NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 5009.295-2023

National food safety standard - General rules for verification of chemical analysis methods

食品安全国家标准 化学分析方法验证通则

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Foreword

This document was issued on 6 September 2023 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 6 September 2024.

It is a GB standard without the /T suffix: compliance is mandatory in China.

1 Scope

GB 5009.295-2023 governs the evidence a chemical analysis method has to produce before it is written into the national food safety standard series and relied on in testing. The vocabulary is fixed first, and it is the part laboratories argue about: method validation, qualitative and quantitative methods, the concentration paid attention to, specificity, detection limit, limit of quantification, measuring range, accuracy, repeatability, reproducibility, intermediate precision, stability, robustness, linear range and detection probability. General requirements follow - which performance parameters a given method must be examined against, how representative foods are selected for the trial, what the validation samples have to satisfy, and how the resulting data are processed. The validation clause then takes each parameter in turn, from specificity through to robustness, and adds the separate case of proving one method equivalent to another. Annex A classifies food samples for validation purposes; Annex B covers the robustness test. Without a common procedure a method looks sound in the laboratory that developed it and falls apart on a different matrix or in a different pair of hands, and a disputed result turns into an argument about the method rather than about the food. For method developers, food inspection laboratories, accreditation assessors and the technical committees that adopt methods into the series.

This Standard specifies the general requirements for the validation of national food safety standard -- chemical analysis methods.

This Standard is applicable to the validation process during the development and revision of national food safety standard -- chemical analysis methods.

2 Terms and definitions

2.1 Method validation

Test activities that provide objective and valid evidence to confirm that the performance parameters of an analytical method meet the intended use of the method.

2.2 Qualitative method

An analytical method that identifies the presence or absence of a target analyte in a sample based on its specific properties.

2.3 Quantitative method

An analytical method that determines the concentration or amount of target analytes under conditions that meet specified precision and accuracy.

2.4 Concentration paid attention to

The concentration that is decisive for determining whether the target analyte in the sample meets the requirements of regulations or standards.

2.5 Specificity

The ability of an analytical method to distinguish between target analytes and interfering substances.

2.14 Intermediate precision

In the same laboratory, over a long period of time (pay attention to small changes in test conditions, such as temperature, humidity, light, etc.), the precision of independent measurement results obtained by using the same method to test the same sample.

2.15 Linear range

Under a certain level of significance, a linear calculation model is used to define the relationship between instrument response and concentration (or amount), which conforms to the interval between the lowest concentration (or amount) and the highest concentration (or amount) of the calculation model.

2.16 Detection probability

The probability that an analytical method will detect the target analyte at a specified concentration and confidence level.

3 General requirements for validation of chemical analysis

methods

3.1 Selection of performance parameters

3.1.1 For qualitative methods, intra-laboratory and inter-laboratory validation parameters shall include method specificity and detection limit.

3.1.2 For quantitative methods, laboratory validation parameters shall include method specificity, detection limit, quantitation limit, measurement range, accuracy, and repeatability. Interlaboratory validation parameters shall include the detection limit, quantification limit, determination range, correctness and reproducibility of the method.

3.1.3 When the analysis method is sensitive to small changes in test conditions such as temperature, humidity, and lighting, the robustness of the method shall be examined, and the intermediate precision index shall be calculated.

3.1.4 When there are two or more methods with the same applicable scope for the same target analyte, the equivalence of the different methods needs to be validated.

3.1.5 When literature data on the stability of a reference material are lacking, its stability shall be validated.

3.1.6 Selection of intra-laboratory and inter-laboratory validation parameters is shown use of the method.

b) For a sample matrix, at least 3 concentration levels are required, including the lowest concentration, the middle concentration (generally the concentration of concern) and the highest concentration of the method's determination range. Their uniformity and stability are tested.

3.3.4 When selecting a standard addition sample for validation, the validation sample can be prepared as follows.

a) The sample matrix shall be selected to be representative and meet the intended use of the method.

b) For a sample matrix, at least 3 concentration addition levels are required, including the lowest concentration, the middle concentration (generally the