National Standard of the People's Republic of China

GB 4789.1 – 2010

National Food Safety Standard
Food Microbiological Examination: General Guidelines

Issued on March 26th, 2010 Implemented on June 1st, 2010

Issued by the Ministry of Health of the People's Republic of China

Preface

This Standard replaces GB/T 4789.1-2008 *Food Microbiological Examination: General Guidelines.*

Compared with GB/T 4789.1-2008, the main changes are as follows:

——Change the Chinese and English titles of the Standard;

——Change the selection of analytical methods.

The issuance status of all the previous editions replaced by this Standard is:

—— **GB 4789.1 – 1984, GB 4789.1 – 1994, GB/T 4789.1 – 2003 and GB/T 4789.1 – 2008.**

National Food Safety Standard
Food Microbiological Examination: General Guidelines

1 Scope

This Standard specifies the basic principles and requirements of food microbiological examination.

This Standard is applicable to food microbiological examination.

2 Cited Normative Documents

The cited normative documents are indispensable for the application of this Standard. For the cited documents indicated with date, all of its subsequent amendment lists (not including errata) or revisions are not applicable to this Standard. The latest versions including all subsequent amendment lists of all cited documents without date indicated are applicable to this Standard.

3 Basic Requirements of Laboratory

3.1 Environment

3.1.1 The laboratory environment shall not impact the accuracy of the test results.

3.1.2 The working and office regions shall be clearly separated from each other.

3.1.3 The working area and general layout of the laboratory shall meet the requirements of testing. The laboratory layout shall be arranged in single-way flowing direction according to the working process, so as to avoid cross-contamination.

3.1.4 The ambient temperature, humidity, illuminance, noise level and cleanliness etc in the laboratory shall meet the working requirements.

3.1.5 Generally, sample examination shall be carried out in clean area (including super-clean work bench or clean laboratory) with obvious signs.

3.1.6 The separation and identification of pathogenic micro-organism shall be carried out in Biosafety Level 2 laboratory (BSL-2).

3.2 Personnel

3.2.1 The analyst shall have adequate education, microbiological professional training and related qualification, and be able to understand and implement the examination correctly.

3.2.2 The analyst shall master the knowledge of safe operation and disinfection for biological examination in laboratory.

3.2.3 During the whole examination, the analyst shall keep personal neatness and sanitation to prevent man-made pollution of the sample.

3.2.4 The analyst shall comply with related regulation requirement of prevention measures to ensure his/her own security.

3.2.5 The analyst with color vision disorder is prohibited from carrying out any color discrimination-involving examination.

3.3 Equipment

3.3.1 The laboratory equipment shall meet the requirements of the examination.

3.3.2 The laboratory equipment shall be placed in suitable locations. The equipment shall be appropriately designed to meet the needs of convenient maintenance, cleaning, disinfection and calibration. The equipment shall be kept under neat and good working status.

3.3.3 The laboratory equipment shall be checked and calibrated (with appropriate label), repaired and maintained periodically to assure their working functions and operational security.

3.3.4 Routine monitoring and application records of the laboratory equipment shall be kept as required.

3.4 Utility for Examination

3.4.1 The routine utilities include inoculation ring or needle, alcohol lamp, forceps, scissors, spoon, sterilized tampon, silica or cotton plug, micropipettor, pipettor, suction ball, test tub, plate, microplate, jar, graduated cylinder, glass rot and L-type glass rod, etc.

3.4.2 All utilities shall be kept under clean and/or sterile status before application. The routine sterilization methods include moist heat sterilization, dry heat sterilization and chemical sterilization, etc.

3.4.3 The utilities for sterilization shall be placed in specified container or packaged/covered with suitable materials, such as special packaging paper or aluminum foil etc, to assure the sterilization effect.

3.4.4 Disposable supplies suitable for microbiological examination can be selected to replace those utilities and materials for repeated use, such as Petri dish, pipettor, dropper, test tub, inoculation ring and so on.

3.4.5 The storage condition of utilities shall be kept dry and clean. Those sterilized and to be sterilized shall be stored separately and with clear status labels.

3.4.6 The temperature and duration of sterilization/disinfection of utilities for microbiological examination shall be recorded.

3.5 Culture Medium and Reagent

3.5.1 Culture Medium

The preparation and quality control of the culture medium shall be carried out according to the procedure specified in GB/T 4789.28.

3.5.2 Reagent

The quality and preparation of test reagents shall be suitable for their intended use. Suitability test shall be carried out for the critical reagents, which have important affect on examination results.

3.6 Strains

3.6.1 Only standard or reference strains stored by professional storage institutes of microbiological strains or other institutes with peer recognition are allowed to be used, with the original source traceable.

3.6.2 For those original separated strains/wild strains that were separated, purified and identified from food, environment and human body, and have not been registered by professional storage institutes of microbiological strains, there shall be systemic and integrated information record, including separation time, source, main features of phenotypic and molecular identification.

3.6.3 The laboratory shall keep adequate standard or reference strains meeting application requirements. During purchasing and generation passage, validation tests shall be carried out and documented.

4 Sample Collection

4.1 Sampling Principle

4.1.1 Sampling plan shall be determined according to the examination objective, food features, batch amount, analytical method and harmful levels of microbial, etc.

4.1.2 Random principle shall be complied during sampling in order to ensure representative samples.

4.1.3 Sterile operation procedure shall be followed during sampling, in order to prevent all potential foreign pollution.

4.1.4 During the storage and transport of the sample, necessary measures shall be carried out to prevent the microbial count change in the sample and to keep the original sample status.

4.2 Sampling Plan

4.2.1 Type

The sampling plan can be classified as Grade 2 and Grade 3. In Grade 2 sampling plan, n, c and m values shall be set; while in Grade 3, n, c, m and M values shall be set.

n: Sample number to be collected from one batch;

c: Max. sample number allowed to excess m value;

m: Acceptance criteria of the microbial test item;

M: Max. security limit of the microbial test item.

Note 1: According to the limit of Grade 2 sampling plan, among n samples, the examination result of microbial test item not more than c samples are allowed to exceed m.

Note 2: According to the limit of Grade 3 sampling plan, among n samples, the examination result of microbial test item of all samples are allowed to be not more than m; the item that is not more than c samples is allowed to range between m and M; no item is allowed to be more than M.

Example: n=5, c=2, m=100 CFU/g, M=1000 CFU/g. That is, five samples are collected from one batch. If the test results of five samples are all less than or equal to m (≤100 CFU/g), such condition is allowed; if the test results of one or two samples range between m and M (100 CFU/g＜X≤1000 CFU/g), such condition is also allowed; if the test results of three or more than three samples range between m and M, such condition is not allowed; if the test result of any sample exceeds M (＞1000 CFU/g), such condition is not allowed either.

4.2.2 Sampling Plan for Different Kinds of Food

Related product specification shall be applied for implementation.

4.2.3 Food Sampling Plan during Foodborne Diseases or Food Safety Incidents

4.2.3.1 During foodborne diseases or food safety incidents caused by pollution of industrial manufactured food, the collection and determination principles of food samples shall be carried out according to Paragraph 4.2.1 and 4.2.2. At the same time, rest food samples on the spot shall be collected.

4.2.3.2 During foodborne diseases or food safety incidents caused by catering units or family cooking, the collection of food samples shall be carried out according the requirement of the hygiene inspection in GB 14938, in order to meet the requirements of cause determination and pathogen confirmation of the foodborne diseases or food safety incidents.

4.3 Sampling Methods of Different Kinds of Food

Sampling shall comply with the sterile operation procedures. Sampling tools and containers shall be sterile, dry, leak-proof and with suitable shape and size.

4.3.1 Instant Pre-Packaged Food

Collect the min. original retail packages. Before examination, the integration of package shall be kept to

avoid pollution.

4.3.2 Non-RTE Pre-Packaged Food

If the original package size is below 500g (for solid food) or 500ml (for liquid food), collect the min. original retail packages; for liquid food above 500ml per package, the liquid shall be shaken or stirred with sterile rod before sampling, and then collect above 5 times amount of examination units of the sample from n containers for one batch after homogenization. For solid food above 500g per package, collect adequate sample with sterile sampler from different parts of the same package and transfer them into one sterile container. And the total sampling amount shall meet the requirement of microbial test items.

4.3.3 Bulk Food or On-Site Produced Food

According to the required examination amount for different kinds and status of food and related analytical method, collect on-site above 5 times amount of examination units of the sample, and then transfer them into a sterile container. And the total sampling amount shall meet the requirement of microbial test items.

4.3.4 Food Sample Related to Foodborne Diseases or Food Safety Incidents

The sample amount shall be adequate according to the requirement of examination for the diagnosis of foodborne diseases and the cause determination of food safety incidents.

4.4 Mark of Collected Sample

Record and sample marking shall be carried out timely and accurately during sampling. The operator shall file the sampling record clearly, including operator, sampling location, time, sample name, source, batch number, amount, storage condition and so on.

4.5 Storage and Transport of Collected Sample

After sampling, the collected sample shall be sent to the laboratory for examination at a storage temperature similar to the original as soon as possible. During transport, the integration of sample shall be kept. If the transport is delayed, the sample shall be stored at a similar temperature to the original.

5 Sample Examination

5.1 Sample Disposal

5.1.1 The sample for examination shall be checked and registered carefully once received by the laboratory.

5.1.2 The examination shall be carried out according related requirement as soon as possible. If the examination is delayed, necessary protection measures shall be carried out to keep the original sample status and prevent change of target microbial count caused by external factors.

5.1.3 Before examination, frozen food shall be thawed at a temperature below 45℃ for less than 15min or at 2℃-5℃ for less than 18h.

5.2 Selection of Analytical Method

5.2.1 Current effective national standard methods shall be selected.

5.2.2 If there are two or more qualitative analytical methods in the food microbiological examination standard, the conventional culture method shall be taken as the basic method.

5.2.3 If there are two or more quantitative analytical methods in food microbiological examination standard, the plate count method shall be taken as the basic method.

6 Biosafety and Quality Control

6.1 Biosafety Requirement of Laboratory

The specified requirement in GB 19489 shall be applied.

6.2 Quality Control

6.2.1 Positive control, negative control and blank control shall be set periodically for experimental strains, culture medium, and reagents.

6.2.2 Instrument control and comparison shall be set for important analytical instruments, especially automatic instruments.

6.2.3 Technical assessment and personnel comparison shall be carried out periodically among analysts.

7 Record and Report

7.1 Record

All information such as observed phenomenon, results and data obtained shall be recorded instantaneously and correctly during examination.

7.2 Report

Results of each examination item shall be reported correctly and objectively according to the requirements in analytical methods.

8 Disposal of Sample Left after Examination

8.1 Only after the examination results have been reported, can the rest sample be disposed. If any pathogens are detected, innocuous disposal shall be carried out for related sample.

8.2 After the examination results have been reported, the rest samples or samples from the same batch shall not be used in the retest of microbial examination items.