

Analisi Normativa

Regolamento CE 2073 2005

Articolo 5

Norme specifiche per le analisi e il campionamento

1. I metodi di analisi e i piani e metodi di campionamento di cui all'allegato I sono applicati come metodi di riferimento.

2. Se necessario per verificare il rispetto dei criteri, sono prelevati campioni dalle aree e dalle attrezzature in cui avviene la lavorazione degli alimenti, impiegando come metodo di riferimento la norma ISO 18593

[...]

4. Quando lo scopo delle prove è di valutare in modo specifico l'accettabilità di una determinata partita di prodotti alimentari o di un processo, la condizione minima richiesta è il rispetto dei piani di campionamento di cui all'allegato I.

5. Gli operatori del settore alimentare possono ricorrere ad altre procedure di campionamento e di prova, a condizione di dimostrare, con soddisfazione dell'autorità competente, che tali procedure forniscono garanzie almeno equivalenti. Tali procedure possono includere l'uso di siti di campionamento alternativi e di analisi degli andamenti

[...]

L'impiego di metodi d'analisi alternativi è accettabile quando tali metodi sono validati in base al metodo di riferimento di cui all'allegato I e se è utilizzato un metodo proprietario certificato da una terza parte in base al protocollo definito nella norma EN/ISO 16140 o ad altri protocolli analoghi accettati a livello internazionale.

Qualora l'operatore del settore alimentare intenda applicare metodi analitici diversi da quelli validati e certificati come indicato al terzo comma, tali metodi sono validati in base a protocolli riconosciuti a livello internazionale e il loro impiego è autorizzato dall'autorità competente.

ISO IEC 17025:2005

1 Scope

1.1 This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

5.4.2 Selection of methods

The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. **Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen.** The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.

NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:

- a) appropriate identification;
- b) scope;
- c) description of the type of item to be tested or calibrated;
- d) parameters or quantities and ranges to be determined;
- e) apparatus and equipment, including technical performance requirements;
- f) reference standards and reference materials required;

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- g) environmental conditions required and any stabilization period needed;*
- h) description of the procedure, including*
 - affixing of identification marks, handling, transporting, storing and preparation of items,*
 - checks to be made before the work is started,*
 - checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,*
 - the method of recording the observations and results,*
 - any safety measures to be observed;*
- i) criteria and/or requirements for approval/rejection;*
- j) data to be recorded and method of analysis and presentation;*
- k) the uncertainty or the procedure for estimating uncertainty.*

5.4.5 Validation of methods

5.4.5.1 *Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.*

5.4.5.2 *The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.*

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- calibration using reference standards or reference materials;*
- comparison of results achieved with other methods;*
- interlaboratory comparisons;*
- systematic assessment of the factors influencing the result;*
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.*

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

5.4.5.3 *The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-*

sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

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