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Standard Guide for Selection and Use of Packaging Materials for Foods to Be Irradiated[1]

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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 disinfest commodities (see Guides F 1355, F 1356, F 1736, and F 1885). Packaging materials serve to protect the product from recontamination after irradiation and may be used to complement other preservation techniques to extend shelf life of the irradiated food.

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 irradiation of prepackaged foods and it examines the criteria for fitness for their use.

1.2 This guide identifies known regulations and 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 foods are to be irradiated and where irradiated foods are distributed.

1.3 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 determine the critical food safety issues and 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.

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

1.5 *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.*

2. Referenced Documents [2]

2.1 *ASTM Standards:*

D 3985 Test Method for Oxygen Gas Transmission Through Plastic Film and Sheeting Using a Coulometric Sensor

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)

F 1736 Guide for Irradiation of Finfish and Shellfish to Control Pathogens and Spoilage Microorganisms

F 1885 Guide for Irradiation of Dried Spices, Herbs, and

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[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* volume information, refer to the standard's Document Summary page on the ASTM website.

Vegetable Seasonings to Control Pathogens and Other Microorganisms

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose*—the quantity of energy from ionizing radiation absorbed per unit mass of specified material. The SI unit for absorbed dose is the gray (Gy). 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 $Gy \cdot sec^{-1}$.

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

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

3.1.4 *good manufacturing practice (GMP)*—procedures established and exercised throughout the production, manufacturing, processing, packing, and distribution of foods, 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.

3.1.4.1 *Discussion*—In the United States, the GMP regulations, which deal primarily with sanitation, are CFR, Title 21, Part 110. **(1)**[3]

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

4. Significance and Use

4.1 The judicious selection of a packaging material is part of Good Manufacturing Practices (GMPs) for the irradiation of prepackaged foods. This guide recognizes the need to evaluate the impact of packaging materials on the safety and quality of foods irradiated to control the proliferation of food borne pathogens, as well as their impact on foods irradiated for other purposes, such 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.

4.3 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, storage temperature and handling of the food after irradiation.

[3] The boldface numbers in parenthesis refer to the list of references at the end of this standard.

5. Regulatory Considerations

5.1 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 during its irradiation. Typically, the requirements for packaging materials for holding foods during irradiation would be that they: *(1)* are approved for contact with the food to be irradiated, *(2)* are resistant to ionizing radiation with respect to their physical properties, and *(3)* are not sources of substances that have toxicological significance as a result of their migration into the food **(2-4)**.

5.2 Canada and the United States have specific regulatory requirements for 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, a regulatory framework may exist in these countries which provides for the direct irradiation of foods.

5.3 A review of the regulations of food irradiation has been compiled by the International Consultative Group on Food Irradiation (ICGFI) under the aegis of the Food and Agriculture Organization (FAO), the International Atomic Energy Agency (IAEA), and the World Health Organization (WHO). Regulations specific to the use of packaging materials for food irradiation for some of the participating countries is available in the ICGFI publication "Regulations in the Field of Food Irradiation" published by the IAEA. **(5)** (See Appendix X1.)

6. Fitness for Use

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

6.2 *Physical Properties*—Physical properties, such as strength, opacity, color, seal integrity, interlaminar bond strength, brittleness resulting from age or temperature, and gas moisture transmission rates, should be examined for change after processing. In general, the absorbed dose ranges used to irradiate foods for pasteurization or disinfestation **(3,6)** do not adversely affect the functional and protective behavior characteristics of packaging materials.

6.3 *Sensorial Effects*—Foods packaged prior to irradiation may become tainted with volatile compounds from the packaging materials 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. Appropriate methods for evaluating these effects are described in Practice E 460, Test Method E 462, and Ref **(7)**.

6.4 *Microbiological Effects*—Packaging systems and irradiation treatments that combine to 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.

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 pasteurization of foods effectively reduces the spoilage bacteria but may be insufficient to destroy spores of *C. botulinum*. The spoilage microflora of foods is recognized as an important hurdle to the growth of *C. botulinum*. 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 or other processes **(8)**. Furthermore, the proliferation of spoilage microflora and the resulting spoilage can be an indicator of product temperature abuse.

7. Packaging Applications

7.1 *Protecting Food*—Many foods are packaged before being irradiated to prevent their recontamination or re-infestation with microorganisms or pests following the irradiation treatment. Splits or punctures in packaging materials, seal failures, or other defects can compromise protection.

7.2 *Preserving Food*—The effect of irradiation on foods usually does not remove the reliance on packaging as a food preservation technique. Food products intended for irradiation must be of good initial quality and be processed and 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 Changes in Food

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

8.2 *Oxidative Changes*—Special attention should be given to assessing flavor, odor, and color changes of fresh or frozen fatty foods (for example, coconut products, dairy products, grains and meats). Irradiation, through the generation of free radicals, can promote the oxidation of fats 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 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 **(9)**.

8.3 *Other Sensory Changes*—In general, packaging is expected to prevent post-irradiation re-infestation by insects or re-inoculation with microorganisms, and minimize moisture loss. 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.

X1.12.1 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.

REFERENCES

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(**9**) Thayer, D. W., "Extending Shelf Life of Poultry and Red Meat by Irradiation Processing," *Journal of Food Prot*., Vol 56, 1993, pp. 831-833.

(**10**) Canada Food and Drug Act, Division 23, Sec B 23.001. Available from Canada Communications Group, Supply & Service, Publishing Centre, 45 Sacre-Coeur Blvd., Hull, Quebec, K1A 0S9, Canada.

(**11**) U.S. Food and Drug Administration, United States Code of Federal Regulations, Title 21, Section 170.39, Threshold of Regulation for Substances Used in Food-Contact Articles; Subpart D, Premarket Notifications (Sections 170.100-170.106); Section 171.1, Petitions; and Section 179.45, Packaging Materials for Use During the Irradiation of Prepackaged Foods. See also: Federal Register Vol 65 (July 13, 2000) pp. 43269-43284, Food Additives: Food Contact Substance Notification System (Proposed Rule) and Federal Register Vol 67 (May 21, 2002) pp. 35724-35731 (Final Rule), Washington, DC.

(**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.