



National Standard of the People's Republic of China

GB 4789.1-2016

National Food Safety Standard Food Microbiological Examination-General Rules

食品安全国家标准

食品微生物学检验总则

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Foreword

This standard replaces GB 4789.1-2010 “National food safety standard Food microbiological examination-General rules.

Compared with GB 4789.1-2010, the major changes of this standard are as follows:

- Additional appendix A, routine laboratory supplies and equipment for microbiology laboratories have been added;
- Basic requirements of the laboratory have been revised;
- Sample Collection has been revised;
- Examination has been revised;
- Treatment of the samples after examination has been revised;
- Normative Reference documents have been deleted.

National Food Safety Standard

Food Microbiological Examination-General Rules

1. Scope

This standard sets out the basic principles and requirements of microbiological test of food.

This standard is applicable to microbiological test of food.

2. Basic Laboratory Requirements

2.1 Inspectors

2.1.1 The inspectors shall have the corresponding professional education or training experience of microbiology and related qualification, and be able to understand and implement the examination correctly.

2.1.2 The inspectors shall master the knowledge of safety operation and disinfection for biological examination in laboratory.

2.1.3 Personal cleanliness and hygiene shall be maintained during the examination to prevent the sample from man-made contaminant.

2.1.4 The inspectors shall comply with the provisions of relevant security measures during the examination to ensure his/her own security.

2.1.5 The inspectors with color vision disorder are prohibited from carrying out any color discrimination-involving examination.

2.2 Environment and facilities

2.2.1 The laboratory environment shall not affect the accuracy of the test results.

2.2.2 The laboratory area shall be clearly separated from the office area.

2.2.3 The working area and general layout of the laboratory shall meet the examination requirements. The laboratory layout shall apply single-direction workflow to avoid cross-contamination.

2.2.4 The temperature, humidity, cleanliness, and illumination as well as noise level in laboratory shall meet the working requirements.

2.2.5 Food sample examination shall be conducted in clean area where shall be indicated with obvious signs.

2.2.6 The separation and identification of pathogenic micro-organism shall be carried out in Biosafety laboratory at Level II or higher level.

2.3 Laboratory equipment

2.3.1 The laboratory equipment shall meet the requirements of the examination. See A.1 for common equipment.

2.3.2 The laboratory equipment shall be placed under appropriate environmental conditions so as to make its maintenance, cleaning, disinfection and calibration easy, keep it neat and make it work in good condition.

2.3.3 The laboratory equipment shall be inspected and/or calibrated (labeled with mark), repaired and maintained regularly to ensure working performance and operational security.

2.3.4 The laboratory equipment shall be provided with daily monitoring or using records.

2.4 Examination supplies

2.4.1 The examination supplies shall meet the requirements of the microbiological examination. The commonly used examination supplies are shown in A.2.

2.4.2 All examination supplies shall be kept clean and/or sterile before use.

2.4.3 The examination supplies requiring sterilizing shall be placed in specific containers or packaged/plugged with suitable materials (such as special packaging paper or aluminum-foil paper) to ensure the sterilization effect.

2.4.4 The storage condition of examination supplies shall be kept dry and clean. And the sterilized and unsterilized supplies shall be stored separately and clearly marked.

2.4.5 The temperature, duration and effective life of sterilization for the sterilized examination supplies shall be recorded.

2.5 Culture media and reagents

The preparation and quality requirements of the culture media and reagents shall be in accordance with the provision specified in GB 4789.28.

2.6 Quality control strains

2.6.1 The laboratory shall keep standard strains that can meet the requirements of the experiment.

2.6.2 Only traceable standard strains stored in special institutions of microbial culture preservation or professional authority institutes shall be used.

2.6.3 The preservation and transferring of standard strains shall be in accordance with the provision in GB 4789.28.

2.6.4 The strains separated in laboratory (wild strains) shall be regarded as the internal quality control strains in laboratory after identification.

3. Sample Collections

3.1 Sampling principles

3.1.1 Sampling should follow the principle of randomness and representativeness.

3.1.2 Sterile operation procedure shall be followed during sampling, so as to prevent all potential foreign contamination.

3.2 Sampling plan

3.2.1 Determine the sampling plan according to the examination objective, product characteristics, lot size, examination method and harmful levels of microorganisms, etc.

3.2.2 The sampling plan can be classified into Grade II and Grade III. There are n, c and m values set in Grade II sampling plan; while n, c, m and M values set in Grade III sampling plan.

n: the number of the samples collected from one batch;

c: the maximum number of the sample allowed to exceed m value;

m: the limit value of the acceptance level of microbiological indicator (Grade III Sampling plan) or maximum safety limit value (Grade II sampling plan);

M: the maximum safety limit value of microbiological indicator.

Note 1: According to the indicators set in Grade II sampling plan, it is allowed to have not more than c samples whose examination value of the corresponding microbiological indicator exceed m among n samples.

Note 2: According to the indicators set in Grade III sampling plan, the examination value of the corresponding microbiological indicator for all the samples are allowed to be not more than m; that for not more than c samples are allowed to be between m and M; while that for no sample is allowed to be more than M among n samples.

For example: n=5, c=2, m=100 CFU/g, M=1000 CFU/g. It means as follows, 5 samples are collected from one batch. If the test results of all the 5 samples are less than or equal to m (≤ 100 CFU/g), the result is acceptable; if the test results (X) of not more than two samples are between m and M ($100 \text{ CFU/g} < X \leq 1000 \text{ CFU/g}$), the result is also acceptable; if the test results of three or more than three samples are between m and M, the result is unacceptable; if the test result of any sample exceeds M (> 1000 CFU/g), then the result is unacceptable, either.

3.2.3 Sampling plan for different kinds of foods shall be implemented in accordance with the provisions of relevant food safety standards.

3.2.4 Collection of food sample during food safety incidents:

a) For food safety incidents caused by food contamination in batch production, the collection and determination of food samples shall be conducted in accordance with the principle of Section 3.2.2 and 3.2.3. The collection shall be focused on the food samples of the same batch.

b) For food safety incidents caused by restaurants or family cooked food, the collection shall be focused on the rest food samples on the spot, so as to meet the requirements of cause determination and pathogen confirmation

of food safety incidents.

3.3 Sampling methods of different kinds of food

3.3.1 Prepackaged food

3.3.1.1 The collected food samples shall be of the same batch, packaged individually and with appropriate number of packages. The sampling size of each sample shall meet the requirements of microbiological indicator examination.

3.3.1.2 For the solid food or liquid food with individual package size of no more than 1000 g or 1000 mL, samples of the same batch should be collected.

3.3.1.3 The liquid food packaged individually, which is more than 1000 mL, shall be shaken or stirred with sterile rod before sampling so as to homogenize the liquid, then collect appropriate amount of the sample, and transfer it to a sterile sampling container as one food sample; for solid food with individual package size of more than 1000 g, respectively collect appropriate amount of sample with a sterile sampler from different positions of the same package, then transfer into one sterile sampling container as one sample.

3.3.2 Bulk food or on-site produced food

Samples were collected from n different parts of the site with the sterile sampler and put into n sterile sampling containers as n food samples. The sampling amount of each sample shall meet the requirements of microbiological indicator examination unit.

3.4 Mark of collected sample

The collected sample shall be recorded and marked correctly and timely. The content includes sampler, sampling site, time, sample name, source, batch number, quantity, storage condition and so on.

3.5 Storage and transport of collected sample

3.5.1 The sample shall be sent to the laboratory for examination as soon as possible.

3.5.2 The sample shall be kept intact during transportation.

3.5.3 The sample shall be stored at a similar temperature to the original, or necessary measures shall be taken to prevent the change of microorganism amount in sample.

4. Examinations

4.1 Sample treatment

4.1.1 After receiving the submitted sample the laboratory shall check and register it carefully to ensure that the relevant information of the sample is complete and meets the examination requirements.

4.1.2 The examination shall be carried out as required as soon as possible. If not, necessary measures shall be taken to keep the original state of the sample and prevent the change of original microorganisms in sample caused by the interference of objective conditions.

4.1.3 The treatment of different food samples shall be in accordance with the provisions of examination methods in corresponding food safety standards.

4.2 Sample examination

Examination shall comply with the provisions of corresponding food safety standards.

5. Biosafety and Quality Control

5.1 Laboratory biosafety requirement

It shall comply with the provisions in GB 19489.

5.2 Quality control

5.2.1 The laboratory shall set up positive control, negative control and blank control as required, and perform quality control for the examination process periodically.

5.2.2 The laboratory shall conduct technical examination periodically for the laboratory personnel.

6. Records and Reports

6.1 Records

All information such as phenomena, results and data observed during examination shall be recorded instantaneously and objectively.

6.2 Reports

The laboratory shall report the examination results accurately and objectively in accordance with the requirements specified in examination methods.

7. Sample Disposal after Examination

7.1 The test sample can be disposed only when the examination results have been reported.

7.2 Bio-safety disposal shall be necessary for the sample detected with pathogens.

7.3 After the examination results have been reported, the rest samples or samples of the same batch shall not be used for the re-examination of microbiological items.

Annex A

Conventional Examination Supplies and Equipment of Microbiological Laboratory

A.1 Equipment

A.1.1 Weighting equipment: balance, *etc.*

A.1.2 Disinfecting/sterilizing equipment: roasting/drying equipment, and autoclaved sterilization device, filtration sterilization device, and ultraviolet equipment, *etc.*

A.1.3 Equipment for media preparation: pH meter, *etc.*

A.1.4 Equipment for sample treatment: homogenizer (shearing or slapping homogenizer), and centrifuge, *etc.*

A.1.5 Dilution equipment: pipette, *etc.*

A.1.6 Incubation equipment: thermostatic incubator, and thermostatic water bath, *etc.*

A.1.7 Microscopic examination counting equipment: microscope, magnifying glass, and vernier caliper, *etc.*

A.1.8 Refrigerating or freezing equipment: refrigerator, and cabinet freezer, *etc.*

A.1.9 Biosafety equipment: biosafety cabinet, *etc.*

A.1.10 Other equipment

A.2 Examination supplies

A.2.1 Conventional examination supplies: inoculating loop (needle), alcohol lamp, tweezer, scissor, medicine spoon, sterilized cotton ball, silicone (cotton) plug, pipette, rubber pipette bulb, test tube, culture dish, conical flask, microplate, jar, measuring cylinder, glass rod and L-shape glass rod, pH test paper, marker, homogenization bag, *etc.*

A.2.2 Examination supplies for on-spot sampling: sterile sampling containers, cotton swab, smearing rod, etalon board for sampling, transfer tube, *etc.*