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China Notifies Draft Hygiene Specifications for Food Radiation Processing

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Report Highlights:

On August 4, 2014, China notified the WTO of Draft National Food Safety Standards on Hygiene Specifications for Food Radiation Processing (SPS/N/CHN/685). The deadline for comments is October 3, 2014. The proposed date of entry into force is not yet determined.

Comments can be sent to China's SPS Enquiry Point at sps@aqsiq.gov.cn.

This report is an INFORMAL translation of this document.

General Information:
BEGIN TRANSLATION

National Standard for Food Safety
Hygiene Specifications for Food Irradiation Processing (Draft)

Issued on:

Implemented on:

Issued by: National Health and Family Planning Committee of China

GB XXXX-2014

Foreword

This Standard replaces GB/T18524-2001 “General Technical Requirements for Food Irradiation”

The Standard shows following main changes when compared with GB/T18524-2001:

- The name of the former Standard is modified;
- The structure of the former Standard is modified;
- Terms and definitions are added;
- Relevant basic hygiene requirements and management rules for the process of irradiation processing, the staff, the records, etc. are stressed;
- Relevant requirements on process control of irradiation processing and safety control of irradiation are added;
- Relevant management requirements for records and documents are added;
- Annex A in the former Standard is deleted, and its relevant content is included in the part regarding control of irradiation processing in this new Standard; Annex B on packaging materials in the former Standard is reserved and changed as Annex A in this new Standard.

Hygiene Specifications for Food Irradiation Processing

1. Scope

This Standard specifies basic hygiene requirements and management rules for irradiators, the process of irradiation processing, personnel, records, etc. for food irradiation processing.

This Standard applies to the irradiation processing of food.

2. Terms and Definitions

2.1 Food Irradiation

Food irradiation refers to the irradiation process that chemical and microbiological irradiation effects are generated in food exposed to ionizing irradiation so as to realize purposes such as inhibition of sprouting, postponement or promotion of ripening, elimination of insects, sterilization and anticorrosion.

2.2 Irradiated Food

Irradiated food refers to the food that is subject to ionizing irradiation of some dose in accordance with the requirements specified by irradiation process specifications for some practical purpose.

2.3 Absorbed Dose (D)

Absorbed dose refers to a fundamental dose quantity D representing the mean energy ($d\varepsilon$) imparted to matter per unit mass (dm) by ionizing radiation, i.e., $D=d\varepsilon/dm$. Its unit name is gray (Gy), and $1\text{ Gy}=1\text{ J}\cdot\text{kg}^{-1}$.

2.4 Dose Uniformity Ratio

Dose uniformity ratio refers to the ratio of the maximum to the minimum absorbed dose.

2.5 Minimum Effective Dose

The minimum effective dose refers to the minimum dose needed to achieve some irradiation purpose during food irradiation, i.e. the lower value of process dose

2.6 Maximum Tolerated Dose

The maximum tolerated dose refers to the maximum dose that presents no negative effect on the quality and functional characteristics of food during food irradiation, i.e. the upper value of process dose.

2.7 Process Dose of Irradiation

The process dose of irradiation refers to the absorbed dose range that is needed to achieve the expected process purpose during food irradiation, with a lower value larger than the minimum effective dose and an upper value smaller than the maximum tolerated dose.

2.8 Food-loading Configuration

Food-loading configuration is the manner in which the food box is placed in the irradiation container.

2.9 Process Specifications of Irradiation

Process specifications of irradiation refer to flows and measures for food production that are taken to ensure irradiation quality to achieve the purpose of food irradiation

2.10 Installation Qualification (IQ)

Installation qualification refers to the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

2.11 Operational Qualification (OQ)

Operational qualification refers to the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

2.12 Performance Qualification (PQ)

Performance qualification refers to the process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

2.13 Routine Monitoring and Control

The purpose of routine monitoring and control is to verify that the specific identified processing of sterilization has been carried out for the product.

3. General Technical Requirements for Irradiators

3.1 Irradiation Sources

Sources of ionizing radiation that may be used in food irradiation include Gamma rays from radionuclides ^{60}Co or ^{137}Cs , X-rays generated from electron accelerators operated at or below an energy level of 5 MeV and electrons generated from electron accelerators operated at or below an energy level of 10 MeV.

3.2 Selection of Factory Site

The selection of factory site shall be made by considering interaction between the factory area and its surroundings and shall comply with the requirements specified in Section 3.1 of GB 14881 and other relevant laws and regulations.

3.3 Design and Construction

The manner of irradiation, conveyor system, dose range and product storage & transport needed for food irradiation, as well as economic feasibility, shall be taken into account for the design of irradiators.

3.3.2 An irradiation treatment workshop shall be set up in a separate factory building, and be designed and constructed in accordance with relevant rules depending on the grades of irradiation sources and

working sites. The availability and accessibility of drainage and ventilation systems shall be fully considered.

3.3.3 Γ irradiators that to be new built, rebuilt or extended shall designed and constructed in accordance with provisions specified in GB 17568 (Design, Construction and Use Standard for Γ Irradiators) and GB 10252 (Protection and Safety Standard for Irradiation of Γ Irradiators), and electron accelerators to be new built, rebuilt or extended shall designed and constructed in accordance with the provisions specified in GB 5172 (Protection Standard on Irradiation of Particle Accelerators) and GB/T 25306 (General Engineering Standard for Electron Accelerators for Irradiation Process).

3.4 Installation Qualification, Performance Qualification and Operational Qualification

Installation qualification shall be performed for the food irradiation processing device which has been installed, so as to ensure that the performance of equipment meets the design requirements; after completion of installation qualification, the performance qualification shall be performed to ensure that the equipment has the capability of irradiation processing for food; the operational qualification shall be carried out for the food before food irradiation, so as to confirm the parameters of irradiation processing.

3.4.1 Before an irradiator is put into operation, installation qualification and operational qualification shall be conducted. The absorbed dose accepted by the homogeneous materials in the typical density range under normal conditions, as well its dose distribution and the repetitiveness of irradiation, for which qualifications has been performed, should be confirmed.

3.4.2 The electronic and mechanical systems of an irradiator shall run reliably and meet the requirements in GB 17568 or GB/T 25306.

3.4.2.1 Dose mapping shall be carried out by a three-dimensional placement (convenient for distinguishing the locations of the maximum absorbed dose from those of the minimum) of dosimeter sets on the real product within the upper and lower density limits for food to be irradiated or on the mimics of a similar density within an irradiation container holding homogeneous materials; the locations for the maximum absorbed dose, the minimum absorbed dose and the absorbed dose of reference points shall be determined. The dose uniformity ratio shall not be larger than 2.

3.4.2.2 The relationship between operational irradiation parameters and overall mean dose for the products with different bulk densities and different bulking manners shall be established to ensure that absorbed doses within the specified value limit are obtained.

3.4.2.3 When the activity of irradiation source increases or the operational parameters change, qualification shall be carried out again to confirm whether the initial qualification is effective or not; or the dose mapping shall be carried out again.

3.4.2.4 When the activity of irradiation source increases or operational parameters change, check & acceptance shall be conducted again so as to confirm whether the initial check & acceptance is effective or not; or the dose mapping shall be carried out again.

3.4.2.5 Equipment shall be examined, maintained and repaired according to the routine and preventive maintenance procedures recommended by the equipment supplier so as to ensure that the irradiator runs in a safe, reliable way, and the maintenance records shall be made properly.

3.4.2.6 When maintenance is likely to affect the structure of irradiation sources, the food-loading configuration or the operational parameters for the irradiator, check & acceptance shall be conducted again.

3.5 Use and Maintenance

3.5.1 An irradiator that has been constructed shall not be used unless an irradiation safety license is obtained after check, acceptance and approval by the competent authority.

3.5.2 A unit that uses the irradiators shall comply with the use standard for irradiators which shall be formulated by the unit itself.

3.5.3 Irradiators shall be examined and maintained on a regular basis to ensure safe use.

4. Process Control for Irradiation Processing

4.1 Pre-irradiation Treatment

4.1.1 Pre-irradiation Requirements

4.1.1.1 General Requirements

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

Food subject to irradiation treatment shall comply with relevant standards and rules, and substandard food shall not be treated by irradiation processing. Food irradiation shall not replace the hygiene control or good production practice during food production, and shall only be used where it is a reasonable process need or is beneficial for consumers.

4.1.1.2 Storage

Irradiated food of different types shall be stored separately with distinct markings. Food subject to special storage requirements (such as low temperature) shall be stored in accordance with its own storage requirements.

4.1.2 Selection of Irradiation Facilities

Irradiation facilities shall be selected according to the type of food to be irradiated, the purpose of irradiation, the product condition (bulk or packaged) and characteristics, as well as the treatment capability of irradiation facilities.

4.1.3 Measurement of Process Dose and Routine Dose of Irradiation

4.1.3.1 A process dose shall be set between the minimum effective dose and the maximum tolerated dose.

4.1.3.2 Dosimetry for commissioning includes the repetitiveness from the irradiation source to the irradiation location, dose distribution in the irradiation field (product), the relationship between operational irradiation parameters and the overall mean dose for the products with different bulk densities and different bulking manners.

4.1.3.3 Daily dosimetry includes sampling and monitoring of product's absorbed dose, calibration of the irradiation field on a regular basis, check of product's dose uniformity ratio and examination of the relationship between the device's operational parameters and the product's absorbed dose.

4.1.3.4 Dosimetry for γ irradiators is carried out in accordance with GB 16334 "Practical Dosiology Guidelines for Food Processing with γ Irradiators". Dosimetry for electron irradiators is carried out in accordance with GB/T 16841 "Dosiology Guidelines for Processing Device of Electron Irradiation Operated at An Energy Level Between 300keV and 25MeV".

4.2 Irradiation Processing

4.2.1 Process Specifications

The process specifications for irradiation shall ensure that irradiated food is segregated from non-irradiated food and that irradiation treatment is able to achieve the predetermined process purpose and to meet hygiene & quality requirements.

4.2.2 Determination of the Process Dose of Irradiation

4.2.2.1 The process dose of irradiation shall be determined in accordance with the food type to be irradiated and the purpose of irradiation, and the absorbed dose for irradiated food shall meet the requirements of GB 14891.

4.2.2.2 The process dose shall be set between the minimum effective dose and the maximum tolerated dose.

4.2.3 Food-loading configuration

4.2.3.1 A separate loading configuration shall be established for each package type of each kind of food.

The instructions of loading configuration shall state the quantities and locations for the food units in the irradiation container.

4.2.3.2 The loading configuration shall be designed to make food filling the container to a maximum limit within the tolerated weight and make food distributed uniformly as possible so as to achieve a minimum dose uniformity ratio.

4.2.4 Dosimetry

4.2.4.1 After establishment of a food-loading configuration, real products or mimics of similar density shall be loaded to measure its dose distribution.

4.2.4.2 For measuring the dose distributions, enough dosimeters shall be placed in the irradiated production load to identify the areas with minimum and maximum doses to select the monitoring locations for routine doses, so as to calculate the relationship between points with routine doses and the points with the maximum or minimum dose. Dosimetry includes sampling and monitoring of the product's absorbed dose, calibration of the irradiation field on a regular basis, check of the product's dose uniformity ratio and examination of the relationship between the device's operational parameters and the product's absorbed dose.

4.2.4.3 During routine irradiation processing, dosimeters shall be distributed in the locations which have known quantitative relationships between the minimum dose and maximum dose and are easy for placement in the container. In addition, dosimeters shall be placed in the area with the maximum dose to measure the maximum dose accepted by food. Relevant records shall be documented and filed.

4.2.4.4 When irradiation parameters change, the dose mapping shall be performed again.

Suitable working dosimeters for working shall be selected depending on requirements on the anticipated applications of irradiation processing, the performance of dosimetry system and the measurement uncertainty in accordance with of GB/T 16640 "Selection and Calibration Guidelines for Dosimetry Systems of Irradiation Processing", and the national standard for the absorbed dose shall be traced regularly.

4.2.5 Repetitive Irradiation

Requirements for repetitive irradiation are the same as those in GB 14891.

4.3 Post-irradiation Treatment

4.3.1 Storage

Products shall be stored in accordance with provisions specified in GB 14881. Irradiated products and non-irradiated food shall be stored in the irradiation division and non-irradiation division respectively.

4.3.2 Product Release

The release procedures for irradiated food shall be established. The procedures shall define the requirements for designated irradiation process and take the system uncertainty into consideration.

Irradiated food that doesn't meet these requirements will be considered as substandard products.

Relevant obligations and rights shall be specified for controlling and disposing of substandard products.

In addition, there shall be total agreement between the irradiation operator and the clients for management of substandard products, which shall be specified in their technical agreements.

Documented procedures and records shall be kept so as to find the causes and problems resulting in substandard products.

5. Staff Management

Personnel worked in irradiation facilities shall comply with the requirements on personal hygiene in GB14881 and shall be competent on the basis of appropriate training, skills and experience for engaging in relevant irradiation technologies.

6. Safety Control of Irradiation

6.1 Detection and Supervision for Protection

A food irradiation enterprise shall establish an effective system for detection and supervision for protection in line with the requirements of GB 18871 “Basic Standard for Protection against Ionizing Irradiation and Safety of Irradiation”.

6.2 Detection and Assessment of Occupational Irradiation

The food irradiation enterprise shall formulate a detection and assessment system for occupational irradiation according to the requirements in GB 5294 “Specifications for Individual Monitoring of Occupational Irradiation Monitoring of External Exposure”.

6.3 Detection for Leakage of External Exposure and Radioactive Contamination

A food irradiation enterprise shall formulate detection systems for the leakage of external exposure and the external radioactive contamination in accordance with GB/T 15447 “Conversion Methods for Absorbed Doses of Different Materials Subject to Irradiation of X Rays, Γ Rays and Electrons”.

7. Packaging and Labeling

7.1 Packaging

Suitable packaging patterns shall be selected depending on the food types and the procedure of irradiation process, and the packaging shall be convenient for irradiation processing. The packaging shall be able to effectively avoid recontamination after irradiation process. For details of packaging materials, see Annex A.

7.2 Labeling

Labeling for irradiated food shall comply with rules specified in GB 7718 and GB 14891.

8. Records and Documentation

8.1 Irradiation Records

8.1.1 Irradiator Records

All materials related to construction, check & acceptance, license registration and maintenance of the irradiator.

8.1.2 Records of Irradiation Process Parameters

Parameters related to irradiation process control and dosimetry for commissioning and daily operation, as well as parameters for daily operation of irradiators.

8.1.3 Records of Irradiation Products

Product type, irradiation purpose, irradiation date, and quality testing after irradiation (including sampling and sample retention after irradiation, and inventory management)

Records for requirements and conditions for irradiation treatment shall be made, kept by special personnel and filed for reference. Irradiation records include:

- a. Name, code, batch No., quantity, date of manufacture and receiving date for irradiated food
- b. Purpose of irradiation
- c. Name and activity of the radionuclide, or the irradiator’s energy, beam current, scan width and conveying speed, as well as the process parameters affecting the absorbed dose for products
- d. Density of irradiated food, the loading configuration of food in the irradiation container or irradiator
- e. Process dose of irradiation
- f. Operational parameters set by irradiators
- g. Date of irradiation
- h. Locations and quantities of routine dosimeter
- i. Minimum absorbed dose, maximum absorbed dose and overall mean dose results monitored by routine dosimeters
- j. Dose uniformity ratio
- k. Types and calibration records of routine dosimeters
- l. Types and calibration records of the reading device for routine dosimeter

m. Monitoring results of retention samples after irradiation

n. Delivery records of irradiated products

8.2 File Management

All records and documents shall be properly kept, and shall be available to authorized personnel and accessible for a period of time established by food control authorities.

Annex A

Packaging Materials Approved as Allowable Pre-packaging Materials for Irradiated Food ^a

No.	Packaging materials	Max Dose	Country ^b	Date ^b
1	Cardboard	10, 35	Britain, Poland	1991 ^c
2	Polyethylene - polyvinyl acetate co-extruded (film)	30	U.S., Canada	1988
3	Ethylene-vinyl acetate copolymer	30	U.S.	1989
4	Fiberboard	10	India	1997
5	Wax-coated fiberboard (fiber box)	10	U.S., Canada	1989
6	Glassine	10	U.S.	1975
7	Glass	10	India	1997
8	Jute bag	10	Britain	1991 ^c
9	Brown paper	0.5	U.S.	1975
10	Nitrocellulose-coated cellophane	10	U.S., India	1975
11	Nylon 11	10	U.S., India	1975
12	Nylon 6	60, 10	U.S., India	1975
13	Paper	10, 35	Britain, Poland	1991 ^c
14	Wax-coated or polyethylene-coated paper, or paper laminated with wax or laminated with polyethylene	10, 35	India, Poland	1990
15	Paper laminated with lead foil	35	Poland	1990
16	Polyamide film, or polyamide-polyethylene co-extruded film	35	Poland	1990
17	Metalized polyester-polyethylene laminated film	35	Poland	1990
18	Polyester-polyethylene laminated film	35	Poland	1990
19	Polyethylene film (of various densities)	60, 35, 10	U.S., Poland, India	1975
20	Polyethylene-paper-aluminum laminated film	35	Poland	1990
21	Polyethylene terephthalate	60	U.S.	1975
22	Polyolefine (of low density, used as the middle layer or sealing layer)		Canada	1989
23	Polyolefin (of high density, used as the outer layer)		Canada	1989
24	Polyolefin film	10	U.S.	1975
25	Polypropylene bag	10, 35	Britain,	1990 ^c

			Poland	
26	Metallized polypropylene (vacuum aluminized)	35	Poland	1990
27	Polystyrene film	10	U.S., India	1975
28	Polystyrene foam tray	10	Canada, India	1989
29	Rubber hydrochloride film	10	U.S., India	1975
30	Tin-coated steel (plate) or glassed steel (plate)	10	India	1997
31	Vegetable parchment	60, 10	U.S., India	1975
32	Vinyl chloride - Vinyl acetate copolymer film	60:10	U.S., India	1975
33	(Poly)vinylidene chloride-coated cellophane	10	U.S.	1975
34	Vinyl chloride - vinylidene chloride copolymer film	10	U.S., India	1995
35	Wood			
36	Viscose fiber			

a: adapted from "Training Manual on Operation of Food Irradiation Facilities" (Vienna International Atomic Energy Agency, 1992)", which was approved by the Secretariat of International Consultative Group on Food Irradiation.

b: approved by the U.S. in 1975; approved by Canada in 1989; Poland: 35kGy, approved in 1986; approved by Britain in 1991; India: 10kGy, improved in 1996. The date listed in the table is the earliest date of approval.

c: apply to dry herbaceous plants.

END TRANSLATION