

ISO 7218:2024-06 (E)

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

| Contents | | Page |
|---------------------|---|-------------|
| Foreword | | vii |
| Introduction | | viii |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 1 |
| 4 | Premises | 5 |
| 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 |
| 5 | Personnel | 8 |
| 5.1 | General | 8 |
| 5.2 | Competence | 8 |
| 5.3 | Verification of ongoing staff competence | 9 |
| 5.4 | Hygiene | 9 |
| 6 | Equipment and consumables | 9 |
| 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 |
| 7 | Sterilization/decontamination and disposal of laboratory materials..... | 34 |
| 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 |
| 8 | Preparation and use of culture media and reagents..... | 35 |
| 9 | Laboratory samples..... | 36 |
| 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 |
| 10 | Examination..... | 39 |
| 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 |
| 11 | Enumeration (quantitative) methods..... | 41 |
| 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 |
| 12 | Detection (qualitative) methods..... | 58 |
| 12.1 | General..... | 58 |
| 12.2 | Principle..... | 58 |
| 13 | Confirmation and identification methods..... | 58 |
| 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 |
| 14 | Selection and characterization of control microorganisms..... | 61 |
| 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 |
| 15 | Test report..... | 63 |
| 16 | Laboratory quality control in microbiology..... | 64 |
| 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 Validation67
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