avoid contamination of the material under investigation.

Sampling shall be carried out in such a manner as to protect the samples, the sampling instruments and the container in which the samples are placed, from adventitious contamination. Special attention shall be paid to avoid cross-contamination during the sampling procedure between different lots. Material adhering to the outside of the sampling instrument shall be removed before the contents are discharged.

6 Sampling of non-packed food products

6.1 Statistical principles

Lot distribution properties affect the efficiency of sampling strategies [5]. Where the variable of interest is randomly distributed within the lot under investigation, the sampling uncertainty can be estimated according to the binomial distribution [6]. However, in reality, non-packed food product lots may show non-random distributions [7], and lot heterogeneity should be taken into account when defining sampling procedures statistically.

This sampling protocol provides a way of estimating the sampling uncertainty associated with the overall GMO content of a lot without imposing any distribution assumption.

The Standard Deviation (SD) of the increment GMO content estimates may be interpreted as an indicator of the lot heterogeneity and in highly heterogeneous lots as an indication of the sampling uncertainty. Generally, the larger the standard deviation, the larger is the sampling uncertainty in highly heterogeneous lots.

6.2 Procedure

6.2.1 General

This protocol is designed to provide an estimate of the GMO content of the lot based on a bulk sample. If an estimate of the sampling uncertainty is required, 6.2.3 describes a procedure to determine it.

6.2.2 Sampling of increments

Lots should be sampled following the technical principles given in ISO 6644 as described in 6.3 and ISO 13690 as described in 6.4.

The number of sampling points, where the increments for creating the bulk sample and the file increment samples are taken is defined according to the lot size. In case of lots from 50 t to 500 t, the size of the bulk sample should be 0,01 % of the total lot size. In case of lots smaller than 50 t, the size of the bulk sample should be 5 kg. In case of lots larger than 500 t, the size of the bulk sample should be 50 kg (see Table 1).