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Microbiology of the food chain — Method validation —

Part 1: Vocabulary

Microbiologie de la chaîne alimentaire — Validation des méthodes — Partie 1: Vocabulaire

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Foreword

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The committee responsible for this document is ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*.

This first edition of ISO 16140-1, together with ISO 16140-2, cancels and replaces ISO 16140:2003, which has been technically revised. It also incorporates the Amendment ISO 16140:2003:Amd.1:2011.

ISO 16140 consists of the following parts, under the general title *Microbiology of the food chain — Method validation*:

— *Part 1: Vocabulary*

— *Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

The following parts are under preparation:

— *Part 3: Protocol for the verification of reference and validated alternative methods implemented in a single laboratory*

— *Part 4: Protocol for single-laboratory (in-house) method validation*

— *Part 5: Protocol for factorial interlaboratory validation of non-proprietary methods*

— *Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing*

Introduction

The use of validated methods is an important requirement for obtaining reliable results with a specific method. It also facilitates the comparability of results obtained with the same method in different laboratories. Validation procedures covered by ISO 16140 (all parts) involve various aspects of validation, such as validation of alternative (proprietary) methods, single laboratory validation, validation of (alternative) methods using a limited number of laboratories, and verification of methods (demonstration of a laboratory to correctly apply a validated method). In addition, there is a close link to ISO 17468 describing the procedure for the validation of the standard methods themselves.

Microbiology of the food chain — Method validation —

Part 1: Vocabulary

1 Scope

This part of ISO 16140 defines general terms and definitions relating to method validation of microbiology in the food chain.

This part of ISO 16140 is applicable to the validation of methods for the analysis (detection or quantification) of microorganisms in

— products intended for human consumption,

— products intended for animal feeding,

— environmental samples in the area of food and feed production, handling, and

— samples from the primary production stage.

2 Terms and definitions

2.1
acceptability limit
AL
maximum positive or negative acceptable difference between the *reference value* (2.60) (or if not known, the accepted reference value) of a *sample* (2.69) and an individual result obtained when applying the operating procedure of an analytical method

Note 1 to entry: Because *accuracy* (2.2) is defined as 'the closeness of agreement between a measured quantity value and an assigned quantity value of a measurand', acceptability limits can be interpreted as the maximum measure of the lack of accuracy for *quantitative methods* (2.57).

2.2
accuracy
measurement accuracy
closeness of agreement between a measured quantity value and an assigned quantity value of a measurand

Note 1 to entry: The concept 'measurement accuracy' is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: The term 'measurement accuracy' should not be used for measurement *trueness* (2.77) and the term measurement *precision* (2.51) should not be used for 'measurement accuracy', which, however, is related to both these concepts.

Note 3 to entry: 'Measurement accuracy' is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

[SOURCE: JCGM, 2012, modified]

2.3
accuracy profile
graphical representation of the capacity of measurement of the *quantitative method* (2.57), obtained by combining acceptability intervals and *β-expectation tolerance intervals* (2.8), both reported to different levels of the *reference value* (2.60)

Note 1 to entry: For a given measurement method, different accuracy profiles can be drawn, depending on the experimental design where data were collected: under *repeatability conditions* (2.64) or *reproducibility conditions* (2.67), for different matrices, etc.

Note 2 to entry: Calculations of accuracy profile elements depend on experimental design.

2.4
alternative method
method submitted for validation
method of analysis that detects or quantifies, for a given category of products, the same *analyte* (2.6) as is detected or quantified using the corresponding *reference method* (2.59)

Note 1 to entry: The method can be proprietary. The term 'alternative' is used to refer to the entire 'test procedure and reaction system'. This term includes all ingredients, whether material or otherwise, required for implementing the method.

2.5
alternative method result
final result of the qualitative or quantitative analysis for the *alternative method* (2.4)

2.6
analyte
component represented in the name of a measurable quantity

[SOURCE: ISO 17511:2003, 3.2]

Note 1 to entry: For food microbiology, this means a microorganism, group of microorganisms, or its products (e.g. toxins) quantified or detected by the method of analysis.

Note 2 to entry: Possible targets of the techniques that are used for detection or enumeration of the analyte can be DNA/RNA, proteins, lipopolysaccharides, or others.

2.7
assigned value
value that serves as an agreed-upon reference for comparison

Note 1 to entry: It is normally derived from or based on experimental work.

2.8
β-expectation tolerance interval
β-ETI
range of values within which a stated proportion of the population is expected to lie

Note 1 to entry: The stated proportion represents the probability that a value falls between an upper and lower bound of a distribution.

Note 2 to entry: Tolerance intervals tend towards a fixed value as the *sample* (2.69) size increases.

2.9
bias
measurement bias
estimate of a systematic measurement error, or the systematic difference between the quantitative *assigned value* (2.7) and the average of measurement *replicate* (2.65) results

2.10
blind replicates
set of *samples* (2.69) submitted to evaluate performance in which the presence and/or concentration of the *analyte* (2.6) is unknown to the analyst

Note 1 to entry: Within *validation* (2.81) studies, *blind replicates* (2.10) are used within the *interlaboratory study* (2.33). The *organizing laboratory* (2.45) prepares *samples* (2.69) and sends them to the *collaborators* (2.13). These samples are labelled (marked) in such a way that the *collaborator* (2.13) does not know if they contain the *analyte* (2.6), or not.

2.11
category
group of *sample* (2.69) *types* (2.78) of the same origin

EXAMPLE Heat-processed milk and dairy products.

2.12
certified reference material
CRM
reference material (2.58) characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

Note 1 to entry: Adapted from ISO Guide 30 and ISO Guide 35.

2.13
collaborator
individual laboratory technician, who works completely independently from other collaborators, using different sets of blind *samples* (2.69) or *test portions* (2.75)

2.14
combined standard deviation
combined standard uncertainty
standard measurement uncertainty that is obtained using the individual standard uncertainties associated with the input quantities in a measurement model

[SOURCE: JCGM, 2012, modified]

2.15
confidence interval
value $(1 - \alpha)$ of the probability associated with a confidence interval or a statistical coverage interval

EXAMPLE Confidence intervals can be obtained for arithmetic means, standard deviations, regression coefficients, etc.

Note 1 to entry: $(1 - \alpha)$ is often expressed as a percentage.

2.16
confidence level
specific probability of obtaining some result from a *sample* (2.69) if it did not exist in the population as a whole

Note 1 to entry: The usual levels of probability are 95 % or 99 %, but any level can be used.

2.17
confirmation procedure or test
procedure or test which is carried out to verify a presumptive result

Note 1 to entry: Not all methods have a confirmation procedure.

2.18
count
observed number of objects

EXAMPLE Colonies or plaques.

2.19
coverage factor
number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

[SOURCE: JCGM, 2012, modified]

2.20
detection level
<qualitative methods> minimum concentration of organisms that produce evidence of growth in a liquid medium with a probability of P = 0,95 when inoculated into a defined culture medium and incubated under defined conditions

Note 1 to entry: The theoretical level that conforms to this definition is three viable cells in an inoculum volume.

Note 2 to entry: The term '*sensitivity*' (2.71) is discouraged for detection level.

2.21
environmental sample
sample (2.69) from a surface of equipment or from the production environment, or from water used in the manufacturing process

2.22
exclusivity study
study involving pure *non-target strains* (2.44), which can be potentially cross-reactive, but are not expected to be detected or enumerated by the *alternative method* (2.4)

2.23
false-negative test result
negative result by the tested method that is actually confirmed as a positive result

2.24
false-positive test result
positive result by the tested method that is actually confirmed as a negative result

2.25
feed
feedstuff
any material or product intended to be, or reasonably expected to be, used for animal consumption

2.26
fitness for purpose
degree whether data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose

2.27
food
foodstuff
any material or product intended to be, or reasonably expected to be, used for human consumption

2.28
fractional recovery
validation (2.81) criterion that is satisfied when *replicate* (2.65) *samples* (2.69) of either the *alternative method* (2.4) or *reference method* (2.59) yield 50 % (range 25 % – 75 %) positive responses

2.29
homogeneity
condition of being of uniform structure or composition with respect to one or more specified properties

Note 1 to entry: A *reference material* (2.58) is said to be homogeneous with respect to a specified property if the property value, as determined by tests on *samples* (2.69) of specified size, is found to lie within the specified uncertainty limits, the samples being taken either from different supply units (bottles, packages, etc.) or from a single supply unit.

[SOURCE: ISO Guide 30:1992, 2.6]

2.30
identification procedure or test
procedure or test yielding the identity of the *analyte* (2.6)

2.31
inclusivity study
study involving pure *target strains* (2.74) to be detected or enumerated by the *alternative method* (2.4)

2.32
in-house reference material
IRM
non-certified material or substance, produced by one laboratory, one or more of whose property values are sufficiently homogeneous and well established to be used for *validation* (2.81)

2.33
interlaboratory study
study performed by multiple laboratories testing identical *samples* (2.69) at the same time, the results of which are used to estimate alternative-method performance parameters

Note 1 to entry: The aim of an interlaboratory study is to determine the variability of the results obtained in different laboratories using identical samples.

2.34
item
single specified *food* (2.27), *feed* (2.25), environmental, or primary production *matrix* (2.38)

EXAMPLE Food *category* (2.11): heat-processed milk and dairy products; food *type* (2.78): pasteurized dairy product; food item: milk-based desserts.

2.35
level of detection
LOD_x
<qualitative methods> measured *analyte* (2.6) concentration, obtained by a given measurement procedure, for which the *probability of detection* (2.53) is x

EXAMPLE LOD_{50} is the level of detection for which 50 % of tests give a positive result.

Note 1 to entry: The term 'level of detection' is used for qualitative methods in microbiology based on *replicate* (2.65) analyses with three different inoculation levels of the target *analyte* (2.6) in a tested *matrix* (2.38). The replicates are analysed, and the number of positive results is recorded (e.g. 20 %, 70 %, and 100 %) respectively at each inoculation level. These data are then used to determine the number of cells that would give 50 % positive using a generalized linear model (see ISO 16140-2). This differs from the procedure used for chemical and physical methods for which a 'limit of detection' is defined as the lowest quantity of an analyte that can be distinguished from the absence of that analyte with a stated *confidence level* (2.16).

2.36
limit of quantification
LOQ
limit of determination
<quantitative methods> lowest *analyte* (2.6) concentration that can be quantified with an acceptable level of *precision* (2.51) and *trueness* (2.77) under the conditions of the test

2.37
line of identity
two-dimensional Cartesian coordinate system, where the identity line is the $y = x$ line

2.38
matrix (product)
all the components of the *sample* (2.69)

2.39
method comparison study
study, performed by the *organizing laboratory* (2.45) to compare the *alternative method* (2.4) with the *reference method* (2.59)

2.40
negative agreement
NA
agreement when the qualitative *alternative method* (2.4) and *reference method* (2.59) both present a *negative test result* (2.43)

2.41
negative control
sample (2.69) in which the target *analyte* (2.6) is either absent or below the *detection level* (2.20) of the method used

2.42
negative deviation
ND
negative result of the *alternative method* (2.4) when the corresponding *reference method* (2.59) result is positive

2.43
negative test result
test result (2.76) indicating the *analyte* (2.6) was not detected in a given *test portion* (2.75) as defined by the procedure of the *qualitative method* (2.56)

2.44
non-target strain
strain, defined according to the scope of the *reference method* (2.59) that would not reasonably be expected to be detected or enumerated by the *alternative method* (2.4)

2.45
organizing laboratory
expert laboratory
independent laboratory
laboratory with responsibility for managing all of the technical and statistical activities involved in the *validation* (2.81) study, i.e. *method comparison study* (2.39) and the *interlaboratory study* (2.33)

Note 1 to entry: The organizing laboratory is not involved in development and/or marketing of a *proprietary method* (2.55) that they will be validating.

2.46
outlier
member of a set of values which is inconsistent with other members of that set

[SOURCE: ISO 5725-1:1994, 3.21, modified]

Note 1 to entry: This extreme value normally appears randomly in less than 1 % of repetitive tests, but more frequently if abnormal situations occur. Statistical test procedures can be used to quantify this probability.

2.47
paired study
paired/matched data
study when the qualitative *reference method* (2.59) and *alternative method* (2.4) have a common first enrichment step

Note 1 to entry: In this case, only one *test portion* (2.75) of a *sample* (2.69) is used to obtain a result with the *reference method* (2.59) and the *alternative method* (2.4). The incubated broth is then used in the second procedure step of both the reference method and the alternative method. The results from both methods are strongly dependent upon each other.

2.48
positive agreement
PA
qualitative *alternative method* (2.4) and *reference method* (2.59) both present a confirmed *positive test result* (2.50) (confirmed positive results)

2.49
positive deviation
PD
(confirmed) positive result of the *alternative method* (2.4) when the corresponding *reference method* (2.59) result is negative

2.50
positive test result
test result (2.76) indicating the presence of the *analyte* (2.6) in a given *test portion* (2.75) as defined by the procedure of the method

Note 1 to entry: When the *reference method* (2.59) or *alternative method* (2.4) provides a preliminary positive test result requiring further testing to confirm this result, this test result can be considered as a presumptive positive test result. If the further testing specified by the method's procedure confirms that the test result can indeed be considered as being positive, the test result can be considered as a confirmed positive test result.

2.51
precision
measurement precision
closeness of agreement between indications or measured quantity values obtained by *replicate* (2.65) measurements on the same or similar objects under specified conditions

Note 1 to entry: Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.

Note 2 to entry: The 'specified conditions' can be, for example, *repeatability conditions* (2.64) of measurement, intermediate precision conditions of measurement, or *reproducibility conditions* (2.67) of measurement (see ISO 5725-3).

Note 3 to entry: Measurement precision is used to define measurement repeatability, intermediate measurement precision, and measurement *reproducibility* (2.66).

Note 4 to entry: Sometimes, 'measurement precision' is erroneously used to mean measurement accuracy.

2.52
primary production sample
sample (2.69) of animal faeces, or from the environment of animals or non-faecal samples from breeding flocks

2.53
probability of detection
POD
proportion of positive analytical outcomes for a *qualitative method* (2.56) for a given *matrix* (2.38) at a given *analyte* (2.6) level or concentration

2.54
processing
any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion, or a combination of those processes

Note 1 to entry: Processed products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

2.55
proprietary method
method with a trademark/brand name, which is owned and generally marketed by a commercial company

EXAMPLE Enzyme-linked immunosorbent assay (ELISA) or polymerase chain reaction (PCR) methods.

Note 1 to entry: Generally, some of the components of the method are undisclosed.

2.56
qualitative method
method of analysis whose response is that the *analyte* (2.6) is either detected or not detected, either directly or indirectly in a specified *test portion* (2.75)

2.57
quantitative method
method of analysis whose response is the amount [*count* (2.18) or mass] of the *analyte* (2.6) measured either directly (e.g. enumeration in a mass or a volume), or indirectly (e.g. colour absorbance, impedance, etc.) in a specified *test portion* (2.75)

2.58
reference material
RM
material or substance whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials

[SOURCE: ISO Guide 30:1992, 2.1, modified]

2.59
reference method
internationally recognized and widely accepted method

Note 1 to entry: For the purpose of this part of ISO 16140, these are ISO standards and standards jointly published by ISO and CEN or other regional/national standards of equivalent standing.

2.60
reference value
quantity value used as a basis for comparison with values of quantities of the same kind

[SOURCE: JCGM, 2012, modified]

2.61
relative level of detection
RLOD
level of detection (2.35) at $P = 0{,}50$ (LOD_{50}) of the (proprietary) *alternative method* (2.4) divided by the level of detection at $P = 0{,}50$ (LOD_{50}) of the *reference method* (2.59)

Note 1 to entry: For the purposes of alternative-method acceptance, the derived RLOD is checked with the *acceptability limit* (2.1) for conformity.

2.62
relative trueness
RT
degree of correspondence between the response obtained by the *reference method* (2.59) and the response obtained by the *alternative method* (2.4) on identical *samples* (2.69)

2.63
repeatability
measurement repeatability
r
measurement precision under a set of *repeatability conditions* (2.64) of measurement

[SOURCE: JCGM, 2012, modified]

2.64
repeatability conditions
repeatability condition of measurement
condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time

[SOURCE: JCGM, 2012, modified]

Note 1 to entry: A condition of measurement is a repeatability condition only with respect to a specified set of repeatability conditions.

Note 2 to entry: In chemistry, the term 'intra-serial precision condition of measurement' is sometimes used to designate this concept.

2.65
replicate
repeating the analysis from different portions of the same *sample* (2.69) to obtain an independent measurement

2.66
reproducibility
measurement reproducibility
R
measurement precision under *reproducibility conditions* (2.67) of measurement

[SOURCE: JCGM, 2012, modified]

Note 1 to entry: Relevant statistical terms are given in ISO 5725-1 and ISO 5725-2.

2.67
reproducibility conditions
reproducibility condition of measurement
condition of measurement, out of a set of conditions that includes different locations, operators, measuring systems, and *replicate* (2.65) measurements on the same or similar objects

Note 1 to entry: The different measuring systems may use different measurement procedures.

Note 2 to entry: A specification should give the conditions changed and unchanged (to a practical extent).

[SOURCE: JCGM, 2012, modified]

2.68
reproducibility standard deviation
standard deviation of *test results* (2.76) obtained under *reproducibility conditions* (2.67)

[SOURCE: ISO 5725-1:1994, 3.19]

2.69
sample
food (2.27), *feed* (2.25), environmental, or primary production specified *item* (2.34) to be included in the *validation* (2.81) as per the intended use of the method

EXAMPLE Food *category* (2.11): heat processed milk and dairy products; food *type* (2.78): pasteurized dairy product; food *item* (2.34): milk-based desserts; sample: vanilla ice cream.

2.70
scope of validation
analytes (2.6), matrices, and concentrations for which a validated method of analysis can be used satisfactorily

2.71
sensitivity
SE
ability of the *reference method* (2.59) or *alternative method* (2.4) to detect the *analyte* (2.6)

2.72
specificity
SP
ability of the *reference method* (2.59) or *alternative method* (2.4) not to detect the *analyte* (2.6)

2.73
systematic error
systematic measurement error
component of measurement error that, in *replicate* (2.65) measurements, remains constant or varies in a predictable manner

Note 1 to entry: An assigned quantity value for a systematic measurement error is a quantity value, or a measured quantity value of a measurement standard of negligible measurement uncertainty, or a conventional quantity value.

2.74
target strain
strain, defined according to the scope of the *reference method* (2.59) that is expected to be detected or enumerated by the *alternative method* (2.4)

2.75
test portion
specified quantity of the *sample* (2.69) that is taken for analysis, e.g. 10 g, 25 g, 375 g of samples, or sponges for *environmental samples* (2.21), or boot socks for *primary production samples* (2.52)

2.76
test result
outcome of an analytical procedure or method

2.77
trueness
measurement trueness
closeness of agreement between the average of an infinite number of *replicate* (2.65) measured quantity values and a reference quantity value

Note 1 to entry: Measurement trueness is not a quantity and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725 (all parts).

Note 2 to entry: Measurement trueness is inversely related to systematic measurement error, but is not related to random measurement error.

Note 3 to entry: Measurement accuracy should not be used for 'measurement trueness' and vice versa.

[SOURCE: JCGM, 2012, modified]

2.78
type
for a given *category* (2.11), a group of *items* (2.34) processed in a similar way, with similar intrinsic characteristics and a similar microbial ecology

EXAMPLE Food *category* (2.11): heat-processed milk and dairy products; food type: pasteurized dairy product.

2.79
unpaired study
unpaired/unmatched data
study when the qualitative *reference method* (2.59) and *alternative method* (2.4) have no common first enrichment step

Note 1 to entry: In this case, both the reference and alternative method use their own *test portion* (2.75) from a *sample* (2.69). These *test portions* (2.75) originate from the same sample. The resulting data are called unpaired but are matched at the level of the sample. The results are still dependent upon each other as they originate from the same sample but due to the normal variation between test portions at a very low level of contamination, one test portion can be contaminated (and thus leads to a positive result) and the other test portion might not be contaminated (and thus does not lead to a positive result). The expected variation between results is, therefore, larger than for a *paired study* (2.47).

2.80
unprocessed products
food (2.27) and *feedstuffs* (2.25) that have not undergone *processing* (2.54), and include products that have been divided, parted, severed, sliced, boned, etc.

EXAMPLE Unprocessed meat means meat that has not undergone any preserving process.

2.81
validation
establishment of the performance characteristics of a method and provision of objective evidence that the performance requirements for a specified intended use are fulfilled

2.82
validation sample
homogeneous naturally or artificially contaminated material with a known *assigned value* (2.7) used for a *validation* (2.81) study

Note 1 to entry: A validation sample can also be a known blank *sample* (2.69).

2.83
verification
demonstration that a validated method functions in the user's hands according to the method's specifications determined in the *validation* (2.81) study and is fit for its purpose

Note 1 to entry: Verification can also be applied to non-validated standardized *reference methods* (2.59).

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Price group A