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Standard Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms[1]

This standard is issued under the fixed designation F1885; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

The purpose of this guide is to present information on the use of ionizing ~~energy (radiation)~~ radiation in treating dried spices, herbs, and vegetable seasonings to ~~reduce~~control pathogens and spoilage microorganisms. Information on handling these commodities before and after irradiation is also provided.

This guide should be followed when using irradiation technology where approved by an appropriate regulatory ~~control~~ authority. It is not to be construed as a requirement for the use of irradiation, or as a rigid code of practice. While the use of irradiation involves certain essential requirements to attain the objectives of the treatment, some parameters can be varied in optimizing the process.

This guide has been prepared from a code of good irradiation practice, published by the International Consultative Group on Food Irradiation (ICGFI) under the auspices of the Joint Food and Agriculture Organization/International Atomic Energy Agency Division of Nuclear Techniques in Food and Agriculture, which serves as the Secretariat to ICGFI (**1**).[2]

1. Scope

1.1 This guide covers procedures for irradiation of dried spices, herbs, and vegetable seasonings for microbiological control. Generally, these items have moisture content of 4.5 to 12 % and are available in whole, ground, chopped, or other finely divided forms, or as blends. The blends may contain sodium chloride and minor amounts of dry food materials ordinarily used in such blends.

1.2 This guide covers gamma, electron beam, and X-radiation treatment. This guide also covers low energy electron beam treatment where only part of the product is irradiated (that is, surface treatment).

1.3 This guide covers absorbed doses ranging from 3 to 30 ~~kiloGray~~kilogray (kGy).

NOTE 1—U.S. regulations permit a maximum dose of 30 kGy. (See 21CFR ~~179.26 Irradiation in the Production, Processing and Handling of Food.)~~179.26.) EU regulations permit a maximum dose of 10 kGy. (See Directive 1999/3/EC.)

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 This document is one of a set of standards that provides recommendations for properly implementing and utilizing radiation processing. It is intended to be read in conjunction with Practice ISO/ASTM 52628.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate ~~safety~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

[1] This guide is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.05 on Food Irradiation.
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[2] The boldface numbers given in parentheses refer to a list of references at the end of the text.

2. Referenced Documents

2.1 *ASTM ~~Standards~~Standards:*[3]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

F1640 Guide for Selection and Use of Contact Materials for Foods to Be Irradiated

2.2 *ISO/ASTM Standards:*[3]

~~ISO/ASTM 51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing~~

ISO/ASTM 51261 ~~Guide for the Selection and~~ Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

ISO/ASTM 51539 Guide for Use of Radiation Sensitive Indicators

ISO/ASTM ~~51431~~51608 Practice for Dosimetry in ~~Electron and X-ray (Bremsstrahlung) Irradiation Facilities for Food Processing~~an X-Ray (Bremsstrahlung) Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV

ISO/ASTM 51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV

ISO/ASTM 51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

ISO/ASTM 51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV

ISO/ASTM 52303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

ISO/ASTM 52628 Practice for Dosimetry in Radiation Processing

ISO/ASTM ~~51539~~52701 Guide for ~~Use of Radiation Sensitive Indicators~~Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.3 *Codex Alimentarius Commission (CAC) Recommended International Codes and Standards:*[4]

CAC/GL21-1997 Rev. 2013, Principles and Guidelines for the Establishment and Application of Microbiological Criteria related to Food

CAC/MISC 5-1993 Amd. 2003, Glossary of Terms and Definitions (Veterinary Drug Residues in Food)

CAC/RCP 1-1969 Rev. 2003, Recommended International Code of Practice—General Principles of Food Hygiene

CAC/RCP 19-1979 Rev. 2003, Recommended International Code of Practice for the Radiation Processing of Food

~~STAN~~CX/STAN 1-1985 Rev. 2010, General Standard for the Labeling of Prepackaged Foods

~~STAN~~CX/STAN 106-1983 Rev. 2003, General Standard for Irradiated Food

~~CAC/RCP19-1979 (Rev. 1) Recommended International Code of Practice for the Operation of Irradiation Facilities for the Treatment of Food~~[4]

2.4 *U.S. Food and Drug Administration, Code of Federal Regulations:*[5]

CFR Title 21, Part 110 Current Good Manufacturing Practices in Manufacturing, Packaging, or Handling Human Food

CFR Title 21, Section 179.25 General Provisions for Food Irradiation

CFR Title 21, Section 179.26 Irradiation in the Production, Processing and Handling of Food

2.5 *ISO Standard:*[6]

ISO 14470-2011 Food Irradiation — Requirements for the Development, Validation and Routine Control of the Process of Irradiation using Ionizing Radiation for the Treatment of Food

2.6 *The European Parliament and the Council of the European Union:*[7]

Directive 1999/3/EC Implementing – EU List of Irradiated Food and Food Ingredients

3. Terminology

3.1 *Definitions:*

3.1.1 Other terms used in this guide may be defined in Terminology E170 and Terminology E3083.

3.1.2 *absorbed ~~dose—~~dose, n—*~~quantity~~quotient of ~~ionizing~~$d\bar{\varepsilon}$ ~~radiation imparted~~by dm, ~~per unit~~where $d\bar{\varepsilon}$ ~~mass of a specified material. The SI unit of absorbed dose is the gray (Gy), where one Gray is equivalent to the absorption of one joule~~is the mean energy imparted by ionizing radiation to matter of mass dm, ~~per~~ thus

$$D = d\bar{\varepsilon}/dm$$

~~kilogram of the specified material (1Gy = 1 J/kg).~~

3.1.2.1 *Discussion—*

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact Customer Service at service @astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] Available from the Joint FAO/WHO Food Standards ~~Program,~~Programme, Joint Office, FAO, Via delle Terme di Caracalla, 00100, Rome, Italy.

[5] Available from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402–9328.

[6] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

[7] Available from the Publications Office of the European Union, 2, rue Mercier, 2985 Luxembourg, Luxembourg, https://publications.europa.eu/en/home.

~~A commonly used definition~~ The SI unit of absorbed dose ~~appears in Terminology~~is the gray ~~E170~~.(Gy), where one gray is equivalent to the absorption of one joule per kilogram of the specified material (1 Gy = 1 J / kg).

3.1.3 *absorbed dose ~~mapping~~—mapping, n*—measurement of absorbed dose within ~~a process load using dosimeters placed at specified locations~~ an irradiated product to produce a ~~one, two,~~one-, two-, or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed dose values.

3.1.4 *dose ~~distribution~~—distribution, n*—~~the~~ variation in absorbed dose within a process load exposed to ionizing radiation.

3.1.5 *dosimetry ~~system~~—system, n*—~~a system~~interrelated elements used for ~~determining~~measuring absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures ~~fro~~for the system's use.

3.1.6 *Good ~~manufacturing practice (GMP)~~—Manufacturing Practice, GMP, n*—procedure established and exercised throughout the production, manufacturing processing, packing, and distribution of foods, encompassing maintenance of sanitation system, quality control and assurance, qualification of personnel and other relevant activities, to ensure the delivery of commercially acceptable and safe product.

3.1.7 *process ~~load~~—load, n*—~~one or more containers of product collectively transported through the irradiator as a whole, for example, a box, tote, pallet, or carrier.~~volume of material with a specified product loading configuration irradiated as a single entity.

3.1.8 *~~spices~~—spices, n*—~~includes~~ dried spices, herbs, and vegetable seasonings.

3.1.9 *transport ~~system~~—system, n*—~~the~~ conveyor or other mechanical system used to move the process load through the irradiator.

4. Significance and Use

4.1 The purpose of irradiation ~~to decontaminate spices, as referred to in this guide, is to reduce the population of pathogens, other~~ of dried spices, herbs, and vegetable seasonings is to control pathogenic bacteria, molds, and yeasts present in ~~the products~~these commodities (~~22-7~~,~~3~~,~~4~~,~~5~~,~~6~~, ~~7~~).

4.2 The process will also kill any insects present, at all stages of development.

NOTE 2—CAC/RCP 19-1979 of the Codex Alimentarius identifies the essential practices to be implemented to achieve effective radiation processing of food, in general, in a manner that maintains quality and yields food commodities that are safe and suitable for consumption.

5. Pre-Irradiation Product Handling

5.1 Upon receipt at the irradiation facility, inspect packages and containers of ~~spices~~ the commodities according to relevant Good Manufacturing Practices (GMPs) to ensure that their integrity has not been compromised. See for example 21 CFR 110.

5.2 ~~Irradiation~~Radiation can be applied to ~~spices as they are prepared for processing in-line, in bulk~~ these commodities in bulk, in-line prior to packaging, or in commercial packages.

5.3 Handling of ~~spices~~ the commodities in an irradiation facility should be in accordance with relevant and current GMPs. There are no special requirements for handling of ~~spices~~ the commodities prior to irradiation except for providing control measures to prevent post-irradiation re-contamination in storage facilities and for assuring separation of irradiated and non-irradiated product.

5.3.1 *Product Separation*—It may not be possible to distinguish irradiated from non-irradiated product by inspection. It is therefore important that appropriate means, such as physical barriers, or clearly defined ~~staging~~ areas, be used to maintain non-irradiated product separate from irradiated product.

6. Packaging and Product Loading Configuration

6.1 ~~*Packaging*~~ *Packaging:*~~Materials.~~

6.1.1 Packaging ~~spices~~commodities prior to irradiation is one means of preventing post-irradiation contamination.

6.1.2 Use packaging materials suitable to the product considering any planned processing (including irradiation) and consistent with any regulatory requirements (see Guide F1640).

6.2 *Product Loading ~~Configuration.~~Configuration:*

~~6.2.1 Irradiation will be facilitated if the product packages are geometrically well defined and uniform. With certain irradiation facilities, it may be necessary to limit use to particular package shapes and sizes based on the density of the product and validation testing at known product densities in the irradiation facility (see ISO/ASTM 51204 and ISO/ASTM 51431).~~

6.2.1 The size, shape, and loading configuration of a process load for ~~spices~~ the commodities to be irradiated should be determined primarily by considering design parameters of the irradiation ~~facility.~~ facility (see Practices ISO/ASTM 51608, ISO/ASTM 51649, ISO/ASTM 51702, and ISO/ASTM 51818). Critical ~~design~~irradiation parameters include the characteristics of product transport systems and of the radiation source as they relate to the dose distribution obtained within the process load. ~~The design parameters of the irradiation facility~~ These parameters and product dose specifications should be taken into account in determining the size, shape, and loading configuration of a process load (7.3).

7. Irradiation

7.1 *Scheduled Process—Standard Operating Procedures (SOPs)—*~~Irradiation of food should conform to a scheduled process. A scheduled process~~ Standard operating procedures for food irradiation ~~is a written procedure that is~~are documented procedures that are used to ensure that the ~~absorbed~~ technologically established dose range and irradiation conditions selected by the radiation processor are ~~adequate under commercial processing conditions to achieve the intended effect on a specific product~~ achievable in a specific facility. The ~~scheduled process~~ procedures should be established by qualified persons having ~~expert~~ knowledge in irradiation requirements specific ~~for~~to the food and the ~~processor's~~ irradiation facility (21 CFR 179.25).

7.1.1 Installation qualification, operational qualification, performance qualification and process control should be performed following the requirements of Practices ISO/ASTM 51702, ISO/ASTM 51608, ISO/ASTM 51649, or ISO/ASTM 51818.

7.2 *Radiation Sources*—The sources of ionizing radiation that may be employed in irradiating ~~spices~~ these commodities are limited to the ~~following: (see Codex STAN 106)~~ following (see CX/STAN 106-1983):

7.2.1 *Isotopic Sources*—~~gamma~~Gamma rays from radionuclides ^{60}Co (1.17 and 1.33 MeV) or ^{137}Cs (0.66 ~~MeV);~~MeV) (see Practice ISO/ASTM 51702);

7.2.2 *Machine Sources*—X-rays and accelerated electrons, (see Practices ISO/ASTM 51608, ISO/ASTM 51649, and ISO/ASTM 51818).

NOTE 3—The ~~USA, other governments, and the Codex Alimentrius Commission currently limit the use of x-rays with energies not to exceed 5 MeV and the energies of electrons not to exceed 10 MeV.~~Codex Alimentarius Commission, as well as regulations in some countries, currently limits the maximum electron and X-ray energies for the purpose of food irradiation (CX/STAN 106-1983).

7.3 *Absorbed Dose*—~~Food irradiation~~ Irradiation specifications from the ~~owner~~processor of the ~~spice~~commodities should include minimum and maximum absorbed dose limits and the volume of interest where these limits should be regarded (see 7.3.3): ~~a minimum~~ the lowest dose necessary to ensure the intended effect ~~and a maximum~~ (for example, microbial load reduction, pathogen inactivation), and a highest dose that does not negatively affect the product quality to prevent product degradation. One or both of these limits may be prescribed by ~~regulation~~ government authorities for a given application. See for example 21 CFR 179.26. It is necessary to configure irradiation parameters to ensure processing is carried out within these ~~limits.~~ limits in the volume of interest. Once this capability is established, it is necessary to monitor and record absorbed dose values during routine processing. (See 11.1.3.)

NOTE 4—The minimum dose absorbed by a certain part of product volume might be zero for some applications where a targeted location of product needs to be treated. The volume of interest might be a thin external layer of the product if it has been demonstrated that microorganism control is satisfactory.

7.3.1 *Dosimetry*—Dosimetry is a major component of a total quality assurance program for adherence to good manufacturing practices used in radiation processing of food. CX/STAN 106-1983 and CAC/RCP 1-1969 strongly emphasize the role of dosimetry for ensuring that irradiation is properly performed, since dosimetry is part of a verification process for establishing that the irradiation process is under control.

7.3.2 *Dosimetry System*—~~Routine dosimetry is part of a verification process for establishing that~~ Dosimetry used in the development, validation, and routine control of the irradiation process ~~is under control. Select and calibrate a dosimetry system~~ shall have measurement traceability to national or international standards and shall have a known level of uncertainty. The selected dosimetry system should be appropriate for the ~~radiaion~~radiation source being ~~used and~~ used, the range of absorbed doses ~~required (see~~ required, and the environmental conditions (e.g., product temperature, irradiation temperature) expected during irradiation (see Guide ISO/ASTM 51261, Practice ISO/ASTM 52628, and Practice ISO/ASTM 52701) **(8)**.

7.3.3 *Absorbed-dose Mapping*—Prior to performing routine irradiation, it is necessary to characterize the dose distribution in the volume of product being irradiated through absorbed dose mapping. Dosimeters placed throughout the product provide dose measurements to identify the magnitude and location of minimum and maximum dose. The absorbed dose map depends on the product based on what the product is, how the product is packaged and oriented in the package, the packaging material, and presentation to the irradiation source. Guidance on dose mapping is given in Guide ISO/ASTM 52303.

7.3.4 ~~*Absorbed-dose Mapping—*~~*Routine Production Dosimetry—*~~Verify that the product receives the required absorbed dose by using proper dosimeter measurement procedures, with appropriate statistical controls and documentation. Place dosimeters in or on the process load at locations of maximum and minimum absorbed dose. If those locations are not accessible, place dosimeters at reference locations that have been previously related to the maximum and minimum~~The irradiation facility is responsible for delivering the absorbed doses within the specified dose range. Dosimetry should be performed following the requirements of Practices ISO/ASTM 51702~~absorbed~~, ISO/ASTM 51608~~dose~~, ISO/ASTM 51649~~locations (see~~, or ISO/ASTM ~~5120~~51818 ~~and .ISO/ASTM 51431.)~~

7.3.4.1 Once the radiation facility has demonstrated the ability to deliver the absorbed dose, it is necessary to monitor and record absorbed dose values during routine processing. (See 11.1.3.)

NOTE 5—Absorbed Dose Required to Accomplish Specific Effect—The minimum absorbed dose that has been shown to achieve the intended objective of the treatment in the volume of interest should be used. Each lot of commodity may differ in microbial load from all other lots. The owner of the commodity is responsible for specifying for each lot the absorbed dose required to reduce the microbial load to the acceptable quality level in the volume of interest. Historical information on previously processed lots may be useful for determining the appropriate dose (see Table A1.1.) The irradiation