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Standard Guide for <u>Selection and Use of</u> Packaging Materials for Foods to Be Irradiated¹

This standard is issued under the fixed designation F 1640; 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

This guide provides information on the selection and use of packaging materials intended to hold food during irradiation with ionizing energy (gamma-rays, X-rays, accelerated electrons). In general, irradiation is used to reduce the incidence of spoilage and pathogenic microorganisms and parasites in foods, control sprouting of tubers and bulbs, and serve as a quarantine treatment for insect disinfestation in fresh fruits disinfest commodities (see Guides F 1355, F 1356, F 1736, and other commodities. F 1885). Packaging materials serve to protect the product from recontamination after irradiation and may be used to complement other preservation techniques to extend the shelf life of the irradiated food.

This guide serves the following purposes: (1) identifying known regulations worldwide pertaining to packaging materials for holding foods during irradiation; (2) examining the selection of packaging materials for intended uses (for example, product protection or preservation effect); and (3) examining the criteria for fitness for use. This guide should be regarded as providing a format to assist manufacturers and users in selecting materials that comply with applicable regulations and have eharacteristics desirable for their intended uses.

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1. Scope

1.1 This guide_provides a format to assist producers and users of food packaging materials to in selecting materials that have the desirable characteristics for their intended use and comply with applicable standards or government authorizations. It outlines parameters that should be considered when selecting food-contact packaging materials intended for use during-the irradiation of prepackaged foods_and it examines the criteria for fitness for their use.

1.2 This guide highlights the role of packaging in conjunction with irradiation in controlling microbial identifies known regulations and chemical spoilage processes.

1.3 This guide regulatory frameworks worldwide pertaining to packaging materials for holding foods during irradiation; but it does not address all regulatory issues associated with the selection and use of packaging materials for foods to be irradiated. It is the responsibility of the user of this guide to determine the pertinent regulatory issues in each country where irradiated foods are to be produced or irradiated and where irradiated foods are distributed.

1.43 This guide does not address all of the food safety issues associated with the synergistic effects of irradiation and packaging as food preservation techniques on the extension of shelf life or food quality. It is the responsibility of the user of this guide to conduct appropriate risk analyses to determine the critical food safety-issues.

1.5 This guide does not address all the effects of irradiation issues and packaging on food quality and shelf life. It is the responsibility of the user of this guide to conduct appropriate product assessment tests to determine the compatibility between the packaging application and irradiation relative to changes in sensory attributes and shelf life.

1.64 This guide does not address the use of irradiation as a processing aid for the manufacture production or sterilization of food packaging materials.

1.75 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 and health practices and determine the applicability of regulatory limitations prior to use.

¹ This guide is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.06 on Food Irradiation Processing and Packaging.

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2. Referenced Documents²

2.1 ASTM Standards:

D 3985 Test Method for Oxygen Gas Transmission Through Plastic Film and Sheeting Using a Coulometric Sensor E 170. Terminology Polating to Padiation Massuraments and Desimatry

E 170 Terminology Relating to Radiation Measurements and Dosimetry

E 460 Practice for Determining Effect of Packaging on Food and Beverage Products During Storage

E 462 Test Method for Odor and Taste Transfer from Packaging Film

F 1355 Guide for Irradiation of Fresh Fruits for Disinfestation as a Quarantine Treatment

F 1356 Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry (to Control-Pathogens)³

2.2 Other Standards:

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For Annual Book of ASTM Standards, Vol 15.09. volume information, refer to the standard's Document Summary page on the ASTM website.

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Canada Food and Drug Act, Division 23, Sec. B23.001³

Relatif aux dossiers de demande d'autorisation d'emploi des constituants de materiaux et objets mis ou destines a ê tre mis au contact des denrees, produits et boissons alimentaires (Journal officiel du 4 Decembre 1986)³

2.3 Federal Standards:

Code Pathogens)

F 1736 Guide for Irradiation of Federal Regulations (CFR), Title 21, § 171.1 Petitions³

21CFR, Part 110, Current Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food⁶

CFR, Title 21, § 179.45 Packaging materials Finfish and Shellfish to Control Pathogens and Spoilage Microorganisms

<u>F 1885</u> <u>Guide</u> for use during the irradiation Irradiation of prepackaged foods⁶ <u>Dried Spices</u>, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms

3. Terminology

3.1 Definitions:

3.1.1 *aerobic environment*<u>absorbed dose</u>—an environment having a level—the quantity of oxygen that will support the growth energy from ionizing radiation absorbed per unit mass of microorganisms requiring molecular oxygen specified material. The SI unit for <u>absorbed dose is the gray (Gy)</u>. One gray is equal to one joule of absorbed energy per kilogram of specified material. Formerly, the unit of absorbed dose was the rad (1 rad = 0.01 Gy).

3.1.1.1 Discussion—A standard definition of absorbed dose appears in Terminology E 170.

3.1.2 *absorbed-dose rate*—the absorbed dose in a specified material per incremental time interval; The SI unit for absorbed-dose rate is Gy·sec⁻¹.

3.1.2.1 Discussion-A standard definition of absorbed doses appears in Terminology E 170.

<u>3.1.3</u> anaerobic environment—an environment having a level of oxygen that will not support the growth of oxygen-requiring microorganisms.

3.1.3 *barrier material*—packaging material capable of restricting the transmission of any substance (for example, moisture, oxygen, carbon dioxide, microorganisms and insects) between the product and ambient environment at a level to achieve the desired effect.

3.1.4 good manufacturing practice (GMP)—systems for sanitation, quality control and assurance, qualification of personnel, and other procedures procedures established and exercised throughout the production, manufacturing, processing, packing, and distribution of foods. I, encompassing maintenance of sanitation systems, quality control and assurance, qualification of personnel and other relevant activities, to ensure the delivery of a commercially acceptable and safe product.

<u>3.1.4.1 Discussion—In the</u> United States, the <u>GMP</u> regulations, which deal primarily with sanitation, are <u>21CFR</u>, <u>CFR</u>, <u>Title 21</u>, Part 110. While the details of the application of such systems may vary, their fundamental relevance at all stages in the food chain should be recognized. (1) $\frac{3}{2}$

3.1.5 modified_atmosphere packaging (MAP)—the use of a_a packaging system to produce for maintaining an environment around the product which that is different from the gaseous composition of air. The process modified atmosphere can include be obtained by application of a vacuum orby gas flush packaging flushing, and may be maintained by use of gas scavengers.

4. Significance and Use

4.1 Compliance with regulatory requirements within each country where an irradiated food is to be sold should be considered when selecting an appropriate packaging material to hold food to be irradiated.

4.2 The

<u>4.1 The judicious</u> selection of a packaging material is-only one step in a part of Good Manufacturing Practice (GMP) program Practices (GMPs) for the irradiation of prepackaged foods. This-selection process guide recognizes the need for food safety risk assessment relative to evaluate the proliferation impact of foodborne pathogens packaging materials on the safety and is not intended quality of foods irradiated to replace GMPs.

4.3 As part control the proliferation of food borne pathogens, afs well as tyheir impact on foodsk irradiated for other purposses, smuch as prevention of re-infestation, delay of ripening, or shelf life extension.

4.2 As part of the evaluation, the packaging selection process should consider the effects of irradiation on the chemical and physical properties of the packaging material.

4.43 Packaging is not considered to be a food preservation technique for overcoming any deficiencies attributable to inadequate GMPs during preparation, storage, or treatment of foods to be irradiated. The quality of the irradiated food will depend heavily on its initial quality, control of the irradiation process, and storage temperature and handling of the food after irradiation.

5. Regulatory Compliance

5.1 Argentina—Packaging materials recognized by the United States Food and Drug Administration (FDA) and listed in 21 CFR § 179.45 are acceptable for the holding of foods during irradiation.

Annual Book

³ The boldface numbers in parenthesis refer to the list of ASTM Standards, Vol 15.07: references at the end of this standard.

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5.2 Canada—Approval for materials for packaging Considerations

5.1 Compliance with regulatory requirements within each country where an irradiated food is to be irradiated must comply with the general food sold should be considered when selecting an appropriate packaging material regulation Sec B23.001 of the Canada Food and Drug Act. Approval is sought through Health Canada, Health Protection Branch, Ottawa. Each material is evaluated on the basis of the food type, postpackaging use conditions and irradiation process.

5.3 France—Regulations for packaging materials used to hold food during irradiation are published in its irradiation. Typically, the *Journal Officiel*, 04.12, 1986.

5.4 *Mexico*—Packaging requirements for packaging materials-recognized by the FDA and listed in 21 CFR § 179.45 are acceptable for the holding of foods during irradiation.

5.5 United States—Packaging materials for use during the irradiation of pre-packaged foods would be that they: (1) are subject to the regulations promulgated by the FDA and listed in 21 CFR § 179.45.

5.5.1 Packaging materials used approved for contact with the irradiation of poultry must allow oxygen food to enter the package to minimize the development of a strict anaerobic environment.

5.5.2 Regulation of materials that are not the subject of existing regulations can be pursued irradiated, (2) are resistant to ionizing radiation with the U.S. Food respect to their physical properties, and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) through the petition process (see 21 CFR § 171.1). Data submitted should establish that the irradiation process does (3) are not cause the transfer sources of odor, flavor, or any substance substances that may have toxicological significance f as a result of their migration into the packaging material to food (2-4).

<u>5.2 Canada and the food, or cause the packaging material to exceed the United States have specific limitation regulatory</u> requirements for migration or extractables provided by regulation.

5.6 Other Countries—Sweden and Germany do not permit the irradiation or sale of irradiated foods. packaging materials that are permitted to hold food during irradiation. Other countries, in general, do not provide a specific list of packaging materials that are permitted to hold food during irradiation. However, regulations a regulatory framework may exist in these countries which make provisions to permit provides for the direct irradiation of foods. Typically, foods.

5.3 A review of the requirements for packaging materials to be used in these countries for holding foods during regulations of food irradiation would be that has been compiled by the materials (I) be approved for International Consultative Group on Food Irradiation (ICGFI) under the packaging aegis of foods, (2) be resistant to ionizing radiation with respect to their physical properties, the Food and (3) not transmit flavors or other substances that may have toxicological significance from Agriculture Organization (FAO), the packaging material International Atomic Energy Agency (IAEA), and the World Health Organization (WHO). Regulations specific to the use of packaging materials for food ($(1,2,3)^4$). It irradiation for some of the participating countries is advisable that available in the country where irradiated foods are to be produced or sold be consulted for specific regulations. ICGFI publication "Regulations in the Field of Food Irradiation" published by the IAEA. (5) (See Appendix X1.)

6. Fitness for Use

6.1 <u>Chemical Effects</u>—The irradiation of packaging materials <u>can will</u> lead to the formation of free radicals or ions, formation of unsaturated molecular bonds, <u>and</u> scission and cross-linking of polymeric <u>chains</u>, and the liberation of <u>gases</u>. <u>chains</u>. These <u>effects can reactions may</u> modify the physical properties of packaging materials <u>and produce low molecular weight radiolytic</u> <u>products with potential to migrate into food</u>. The extent of the radiation-induced changes is a function of polymer type, additives in the material, the absorbed dose and absorbed-dose rate, <u>and the atmosphere during irradiation</u>. These factors should be taken <u>into account when evaluating the suitability</u> of <u>irradiation</u>, <u>a packaging material</u> and <u>to ensure that</u> the <u>i naturre andi quantity</u> of <u>any substances that may migrate frosm the packaging material into the food will not</u> render the food unsafe or otherwise undesirable for consumption.

6.2 <u>Physical Properties</u>—Physical properties, such as strength, opacity, color, seal integrity, <u>delamination of multi-layer</u> structures, <u>brittleness</u>, <u>interlaminar bond strength</u>, <u>brittleness resulting from age or temperature</u>, and <u>gas moisture</u> transmission rates, should be examined for change <u>after processing</u>. In general, the <u>functional and protective behavior characteristics of</u> packaging materials should not be adversely affected by the absorbed-dose absorbed dose ranges used to irradiate foods for pasteurization or disinfestation (2, 4).

6.3 The risk(3,6) do not adversely affect the functional and protective behavior characteristics of t_packaging materials.

<u>6.3 Sengsorial Effects</u>—Foods packaged prior to irradiation may become tainted with volatile compounds from the packaging materials by during and following irradiation. The significance of this effect should be determined with appropriate sensory tests. Odor intensity of irradiated packaging material alone is not always an adequate measure of potential tainting of the food.—For approaches to Appropriate methods for evaluating the fitness of packaging materials, see these effects are described in Practice E 460, Test Method E 462, and Ref (7).

6.4 <u>Microbiological Effects</u>—Packaging systems and irradiation treatments that<u>-collectively_combine_to</u> enhance shelf-life extension should be assessed for their risk of contributing to a favorable environment for growth of foodborne pathogens and subsequent development of a toxic or infectious product.-A

Note 1—For example attention should be given to foods that may harbor spores of *Clostridium botulinum*, particularly when the product environment is anaerobic, the temperature is neither refrigerated nor frozen, the product is low-acid and the product medium is capable of supporting the outgrowth of *C. botulinum* spores. Irradiation at absorbed-dose ranges recommended for the treatment of the pasteurization of foods effectively reduces the spoilage

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bacterial but is <u>may be</u> insufficient to destroy spores of *C. botulinum*. The spoilage microflora of foods is recognized as an important hurdle to the growth of *C. botulinum*. Furthermore, the proliferation of spoilage microflora and the resulting spoilage can be an indicator of product temperature abuse. The rate of spoilage and characteristics of the spoiled product are dependent on factors such as the microbial load before and after irradiation, storage temperature, and the use of a modified atmosphere condition or other processes (68). Furthermore, the proliferation of spoilage microflora and the resulting spoilage can be an indicator of product temperature abuse.

7. Packaging Applications

7.1 *Requirements for Protecting Protecting Food*—It is generally a requirement to package food_Many foods are packaged before it is being irradiated to prevent their recontamination or reinfestation of the food re-infestation with pests or microorganisms or pests following the irradiation treatment. Splits or punctures in packaging material—ors, seal failures, or other defects can compromise protection.

7.2 Requirements for Preserving Preserving Food—Modified Atmosphere Packaging (MAP)—The effect of foods is often used to complement other preservation techniques to minimize the rate of product deterioration. The effects of irradiation on foods usually does not-necessarily remove the reliance on packaging as a food preservation technique. Food products intended for irradiation-should must be of good initial quality and-should have been be processed and-held under stored according to GMPs to minimize changes in chemical or microbial processes that may contribute to product spoilage. The effects of irradiation on oxidative processes and the succession of surviving microorganisms may raise sensory and food safety concerns that will influence the selection of the packaging material or processing system used for a food. Modified Atmosphere Packaging (MAP) of foods is often used to complement other preservation techniques to minimize the rate of product deterioration (8).

8. Sensory-Considerations-Changes in Food

8.1 Irradiation should not result in unacceptable sensory changes in the food. The <u>sensitivity degree and nature</u> of <u>a food to</u> radiation-induced changes <u>can be affected by irradiation conditions</u>, in the <u>availability food is a function</u> of the absorbed dose, the <u>absorbed-dose rate</u>, the presence of oxygen during irradiation, the composition of the food, product <u>composition</u>, and product temperature at <u>the</u> time of <u>irradiation</u>. The effects of radiation-induced changes <u>can be minimized by controlling irradiation</u> conditions, the availability of oxygen, product composition, <u>irradiation</u>, and <u>irradiation temperature</u>. <u>other factors</u>. The effects of irradiation on sensory attributes <u>are can</u> also <u>dependent on be affected by</u> methods of product formulation, <u>packaging</u>, and <u>packaging and</u> cooking conditions. The effects of radiation-induced changes can be minimized by controlling these factors.

8.2 *Fatty Foods*— SpecialOxidative Changes—Special attention should be given to assessing flavor, odor, and color changes of fresh or frozen fatty foods (for example, meat, poultry, seafood, and coconut products, dairy products, grains and meats). Irradiation, through the generation of free radicals, can promote the oxidation of foods, particularly fatty fatts in such foods. In general, the higher the absorbed dose and irradiation temperature, the greater the probability of producing sensory changes in food. Packaging of fatty foods in a low oxygen atmosphere can reduce the extent of oxidative changes of the food during irradiation, especially if the product is kept frozen during the treatment (59).

8.3 *Fresh Fruits and other CommoditiesOther Sensory Changes*—In general, packaging-used for these foods serves is expected to prevent post-irradiation re-infestation by insects or re-inoculation with fungi, microorganisms, and to minimize moisture loss. The Additionally, the use of packaging in conjunction with irradiation should not contribute to pitting of the surface tissue of the food, irreversibly impair the ripening process, or cause uncharacteristic textural changes.

9. Keywords

9.1 bacteria; food; irradiation; MAP; modified atmosphere packaging; packaging; pathogens

APPENDIX

(Nonmandatory Information)

X1. NATIONAL REGULATIONS ON PACKAGING MATERIALS

X1.1 Argentina—"The packaging material shall not have a harmful effect on the contents and shall not produce abnormal odors or toxic products during irradiation. It shall require approval by the National Health Authority" (Food Code, Article 174, Para. 5.1 of the Annex).

X1.2 *Bangledesh*—"The packaging materials to be used in the irradiation of prepackaged foods shall be defined in the national authorization for the specific food item" (Sec. 5.2 of Standard 1077, Specification for Irradiated Foods).

X1.3 Brazil—"Packaging materials to be used for the irradiation of prepackaged food must be of a type and quality that is appropriate for this process in conformity with the specific standards established by the Ministry of Health" (Directive No. 9, 8 March 1985, Para. 3.2.1).

X1.4 *Canada*—Approval for materials for packaging food to be irradiated must comply with the general food packaging material regulation of the Canada Food and Drug Act. (10) Approval is sought through Health Canada, Health Protection Branch, Ottawa. Each material is evaluated on the basis of the food type, post-packaging use conditions, and irradiation process.

X1.5 Costa Rica — "Packaging material shall be of suitable quality and of acceptable and appropriate hygienic condition and be handled before and after irradiation in conformity with adequate manufacturing practices, taking into account particular technological exigencies of the process" (General Standard for Irradiated Foods, NCR 167:1993, Para. 4.2).

X1.6 *Cuba*—Packaging materials for the irradiation of prepackaged foods must be of a type and material approved for that particular food and irradiation process in question (Sanitary Standards for Foods, Irradiated food regulation No. 38-08, Para. 3.13).

X1.7 India—Packaging materials are described in Schedule VII of the Rules Control of the Irradiation of Food, 1990, Department of Atomic Energy, Published in Gazette of India, Part II Sec. 3(I), p. 478-487, Section 9(2)(b).

X1.8 Indonesia — The general requirements contained in the Codex General Standard are listed in Annex 2 of Regulations on Irradiated Food, No. 826/MENKES/PER/XII/1987.

X1.9 Mexico—Packaging materials that may be used in the irradiation of food are listed in Appendice A to the Mexican Standard NOM-033-SSA-1993.

X1.10 *People's Republic of China*—Packaging material for irradiated food shall be non-toxic, stable, and conforming to hygienic standards and to the requirements of irradiation technology (Provision Regulation for Hygienic Control of Irradiated Foods, Article 14).

X1.11 Syrian Arab Republic-As provided in the Decrees No. 119, para 4.2 of the National Standard 402.

X1.12 United States (11)—Packaging materials for use during the irradiation of pre-packaged foods shall be used in conformity to a regulation promulgated by the Food and Drug Administration (FDA) resulting from submission of a food additive petition; the subject of a letter from the FDA stating no objection to its use under the Threshold of Regulation process; or be the subject of an effective Food-contact Notification to the FDA.

<u>X1.12.1</u> Packaging materials used for the irradiation of poultry must allow oxygen to enter the package to minimize the development of a strict anaerobic environment. (12)

X1.13 Yugoslavia — Food packaging materials for the use of irradiating foods are subject to the provisions of the "Regulation concerning the Condition of Trade in Irradiated Food and other Items in General Use," published in the Yugoslav Gazette Bo. 68 of 28 December 1984.

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- (12) U.S. Department of Agriculture, Code of Federal Regulations, Title 9, Section 381.147, Restrictions on the Use of Substances in Poultry Products, Washington DC.

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