

# ISO 7218:2024-06 (E)

## Microbiology of the food chain - General requirements and guidance for microbiological examinations

---

<b>Contents</b>		<b>Page</b>
<b>Foreword</b> .....		<b>vii</b>
<b>Introduction</b> .....		<b>viii</b>
<b>1 Scope</b> .....		<b>1</b>
<b>2 Normative references</b> .....		<b>1</b>
<b>3 Terms and definitions</b> .....		<b>1</b>
<b>4 Premises</b> .....		<b>5</b>
4.1 General.....		5
4.2 Biosafety considerations.....		5
4.3 Laboratory design.....		5
4.4 Laboratory areas.....		5
4.4.1 General.....		5
4.4.2 Areas associated with samples and testing.....		6
4.4.3 General areas.....		6
4.5 Layout and fittings of the premises.....		6
4.5.1 Objectives.....		6
4.5.2 Fittings.....		7
4.5.3 Other arrangements for laboratory premises.....		7
4.5.4 Cleaning and disinfection.....		8
<b>5 Personnel</b> .....		<b>8</b>
5.1 General.....		8
5.2 Competence.....		8
5.3 Verification of ongoing staff competence.....		9
5.4 Hygiene.....		9
<b>6 Equipment and consumables</b> .....		<b>9</b>
6.1 General.....		9
6.2 Sterilization and other heating equipment.....		10
6.2.1 General.....		10
6.2.2 Autoclave.....		10
6.2.3 Culture media preparator.....		11
6.2.4 Steamers, including boiling-water baths.....		12
6.2.5 Sterilizing oven.....		12
6.2.6 Microwave oven.....		13
6.2.7 Hotplate, induction cooker and heating mantle.....		14
6.2.8 Gas burner or wire incinerator.....		14
6.3 Temperature controlled equipment and monitoring devices.....		15
6.3.1 General.....		15
6.3.2 Incubator.....		15
6.3.3 Thermostatically controlled bath.....		16
6.3.4 Heating blocks.....		17
6.3.5 Refrigerators and cold-storage rooms.....		18
6.3.6 Freezer and deep freezer/ultra-low temperature freezer.....		19
6.3.7 Temperature-monitoring devices, including automatic recorders.....		19
6.3.8 Balances and gravimetric diluters.....		20
6.4 Defined volume inoculation equipment.....		21
6.4.1 Pipettes and pipettors.....		21
6.4.2 Dispensers.....		22
6.4.3 Spiral platers.....		23

6.4.4	Serial diluters.....	24
6.5	Protective cabinets.....	24
6.5.1	Description.....	24
6.5.2	Use.....	25
6.5.3	Cleaning and disinfection.....	25
6.5.4	Maintenance and inspection.....	26
6.6	Homogenizers, blenders, mixers and shakers.....	26
6.6.1	Homogenizers and blenders.....	26
6.6.2	Vortex mixers.....	27
6.7	Stills, deionizers and reverse-osmosis units.....	28
6.7.1	Description.....	28
6.7.2	Use.....	28
6.7.3	Maintenance.....	28
6.7.4	Verification.....	28
6.8	Separation and concentration equipment.....	28
6.8.1	Immunomagnetic separator (IMS).....	28
6.8.2	Centrifuge.....	29
6.8.3	Filtration systems.....	29
6.9	Modified atmosphere equipment.....	29
6.9.1	Description.....	29
6.9.2	Use.....	29
6.9.3	Maintenance.....	30
6.9.4	Verification.....	30
6.10	Other equipment.....	30
6.10.1	pH meter.....	30
6.10.2	Colony-counting device.....	31
6.10.3	Timers and timing devices.....	31
6.10.4	Optical microscope.....	32
6.10.5	Glass washers, glassware and other laboratory ware.....	32
6.10.6	Disposable equipment and consumables.....	33
6.10.7	Other equipment and software.....	34
<b>7</b>	<b>Sterilization/decontamination and disposal of laboratory materials.....</b>	<b>34</b>
7.1	Sterilization.....	34
7.1.1	General.....	34
7.1.2	Sterilization by dry heat.....	34
7.1.3	Sterilization by moist heat (steam).....	34
7.2	Decontamination and disinfection.....	34
7.2.1	Decontamination of glassware and materials before use.....	34
7.2.2	Decontamination of glassware and materials after use.....	34
7.3	Waste management.....	35
7.4	Washing.....	35
<b>8</b>	<b>Preparation and use of culture media and reagents.....</b>	<b>35</b>
<b>9</b>	<b>Laboratory samples.....</b>	<b>36</b>
9.1	Sampling techniques and sampling plans.....	36
9.1.1	General.....	36
9.1.2	Sampling.....	36
9.2	Sample transport.....	36
9.3	Sample receipt.....	37
9.4	Sample handling.....	37
9.4.1	General.....	37
9.4.2	Storage before examination.....	38
9.4.3	Test portions.....	38
9.4.4	Storage of laboratory samples after examination.....	38
9.5	Pre-testing of samples.....	38
<b>10</b>	<b>Examination.....</b>	<b>39</b>
10.1	Hygienic precautions during sample preparation and examination.....	39
10.1.1	General.....	39
10.1.2	Basic precautions.....	39
10.1.3	Sample handling.....	39
10.1.4	Sample handling tools and implements.....	40
10.1.5	Spillages.....	40
10.1.6	Process controls.....	40
10.1.7	Aerosols.....	40

10.1.8	Molecular methods.....	41
10.2	Preparation of initial suspension and dilutions.....	41
10.2.1	General.....	41
10.2.2	Concentration.....	41
<b>11</b>	<b>Enumeration (quantitative) methods.....</b>	<b>41</b>
11.1	General.....	41
11.2	Enumeration using a solid medium.....	42
11.2.1	General.....	42
11.2.2	Pour plate technique.....	42
11.2.3	Surface plating techniques.....	43
11.2.4	Enumeration of yeasts and moulds.....	44
11.2.5	Incubation.....	45
11.2.6	Calculation and expression of results obtained with solid culture media.....	45
11.2.7	Calculations for enumeration methods.....	47
11.3	Enumeration using liquid media.....	54
11.3.1	Principle.....	54
11.3.2	General MPN procedure.....	54
11.3.3	Limitations of MPN.....	54
11.3.4	Inoculation procedure.....	55
11.3.5	Choice of MPN configuration.....	55
11.3.6	Incubation.....	56
11.3.7	Interpretation and expression of results.....	56
11.3.8	Determination of MPN values using MPN calculators.....	56
11.3.9	Rarity categories.....	57
11.4	Estimates of uncertainty of test results.....	57
<b>12</b>	<b>Detection (qualitative) methods.....</b>	<b>58</b>
12.1	General.....	58
12.2	Principle.....	58
<b>13</b>	<b>Confirmation and identification methods.....</b>	<b>58</b>
13.1	General.....	58
13.2	Preparation of a pure culture.....	59
13.3	Confirmation methods.....	59
13.3.1	Latex agglutination test.....	59
13.3.2	Nucleic acid hybridization or molecular amplification methods.....	59
13.3.3	Slide agglutination tests.....	60
13.4	Identification methods.....	60
13.4.1	Biochemical galleries.....	60
13.4.2	DNA sequencing.....	60
13.4.3	Mass spectrometry.....	61
<b>14</b>	<b>Selection and characterization of control microorganisms.....</b>	<b>61</b>
14.1	General.....	61
14.2	Characterization of microorganisms.....	62
14.2.1	General.....	62
14.2.2	Phenotypic characterization.....	62
14.2.3	Molecular characterization.....	62
14.3	Selection of control microorganisms.....	62
<b>15</b>	<b>Test report.....</b>	<b>63</b>
<b>16</b>	<b>Laboratory quality control in microbiology.....</b>	<b>64</b>
16.1	General.....	64
16.2	Internal quality control.....	65
16.2.1	General.....	65
16.2.2	Process controls.....	65
16.2.3	Replicate testing.....	66
16.2.4	Spiked samples.....	66
16.2.5	IQC assessment using control charts.....	66
16.3	External quality assessment.....	66

**17 Validation and verification of microbiological methods..... 67**  
17.1 General.....67  
17.2 Performance characteristics.....67  
17.3 Validation .....67  
17.4 Verification..... 68  
**Annex A (informative) Properties of disinfectants ..... 69**  
**Annex B (informative) Confidence intervals for colony count technique..... 70**  
**Annex C (normative) General confirmation tests ..... 73**  
**Bibliography..... 78**