



SLOVENSKI STANDARD SIST EN ISO 19020:2017

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Mikrobiologija v prehranski verigi - Horizontalna metoda za imunoencimsko ugotavljanje stafilokoknih enterotoksinov v živilih (ISO 19020:2017)

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

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

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

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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.

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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of an identical text or by endorsement, at the latest by December 2017, and conflicting national standards shall be withdrawn at the latest by December 2017.

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**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*

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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).

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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.

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