SLOVENSKI STANDARD
SIST EN ISO 6887-1:2017/oprA1:2023

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Mikrobiologija v prehranski verigi - Priprava preskusnih vzorcev, osnovne suspenzije in decimalnih razredčin za mikrobiološko preiskavo - 1. del: Splošna pravila za pripravo osnovne suspenzije in decimalnih razredčin - Dopolnilo A1: Zahteve in navodila o uporabi testnega vzorca večje velikosti za kvalitativne metode (ISO 6887-1:2017/DAM1:2023)

Microbiology of the food chain - Preparation of test samples, initial suspension and decimal dilutions for microbiological examination - Part 1: General rules for the preparation of the initial suspension and decimal dilutions - Amendment 1: Requirements and guidance on the use of larger test portion size for qualitative methods (ISO 6887-1:2017/DAM1:2023)

Mikrobiologie der Lebensmittelkette - Vorbereitung von Untersuchungsproben und Herstellung von Erstverdünnungen und von Dezimalverdünnungen für mikrobiologische Untersuchungen - Teil 1: Allgemeine Regeln für die Herstellung von Erstverdünnungen und Dezimalverdünnungen - Änderung 1: Anforderungen und Leitlinien für die Verwendung größerer Prüfmengen bei qualitativen Verfahren (ISO 6887 1:2017/DAM 1:2023)

Microbiologie de la chaîne alimentaire - Préparation des échantillons, de la suspension mère et des dilutions décimales en vue de l'examen microbiologique - Partie 1: Règles générales pour la préparation de la suspension mère et des dilutions décimales - Amendement 1: Exigences et recommandations sur l'utilisation d'une taille de prise d'essai plus grande pour les méthodes qualitatives (ISO 6887-1:2017/DAM1:2023)

Ta slovenski standard je istoveten z: **EN ISO 6887-1:2017/prA1**

ICS:

07.100.30	Mikrobiologija živil	Food microbiology

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DRAFT AMENDMENT
ISO 6887-1:2017/DAM 1

ISO/TC **34**/SC **9** Secretariat: **AFNOR**

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Microbiology of the food chain — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination —

Part 1: General rules for the preparation of the initial suspension and decimal dilutions

AMENDMENT 1: Requirements and guidance on the use of larger test portion size for qualitative methods

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This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 463, *Microbiology of the food chain*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Microbiology of the food chain — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination —

Part 1: General rules for the preparation of the initial suspension and decimal dilutions

AMENDMENT 1: Requirements and guidance on the use of larger test portion size for qualitative methods

3.2

Replace the text with the following:

3.2
composite sample
mixed sample of a number of the same items of food, animal feed, animals or environment, prepared in or out of the laboratory from which a test portion is taken for examination.

Note 1 to entry: See Table A.1 for illustration of a composite sample.

3.3

Replace the text with the following:

3.3
pooled sample
mixed sample of a number of the same items of food, animal feed, animals or environment, prepared in or out of the laboratory where the complete mixture is the test portion and is taken as a whole for examination.

Add after 3.10 the following:

3.11
category
group of sample types of the same origin

EXAMPLE Heat-processed milk and dairy products.

[SOURCE: ISO 16140-1:2016]

3.12
type
for a given category, a group of items processed in a similar way, with similar intrinsic characteristics and a similar microbial ecology

EXAMPLE Food category: heat-processed milk and dairy products; food type: pasteurized dairy product.

[SOURCE: ISO 16140-1:2016]

3.13
item
single specified food, feed, environmental, or primary production matrix

EXAMPLE Food category: heat-processed milk and dairy products; food type: pasteurized dairy product; food item: milk-based desserts.

[SOURCE: ISO 16140-1:2016]

3.14
larger test portion
measured (volume or mass) representative sample taken from the laboratory sample (3.1) or test sample (3.4) for use in the preparation of the *initial suspension* that is larger than the test portion size that has been described in the original method and/or validation document

9.3

Replace the text with the following:

9.3 Composite sample and larger test portion

9.3.1 Composite sample

A composite sample is where a number of the same items are mixed, and a test portion is taken for examination in the laboratory as illustrated in Annex A (Table A.1). The size of the test portion removed from the composite sample will remain the same as described in the original method and/or validation document.

Compositing shall be applicable to qualitative tests only.

A number of items may be composited at the sampling stage by the client (out of the laboratory) or by the laboratory (at client's request). Only items from the same origin or source (e. g. same batch or lot) shall be composited.

9.3.2 Larger test portion

A larger test portion is a sample that is larger than the test portion size that has been described in the original method and/or validation document.

Testing a larger test portion may be necessary 1) to reflect microbiological quality of a large batch of product, 2) in case when a large number of environmental samples are taken or 3) as sometimes required by national or regional legislation.

A larger test portion can originate from a single larger test portion (9.3.2.1) or from the pooling of samples (9.3.2.2).

If a laboratory sample larger than the maximum sample size has been submitted, the sample can be split into multiple test portions based on the maximum sample size (e.g. if a laboratory sample of 750 g has been received for *Salmonella* testing it can be prepared as two 375 g test portions).

9.3.2.1 Larger single test portion

A larger single test portion is a sample that is larger than the test portion size that has been described in the original method and/or validation document originating from a single sample. A larger single test portion can be applied to both qualitative and quantitative testing.

9.3.2.2 Pooled sample

A pooled sample is a sample where a number of items have been combined and the complete mixture is taken as a whole for examination in the laboratory. Items can be pooled either:

a. out of the laboratory, where individual samples are combined into one larger pooled sample

b. or in the laboratory where individual test portions are combined into one larger (pre-) enrichment as illustrated in Annex A (Table A.1).

c. or in the laboratory , where individual (pre-) enriched test portions items are combined into one and carried through as a single test as illustrated in Annex A (Table A.1)

A number of items may be pooled at the sampling stage by the client or laboratory (at client's request). Pooling shall be applicable to qualitative tests only. Only items from the same origin or source (e. g. same batch or lot) shall be pooled.

9.3.3. Procedure for larger test portion size

Items can either be composited, pooled out of the laboratory or in the laboratory as test portion or as (pre) enriched test portion but not as two or more combinations (i.e., pooling of (pre) enriched as well as test portion is not allowed).

To minimize the risk of false negative results when testing a larger single test portion or pooled test portion.

— The primary diluent shall be pre warmed to the intended incubation temperature with the same tolerance range.

— The temperature profile of the larger enrichment volume should be checked to ensure that the time taken to reach the target incubation temperature and overall incubation time are as specified in the individual standard. For example, in ISO 6579-1:2017 the pre-enrichment incubation time is between 16 h and 20 h. For larger test portion size the pre-enrichment incubation time shall be between 34 °C and 38 °C for a minimum of 16 h.

— When testing a larger single test portion, pooled test portion and pooled (pre-) enrichment test portion, the dilution ratio (sample/diluent) used in the validated method shall remain the same. This ratio may be increased to overcome the inhibitory effects coming from the sample (examples are described in ISO 6887-4:2017, 9.1.4.4).

Additional, pooling instructions may be described in individual standards (e.g. maximum sample size and food category).

9.3.4 Validation and verification of larger test portion size

The validated larger test portion size can be used in other laboratories once this has been validated in an interlaboratory study in accordance with ISO 16140-2 or ISO 16140-5. See the flow diagram in ISO 16140-4:2020, Figure 1. Once validated in an interlaboratory study, any laboratory can implement the larger test portion size after verification in accordance with ISO 16140-3. If not validated in an interlaboratory study, validation in accordance with the procedure described in Annex H of ISO 16140-4:2020/Amd1:xxx is necessary for each laboratory wishing to test a larger test portion size.

Reference methods which were validated using larger test portion size in accordance with ISO 17468 and alternative (proprietary) methods which were validated using larger test portion size in accordance with ISO 16140-2 only need to be verified by a laboratory following ISO 16140-3.

Once the larger test portion size has been validated, all test portions smaller than the largest validated test portion size can be used for routine testing for this particular (food) category at the same sample/diluent ratio. For example, a method that has been validated for 375 g test portions can be used for 25 g, 100 g, etc., up to 375 g test portions.

Laboratories applying sample or test portion pooling that exceeds the maximum sample size stated in the method shall carry out a validation using the procedure as described in Annex H of ISO 16140-4:2020/Amd1:xxx.

The relative level of detection (RLOD) approach described in ISO 16140-4:2020, 6.1.1.3 shall be used to demonstrate that a larger test portion size provides similar or lower level of detection (LOD_{50}) compared to the LOD_{50} of the (validated) test portion size as described in the method. The corresponding procedure is described in Annex H of ISO 16140-4:2020/Amd1:xxx.

Annex A

Replace the texts with the following: