



National Standard of the Peoples Republic of China

National Food Safety Standard

Hygienic Specifications for Food Irradiation Processing

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Preface

This standard replaces GB/T 18524-2001 General Technical Requirements for Food Irradiation.

Compared with GB/T 18524-2001, this standard mainly changes as follows:

- The name of the standard is revised to National Food Safety Standard Hygienic Standard for Food Irradiation Processing
- Revised the structure of the standard;
- Added the terms and definitions;
- Supplemented basic hygiene requirements and management guidelines for irradiation processing, personnel and records, etc.;
- Added relevant requirements for radiation processing process control and radiation safety control;
- Added management requirements for records and documents;
- Deleted the appendix A in the original standard, and relevant contents are included in the irradiation processing control section. Deleted the appendix B related to the packaging materials in the original standard, and relevant contents are included in the packaging section.

National Food Safety Standard

Hygienic Specifications for Food Irradiation Processing

1 Scope

This standard defines the basic hygiene requirements and management guidelines for irradiation devices, irradiation processing, personnel and records for food irradiation processing. This standard applies to food irradiation processing.

2 Terms and definitions

The terms and definitions in GB 14881- 2013 apply to this standard.

2.1 Food irradiation

The radiation process of inhibiting germination, delaying or promoting maturation, disinsection, disinfection, sterilization and anti-corrosion by use of the radiation chemistry and radiation microbiology effects produced by ionizing radiation in food.

2.2 Absorbed dose D

For any ionizing radiation, the average energy of the substance with mass dm $\overline{d\epsilon}$ divided by the quotient of dm , i.e. $D = \overline{d\epsilon} / dm$, unit: $J \cdot kg^{-1}$ (Joule/kg), name: Gray, symbol: Gy, $1Gy = 1J \cdot kg^{-1}$.

2.3 Dose unevenness

The ratio of the maximum absorbed dose to the minimum absorbed dose within the processing load.

2.4 Minimum effective dose

When food is irradiated, the lowest dose required to achieve a certain irradiation purpose, i.e., the lower limit of the process dose.

2.5 Maximum tolerant dose

When food is irradiated, the maximum dose that will not adversely affect the quality and functional characteristics of food, i.e. the upper limit of process dose.

2.6 Irradiation process dose

The lower limit value of the absorbed dose range required to achieve the expected technological purpose in food irradiation shall be greater than the lowest effective dose and the upper limit value shall be less than the highest tolerated dose.

2.7 Food loading mode

The placement of food containers in the irradiation container.

2.8 Installation qualification

The process of obtaining evidence and documenting that the equipment has been provided and

installed in accordance with the instructions.

2.9 Operational qualification

When the equipment runs according to the program, obtain evidence and document that the installed equipment runs within the expected range.

2.10 Performance qualification

When the installed running equipment runs according to the program, obtain evidence and document that the equipment runs according to the specified standards to produce qualified food.

3 Basic principles of food irradiation

3.1 Food for irradiation treatment shall be treated, processed and transported in accordance with GB 14881 and relevant national food safety standards.

3.2 Food irradiation cannot replace the hygiene control or good production standards in food production and processing, and can only be used under reasonable technological requirements or conditions beneficial to the health of consumers. The irradiation processing method is not allowed to deal with inferior and unqualified food.

3.3 The irradiation dose shall be accurate and reliable. The lowest dose required by the process shall be adopted as far as possible. The dose unevenness shall not exceed 2.0.

3.4 Irradiation treatment shall not adversely affect the structural integrity, functional properties and sensory properties of the food. The irradiated food shall conform to the corresponding provisions of the relevant national food safety standards and product standards.

3.5 The types of irradiated food shall be within the scope specified in GB 14891, and irradiation treatment is not allowed for other foods.

3.6 Except for the special cases specified in 5.2.5, repeated irradiation is not allowed under other circumstances.

4 General technical requirements for irradiation devices

4.1 Radiation sources

The electron beams with energy not higher than 10MeV produced by X-rays, electron accelerators energy with energy not higher than 5MeV produced by the gamma rays, electron accelerators produced by ^{60}Co or ^{137}Cs radionuclides, the ionizing radiation sources available for food irradiation.

4.2 Irradiation devices

The location, design and building of irradiation devices shall conform to relevant national standards and meet the hygiene requirements for food irradiation processing.

4.3 Installation, operational and performance qualifications of irradiation devices

4.3.1 After the irradiation device is installed, it must conduct installation qualification to ensure that the performance of the device can meet the design requirements; After the installation qualification is completed, the operational qualification shall be carried out to ensure that the equipment can operate according to the set procedures.

4.3.2 The food shall be subject to the performance qualification before irradiation to confirm the absorbed dose under normal operation conditions as well as its distribution and the repeatability of irradiation.

4.3.2.1 Place dosimeters in a three-dimensional manner in an irradiation container filled with simulants with a density similar to that of the food to be irradiated (easy to distinguish the positions of maximum and minimum absorbed doses), to determine the positions of maximum absorbed dose, minimum absorbed dose and reference point absorbed dose.

4.3.2.2 Establish the relationship between the dose distribution in products with different packing densities and packing methods and the irradiation operation parameters, to ensure that the products obtain absorbed dose within the prescribed limit.

4.3.2.3 When the activity of the radiation source increases or the operating parameters change, it must perform a re-qualification to determine whether the initial qualification is valid or not. Otherwise, the dose distributions must be re-measured.

4.3.2.4 When the equipment maintenance may affect the radiation source structure, food loading mode or operation parameters of the irradiation device, it must perform another performance qualification.

4.3.3 The electromechanical system of the irradiation device must operate reliably and meet the requirements of GB 17568 or GB/T 25306.

4.4 Use and maintenance

4.4.1 The irradiation device cannot be used before it passes the acceptance and obtains a radiation safety license according to relevant national regulations after it is built.

4.4.2 The department using the irradiation device shall prepare the specifications for the use of the irradiation device and use the irradiation device according to the specifications.

4.4.3 Irradiation devices shall be inspected and maintained regularly to ensure the safe use.

5 Irradiation processing process control

5.1 Preparation before irradiation

5.1.1 Requirements before irradiation

5.1.1.1 Food packaging before irradiation

Select appropriate packaging method according to the food type and the irradiation processing process, and the packaging shall facilitate the irradiation processing. Packaging shall be able to effectively avoid the re-contamination after irradiation processing. Packaging shall conform to relevant standards and regulations.

5.1.1.2 Storage of food before irradiation

Different types of irradiated food shall be stored separately with clear mark. Foods with special storage requirements such as low temperature shall meet their storage requirements.

5.1.2 Selection of irradiation equipment

The irradiation equipment shall be selected according to the type of irradiated food, irradiation purpose, product status (e.g. bulk or shaped packaging) and its characteristics as well as the processing capacity of the irradiation equipment.

5.1.3 Measurement of irradiation process dose and conventional dose

5.1.3.1 The process dose shall be set between the lowest effective dose and the highest tolerated dose.

5.1.3.2 The dose measurement shall include the repeatability from the irradiation source to the irradiation location, the dose distribution in the irradiation field (in the product), and the relationship between the irradiation operation parameters and the absorbed dose of the product in products with different packing densities and packing methods.

5.1.3.3 Daily dose monitoring shall include sampling and monitoring the absorbed dose of products, regularly calibrating the irradiation field, checking the unevenness of product dose, testing the operating parameters of the device and the relationship with the absorbed dose of products.

5.1.3.4 Dose measured by γ -irradiation device shall be performed in accordance with GB 16334. Dose measured by electron beam irradiation device shall be performed in accordance with GB/T 16841.

5.2 Irradiation Processing

5.2.1 Formulation of process specifications and food safety requirements

The irradiation process specifications shall ensure that the irradiated food is separated from the non-irradiated food, and the irradiation treatment can achieve the established process purpose and hygienic quality requirements.

5.2.2 Determination of irradiation process dose

5.2.2.1 The irradiation process dose shall be determined according to the type of irradiated food and the irradiation purpose, and the absorbed dose of irradiated food shall meet the requirements of GB 14891.

5.2.2.2 The process dose shall be between the lowest effective dose and the highest tolerated dose.

5.2.3 Establishment of food loading mode

5.2.3.1 It shall establish a separate loading mode for different packaging of each type of food. The number and location of the food unit in the irradiation container shall be indicated in the loading mode description.

5.2.3.2 The loading mode shall be designed to fill the container space to the maximum within the allowable weight range of the irradiation container and distribute it as evenly as possible to minimize the dose unevenness.

5.2.4 Measurement of dose

5.2.4.1 After the food loading mode is established, it shall load actual products or simulants with approximate density, to measure its dose distribution and verify the loading mode.

5.2.4.2 When measuring the dose distribution, it shall place a sufficient number of dosimeters in the irradiation product load to determine the minimum and maximum dose regions, and then select the conventional dose monitoring location, and calculate the relationship between the dose at the conventional dose point and the maximum dose and the minimum dose. Dose measurement shall include sampling and monitoring the absorbed dose of products, checking the unevenness of product dose, testing the operating parameters of the device and the relationship with the absorbed dose of products.

5.2.4.3 In the conventional irradiation processing, dosimeters shall be placed at a location that the minimum dose is easily placed in the irradiation container or at a easily placed location with known quantitative relation to the minimum dose zone. In addition, dosimeters shall be placed in the maximum dose zone to monitor the maximum dose acceptable to the food. And make proper records and archives.

5.2.4.4 When the irradiation parameters change, the dose distribution shall be measured again. The applicable working dosimeter for dose measurement shall be selected according to the expected radiation processing application of the device, the performance of the dose measurement system and measurement uncertainty and other requirements, in accordance with provisions of GB/T 16640, and shall be regularly traceable to the national absorbed dose standard.

5.2.5 Repeated irradiation

5.2.5.1 Repeated irradiation is not allowed except for low-moisture food (such as grains, beans, dehydrated food and similar products), which can perform the repeated irradiation for the purpose of controlling the re-invasion of pests.

5.2.5.2 Irradiation of the following foods does not belong to repeated irradiation:

- Foods made of raw materials irradiated with dose less than 1kGy;
- Foods containing less than 5% of irradiated ingredients;
- Foods irradiated in multiple times with all required absorbed doses in order to achieve special technological purposes.

5.2.5.3 The cumulative dose of repeatedly irradiated food shall not exceed 10kGy.

5.3 Post-irradiation treatment

5.3.1 Storage

Irradiated products and non-irradiated products shall be stored in the irradiated area and non-irradiated area respectively. The storage of products before release shall conform to the provisions in Chapter 10 of GB 14881 - 2013.

5.3.2 Product release

Radiation release procedures for products shall be established. The procedure shall define the requirements for the specified irradiation process and shall consider the uncertainty of the measurement system. In case of failure to meet these requirements, irradiated products are considered as unqualified products.

Relevant responsibilities and rights for controlling and treating unqualified irradiated products shall be stipulated.

In addition, the management of unqualified products is subject to the agreement of irradiation operators and customers, and shall be stipulated in the technical agreement. Documented procedures and records shall be kept so as to find out the causes and problems of nonconformity.

6 Personnel management

6.1 Personnel working with irradiation facilities shall comply with relevant national laws and regulations.

6.2 Personnel shall receive corresponding training in radiation technology and have the necessary skills and experience.

7 Irradiation safety management

7.1 Protection test and supervision

Irradiated food enterprises shall establish an effective protection test and supervision system, which shall meet the requirements of GB 18871.

7.2 Test and evaluation of occupational irradiation

Irradiated food enterprises shall establish test and evaluation system of occupational irradiation, which shall meet the requirements of GB 5294.

7.3 Test of external irradiation leakage and radioactive pollution

Irradiated food enterprises shall establish a system for testing the level of external irradiation leakage and surface radioactive pollution, which shall comply with GBZ 141, Specifications for Radiological Protection Test of γ -rays and Electron Beam Irradiation Devices.

8 Labeling

Labeling of irradiated food shall conform to 4.1.11.1 of GB7718 and GB 14891.

9 Records and documents management

9.1 Radiation records

9.1.1 Radiation device records

All materials related to the building, acceptance, license registration and maintenance of irradiation devices shall be recorded.

9.1.2 Records of irradiation process parameters

Relevant irradiation processing control, dose test and daily operation parameters of irradiation devices during enabling and daily operation shall be recorded.

9.1.3 Records of irradiated products

The type of product, irradiation purpose, irradiation dose, irradiation date, and product quality test after irradiation (including post-irradiation sampling, sample retention, inventory management, etc.)

shall be recorded.

Requirements and conditions for irradiation treatment shall be recorded and kept by special personnel for future reference. Records of irradiation treatment and conditions shall include but not limited to the following contents:

- a) Name, code, batch number and quantity of the irradiated food, ex-factory date and receipt date, name, address and contact information of the entrusting party of irradiated food;
- b) Irradiation purpose;
- c) Name and activity of the radionuclide of the radiation source, or the energy, beam current, scanning width, transmission speed of the irradiation device as well as the processing parameters affecting the absorbed dose of food;
- d) Density of the irradiated food, the loading mode of food in the irradiation container or irradiation device;
- e) Irradiation process dose;
- f) Operating parameters of the irradiation device;
- g) Date of irradiation;
- h) Location and quantity of conventional dosimeters;
- i) Results of minimum absorbed dose, maximum absorbed dose and overall average dose monitored by conventional dosimeters;
- j) Dose unevenness;
- k) Types and calibration records of conventional dosimeters;
- l) Types and calibration records of the dosimeter reading device;
- m) Monitoring results of samples after irradiation;
- n) Outbound records of irradiated products.

9.2 Documents Management

All records shall be kept properly and shall be kept for reference within the shelf life of the food for at least 2 years.