

National Standard of the People's Republic of China

GB 4789.1-2016

National food safety standard

Food microbiological examination-General rules



Issued on 2016-12-23 Implemented on 2017-06-23

Issued by NHFPC and CFDA

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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:

—Annex A - Conventional laboratory supplies and equipment of microbiological laboratory has been added;

- the laboratory basic requirements have been revised;
- the sample collection has been revised;
- the examination has been revised;
- the sample treatment after examination has been revised;
- the normative references have been deleted.

National food safety standard

Food microbiological examination-General rules

1 Scope

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

This standard applies to food microbiological examination.

2 Laboratory Basic Requirements

2.1 Inspection personnel

2.1.1 The inspection personnel shall have the corresponding microbial professional education or training experience and related qualification, and be able to understand and implement the examination correctly.

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

2.1.3 During the process of examination, the inspection personnel shall keep personal neat and hygiene to prevent the sample from man-made contaminant.

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

2.1.5 The personnel with color vision disorder cannot engage in any experiments involving color discrimination.

2.2 Environment and facilities

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

2.2.2 The laboratory area and office area shall be clearly separated from each other.

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

2.2.4 The ambient 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 carried out in clean area where shall be indicated with obvious signs.

2.2.6 The separation and identification of pathogenic microorganism 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 in suitable environmental conditions, for easy maintenance, cleaning, disinfection and calibration, and shall be maintained under neat and good working status.

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

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

2.4 Examination supplies

2.4.1 The examination supplies shall meet the requirements of the microbiological examination. See A.2 for common examination supplies.

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

2.4.3 The examination supplies needed to be sterilized shall be placed in specific containers or packaged/plugged with suitable materials (such as special packaging paper or aluminum-foil paper, etc.) and shall be ensured the sterilization effect.

2.4.4 The storage condition of examination supplies shall be kept dry and clean. Those sterilized and unsterilized supplies shall be stored separately and indicated with clear labels.

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 performed according to the provision of GB 4789.28.

2.6 Quality control strains

2.6.1 The laboratory shall keep standard strains that can meet experimental requirements.

2.6.2 Only traceable standard strains stored in special institutes or professional authority institutes for culture collection of microorganisms shall be used.

2.6.3 The preservation and passage of standard strains shall be performed according to the provision of GB 4789.28.

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

3 Sample Collections

3.1 Sampling principles

3.1.1 The sample collection shall comply with the principle of randomness and representativeness.

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

3.2 Sampling program

3.2.1 Sampling program shall be determined according to the examination objective, food characteristics, batch amount, examination method and harmful levels of microorganisms, etc.

3.2.2 The sampling program is divided into Grade II and Grade III sampling program. There are n , c and m values set in Grade II sampling program; while n , c , m and M values set in Grade III sampling program.

n : the number of samples that shall be collected from one batch;

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

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

M: the maximum safety limit value of microbiological indicator.

Note 1: According to the indicators set in Grade II sampling program, the examination value of the corresponding microbiological indicator for not more than c samples among n samples are allowed to be greater than m.

Note 2: According to the indicators set in Grade III sampling program, the examination value of the corresponding microbiological indicator for all the samples are allowed to be not greater 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 that 5 samples are collected from one batch, if the examination results of the 5 samples are all less than or equal to m (≤ 100 CFU/g), the result is acceptable; if the examination 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 examination results of three or more than three samples are between m and M, the result is unacceptable; if the examination result of any sample exceeds M (> 1000 CFU/g), then the result is also unacceptable.

3.2.3 Sampling program for different kinds of food shall be performed according to the provisions in relevant standard of food safety.

3.2.4 Collection of food sample during food safety incidents:

- a) For food safety incidents caused by batch produced food contamination, the collection and determination principle of food samples shall be performed according to 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 Food samples of the same batch with individual package and appropriate number of packages shall be collected. 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 less than or equal to 1000 g or 1000 mL, the package of the same batch shall be taken.

3.3.1.3 For the liquid food with individual package size of greater than 1000 mL, shake or stir the liquid with sterile rod before sampling, homogenize the liquid and then collect the sample, and transfer to a sterile sampling container as one food sample; for solid food with individual package size of greater 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

Collect samples with a sterile sampler from n different positions on site, then put into n sterile sampling containers as n 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 sampling person, sampling site, time, sample name, source, batch number, quantity, storage condition and other information.

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 During transport, the sample shall be kept intact.

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 The submitted sample shall be checked and registered carefully once received by the laboratory, to ensure that the relevant information of 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 all kinds of food samples shall be performed according to the provisions of examination methods in relevant food safety standards.

4.2 Sample examination

Examination shall be performed according to the provisions of relevant standards of food safety.

5 Biosafety and Quality Control

5.1 Laboratory biosafety requirement

It shall comply with the provisions of GB 19489.

5.2 Quality control

5.2.1 The laboratory shall set positive control, negative control and blank control according to the requirements and perform the quality control for the examination process regularly.

5.2.2 The laboratory shall perform technical examination for the laboratory personnel regularly.

6 Records and Reports

6.1 Records

Information including phenomena observed during examination, results and data shall be recorded instantaneously and objectively.

6.2 Reports

The laboratory shall report the examination result accurately and objectively according to the requirements specified in examination method.

7 Sample Treatment after Examination

7.1 Only after the examination results have been reported, can the test sample be treated.

7.2 Harmless treatment shall be performed for the sample detected with pathogens.

7.3 After the examination results have been reported, the remaining samples or samples of the same batch will not be performed the re-examination of microbiological items.

Annex A

Conventional examination supplies and equipment in microbiological laboratory

A.1 Equipment

A.1.1 Weighing equipment: balance, etc.

A.1.2 Sterilization and disinfection equipment: roasting/drying equipment, autoclaved sterilization, filtration sterilization, ultraviolet and other equipment.

A.1.3 Media preparation equipment: pH meter, etc.

A.1.4 Sample treatment equipment: homogenizer (shearing or slapping homogenizer), and centrifuge, etc.

A.1.5 Diluent 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 and freezing equipment: refrigerator, and cabinet freezer, etc.

A.1.9 Biosafety equipment: biosafety cabinet.

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, plate, conical flask, microplate, wide mouthed bottle, measuring cylinder, glass rod and L-shape glass rod, pH test paper, marking pen, and homogenization bag, etc.

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