

STN	Mikrobiológia potravinárskeho reťazca Horizontálna metóda na dôkaz stafylokokových enterotoxínov v potravinách imunoenzymatickou metódou (ISO 19020: 2017)	STN EN ISO 19020 56 0119
------------	---	--

Microbiology of the food chain - Horizontal method for the immunoenzymatic detection of staphylococcal enterotoxins in foodstuffs (ISO 19020:2017)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/17

Obsahuje: EN ISO 19020:2017, ISO 19020:2017

125638

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2018
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.

EUROPEAN STANDARD

EN ISO 19020

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2017

ICS 07.100.30

English Version

Microbiology of the food chain - Horizontal method for the immunoenzymatic detection of staphylococcal enterotoxins in foodstuffs (ISO 19020:2017)

Microbiologie de la chaîne alimentaire - Méthode horizontale de détection des entérotoxines staphylococciques par test immuno-enzymatique dans les aliments (ISO 19020:2017)

Mikrobiologie der Lebensmittelkette - Horizontales Verfahren für den immunenzymatischen Nachweis von Staphylokokken-Enterotoxinen in Lebensmitteln (ISO 19020:2017)

This European Standard was approved by CEN on 14 May 2017.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 19020:2017) has been prepared CEN/TC 275 "Food analysis - Horizontal methods" the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 34 "Food products".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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

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

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 19020:2017 has been approved by CEN as EN ISO 19020:2017 without any modification.

**Microbiology of the food chain —
Horizontal method for the
immunoenzymatic detection of
staphylococcal enterotoxins in
foodstuffs**

*Microbiologie de la chaîne alimentaire — Méthode horizontale de
détection des entérotoxines staphylococciques par test immuno-
enzymatique dans les aliments*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Principle.....	2
5 Reagents.....	2
6 Apparatus.....	2
7 Sampling.....	3
8 Procedure.....	3
8.1 Preparation of test portion.....	3
8.2 Storage of the test sample.....	3
8.3 Extraction.....	4
8.4 Concentration of the extract (mandatory for milk and dairy products).....	5
8.5 Recovery of the concentrated extract.....	5
8.6 Storage and steps before detection.....	6
8.7 Detection.....	6
8.8 Performance criteria.....	6
9 Quality control.....	6
10 Expression of results.....	7
11 Confirmation.....	7
12 Performance characteristics of the method.....	7
13 Test report.....	9
Annex A (informative) Results of interlaboratory studies: 2013.....	10
Annex B (informative) Results of interlaboratory studies: 2014.....	15
Annex C (informative) Note on interferences.....	21
Bibliography.....	22

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 275, *Food Analysis — Horizontal methods*, in collaboration with ISO Technical Committee TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in accordance with the agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

Staphylococcal enterotoxins (SEs) are proteins that can be produced in foods, by certain strains of the coagulase positive staphylococci (CPS), mainly *Staphylococcus aureus*. These SEs are heat and acid stable toxins that cause nausea, vomiting, abdominal pain and diarrhoea when ingested. Due to their stability SEs might still be present even when coagulase positive staphylococci cannot be detected. SEs consist of a family of more than 20 structurally-related globular monomeric proteins with molecular weights of 19 kDa to 30 kDa.^[1] These proteins are relatively stable under changing environmental conditions, such as heat treatment, freezing and change in pH; moreover, they are resistant to proteolytic digestion. Typically, and depending on the sensitivity of affected individuals, nanogram (ng) amounts of enterotoxin can cause intoxication with the symptoms described above. Due to the influence of SEs on human health, the European Union has adopted legislation in order to increase consumer protection by defining microbiological criteria for foodstuffs, such as CPS enumeration and detection of SEs.^[2]

Several methods have been developed for the detection and/or quantification of SEs. Some of these methods are based on enzyme immunoassay (EIA). Other methods are based on the chemical analysis using liquid chromatography with tandem mass spectrometry (LC-MS/MS) for the detection and quantification of SEs. As these latter methods are currently under development, EIA methods have been chosen as the starting point for standardization of a detection method for SEs.

The aim is to detect SEs using commercially available test kits. This document describes the protocol for the extraction of SEs from food samples. Moreover, criteria for the performance of the kits have been evaluated on five types of food matrices before use based on the criteria given in this document.

Response rates of different staphylococcal food poisoning outbreaks were modelled as a function of ingested doses.^[3] For this purpose, data from the literature as well as data from the European Union Reference Laboratory for CPS were used.

The United States Environmental Protection Agency (US EPA) benchmark dose methodology was applied to this data set and helped to establish the benchmark dose (BMD).^[4] The BMD is defined as the dose of a hazard (staphylococcal enterotoxin) likely to trigger health symptoms in a given percentage of the exposed population. The BMD lower limit (BMDL) is the lower 95 % (or 90 %) confidence interval of the BMD. This value was used to set up the acceptable value for the limit of detection 50 (LOD₅₀) of the various commercially available SE detection kits.

Microbiology of the food chain — Horizontal method for the immunoenzymatic detection of staphylococcal enterotoxins in foodstuffs

1 Scope

This document specifies a screening method for the detection of staphylococcal enterotoxins SEA, SEB, SECs, SED and SEE in foodstuffs. It consists of two main steps: a) extraction followed by a concentration based on dialysis principle; and b) an immunoenzymatic detection using commercially available detection kits.

This document is applicable to the screening of staphylococcal enterotoxins SEA to SEE in products intended for human consumption.

Other staphylococcal enterotoxins such as types SEG, SEH, SEI, SER, SES and SET can also cause illness. Due to the lack of commercially available detection kits, this document is applicable only to types SEA to SEE, but may apply to other types of toxins, subject to validation of the method.

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.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7218, *Microbiology of food and animal feeding stuffs — General requirements and guidance for microbiological examinations*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN