



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 31604.59-2023

**National food safety standard - Food contact materials and
products - General rules for verification of chemical analysis
methods**

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Table of Contents

1 Scope	3
2 Terms and Definitions	3

1 Scope

This Standard specifies general requirements for the verification of chemical analysis methods for food contact materials and products.

This Standard is applicable to the verification of the formulation and revision process of chemical analysis methods for food contact materials and products in national food safety standards.

2 Terms and Definitions

What is defined in GB 5009.295-2023 and the following terms and definitions are applicable to this document.

2.1 Chemical Alternative Solvents

Chemical solvents used to replace oil-containing food simulants (vegetable oil) in chemical solvent substitution test, such as. 95% (volume fraction) ethanol solution, isooctane, n-hexane and n-heptane, etc.

2.2 Soaking Solution

The solution obtained after food contact materials and products undergo a migration test with food simulants or chemical alternative solvents.

3 General Requirements for the Verification of Chemical

Analysis Methods for Food Contact Materials and Products

3.1 For qualitative method, intra-laboratory and inter-laboratory verification parameters shall

include the specificity and detection limit of the method.

3.2 For quantitative method, intra-laboratory verification parameters shall include the

specificity, detection limit, quantification limit, determination range, accuracy and repeatability of the method; inter-laboratory verification parameters shall include the detection limit, quantification limit, determination range, accuracy and reproducibility of the method.

each type of food contact materials, select at least one subtype of food contact materials. For each subtype, select at least one representative material (or product).

4.1.1.4 When selecting composite materials and products for food contact for the method

verification, the number of types of food contact materials covered shall be calculated based on the types corresponding to the materials of each layer within the effective barrier layer.

4.1.2.1 Verification samples can be selected from certified reference materials / standard

samples, quality control samples that comply with the proficiency verification requirements, or standard addition samples.

4.1.2.2 When selecting certified reference materials / standard samples for verification, there

shall be at least 3 concentration levels, including the lowest concentration, intermediate concentration (generally, the concentration of concern) and the highest concentration of the determination range of the method.

4.1.2.3 When selecting quality control samples that comply with the proficiency verification

requirements, the verification samples must satisfy the following conditions.

- a) The selection of sample matrix shall be representative and satisfy the expected use of the method;
- b) For a sample matrix, at least 3 concentration addition levels are required, including the lowest concentration, intermediate concentration (generally, the concentration of concern) and the highest concentration of the determination range of the method. In addition, their uniformity and stability shall be tested.

4.1.2.4 When selecting standard addition samples for verification, the verification samples can

be prepared in accordance with the following method.

- a) The selection of sample matrix shall be representative and satisfy the expected use of the method;
- b) For the selected representative material (or product), after homogenizing it in accordance with the method, add the target analyte to it. At least 3 concentrations are required to be added, including the lowest concentration, intermediate concentration (generally, the concentration of concern) and the highest concentration of the determination range of the method.

4.1.3.1 When it is necessary to send and transport the verification samples, each sample shall

be individually sealed and packaged, and the packaging used shall not contain substances that may affect the detection of the target analyte. Severe friction or collision of samples during transportation shall be avoided.

4.1.3.2 If the target analyte is a volatile substance, effective measures shall be taken to avoid

losses caused by the volatilization of the target analyte during the transportation of the samples, such as. multiple sealing of the samples and maintaining at a low temperature, etc.

4.2.1.1 Verification requirements

The analysis method's capability of distinguishing the target analyte from other substances (including but not limited to impurity components, such as. isomers and homologues that may be included in the industrial grade target analyte, and oxidation / reduction / decomposition / hydrolysis / pyrolysis that may occur during industrial production of the target analyte, as well as matrix components, etc.) shall be verified. There shall be no interference factors (signals and interference peaks, etc.) that may lead to errors in the qualitative determination of the target analyte and affect the accuracy of the quantitative determination.

4.2.1.2 Verification method

Analyze representative samples that match the scope of application of the method, and check whether there are interferences (signals and peaks, etc.) that may lead to errors in the qualitative determination of the target analyte and / or affect the accuracy of the quantitative determination;

add a certain concentration of substances that may interfere with the qualitative and / or quantitative determination of the target analyte to the representative materials (or products), then, perform analysis to check whether these interfering substances can be

effectively identified.

4.2.2.1 Verification requirements

The detection probability of the target analyte at the detection limit level shall be not lower than 95% (at the 95% confidence level); the detection limit of each representative material (or product) needs to be independently verified.

4.2.2.2.1 Estimation methods

The estimation methods for the detection limit include.

a) Signal-to-noise ratio method (applicable to spectroscopy, chromatography and mass spectrometry). add the target analyte to the blank sample matrix, and take the addition concentration when the signal-to-noise ratio is 3 as the estimated detection limit;

b) Blank standard deviation method (applicable to non-zero response values of blank samples). by analyzing a large number of sample blanks, determine the detection limit.

The number of independent tests shall be no less than 10 times ($n \geq 10$). Calculate the standard deviation of the sample blank response values. The concentration corresponding to the average value of the sample blank response values plus 3 times the standard deviation is the estimated detection limit;

c) Calibration equation estimation method (applicable to instrumental method). if sample data at or near the detection limit cannot be obtained, take $3S/b$ (S is the standard deviation of the calibration curve, and b is the slope of the calibration curve)

as the estimated detection limit;

d) Stepwise dilution method (applicable to all methods). at certain concentration intervals, conduct stepwise dilution on the target analyte; in accordance with the method to be verified, perform the detection. The concentration, at which the target analyte can be detected, is the estimated detection limit.

4.2.2.2.2 Determination method

Select representative materials (or products) of the matrix blank, each containing at least 20 parallel samples. Respectively add target analytes with estimated detection limit concentrations.

When the detection probability of the target analyte is not lower than 95%, it is determined as the detection limit; when it is impossible to obtain the matrix blank sample of a certain representative material (or product), a matrix blank sample of the same material type and for non-food contact use can be used for verification; when the matrix blank sample of all representative materials (or products) cannot be obtained, isotope-labeled compounds or structural analogs of the target analyte can be used for verification.