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Standard Guide for Packaging Materials for Foods to Be Irradiated[1]

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. 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 and other commodities. 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 characteristics desirable for their intended uses.

1. Scope

1.1 This guide outlines parameters that should be considered when selecting food-contact packaging materials intended for use during the irradiation of prepackaged foods.

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

1.3 This guide does not address all regulatory issues associated with 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 distributed.

1.4 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. 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 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.

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

1.7 *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

2.1 *ASTM Standards:*

D 3985 Test Method for Oxygen Gas Transmission Through Plastic Film and Sheeting Using a Coulometric Sensor[2]

E 460 Practice for Determining Effect of Packaging on Food and Beverage Products During Storage[3]

E 462 Test Method for Odor and Taste Transfer from Packaging Film[3]

F 1355 Guide for Irradiation of Fresh Fruits for Disinfestation as a Quarantine Treatment[3]

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

2.2 *Other Standards:*

Canada Food and Drug Act, Division 23, Sec. B23.001[4]

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[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] *Annual Book of ASTM Standards*, Vol 15.09.

[3] *Annual Book of ASTM Standards*, Vol 15.07.

[4] Available from Canada Communications Group, Supply & Service, Publishing Centre, 45 Sacre-Couer Blvd., Hull, Quebec, K1A 0S9, Canada.

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tre mis au contact des denrees, produits et boissons alimentaires (Journal officiel du 4 Decembre 1986)[5]

2.3 *Federal Standards:*

Code of Federal Regulations (CFR), Title 21, § 171.1 Petitions[6]

21CFR, Part 110, Current Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food[6]

CFR, Title 21, § 179.45 Packaging materials for use during the irradiation of prepackaged foods[6]

3. Terminology

3.1 *Definitions:*

3.1.1 *aerobic environment*—an environment having a level of oxygen that will support the growth of microorganisms requiring molecular oxygen for respiration.

3.1.2 *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 established and exercised throughout the production, manufacturing, processing, packing, and distribution of foods. In the United States, the regulations, which deal primarily with sanitation, are 21CFR, 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.

3.1.5 *modified atmosphere packaging (MAP)*—the use of a packaging system to produce an environment around the product which is different from the gaseous composition of air. The process can include vacuum or gas flush packaging and 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 selection of a packaging material is only one step in a Good Manufacturing Practice (GMP) program for the irradiation of prepackaged foods. This selection process recognizes the need for food safety risk assessment relative to the proliferation of foodborne pathogens and is not intended to replace GMPs.

4.3 As part of food safety risk assessment, the packaging selection process should consider the effects of irradiation on the chemical and physical properties of the packaging material.

4.4 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 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.

5.2 *Canada*—Approval for materials for packaging food to be irradiated must comply with the general food 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 the *Journal Officiel, 04.12, 1986.*

5.4 *Mexico*—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 are subject to the regulations promulgated by the FDA and listed in 21 CFR § 179.45.

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

5.5.2 Regulation of materials that are not the subject of existing regulations can be pursued with the U.S. Food 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 not cause the transfer of odor, flavor, or any substance that may have toxicological significance from the packaging material to the food, or cause the packaging material to exceed the specific limitation for migration or extractables provided by regulation.

5.6 *Other Countries*— Sweden and Germany do not permit the irradiation or sale of irradiated foods. Other countries, in general, do not provide a specific list of packaging materials that are permitted to hold food during irradiation. However, regulations may exist in these countries which make provisions to permit the direct irradiation of foods. Typically, the requirements for packaging materials to be used in these countries for holding foods during irradiation would be that the materials (*1*) be approved for the packaging of foods, (*2*) be resistant to ionizing radiation with respect to their physical properties, and (*3*) not transmit flavors or other substances that may have toxicological significance from the packaging material to the food **(1,2,3)**[7]. It is advisable that the country where irradiated foods are to be produced or sold be consulted for specific regulations.

[5] Available from Journel Official, 26 Rue Desaix, 75727 Paris, CEDEX 15, France. Available in the United States from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22151 as Order No. DE88700050.

[6] Available from U.S Government Printing Office, Superintendent of Documents, Washington, DC 20402-9328.

[7] The boldface numbers given in parentheses refer to a list of references at the end of the text.

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6. Fitness for Use

6.1 The irradiation of packaging materials can lead to the formation of free radicals or ions, formation of unsaturated molecular bonds, scission and cross-linking of polymeric chains, and the liberation of gases. These effects can modify the physical properties of packaging materials. The extent of the radiation-induced changes is a function of polymer type, additives in the material, the absorbed dose and absorbed-dose rate of irradiation, and the irradiation atmosphere.

6.2 Physical properties, such as strength, opacity, color, seal integrity, delamination of multi-layer structures, brittleness, and gas transmission rates, should be examined for change. In general, the functional and protective behavior characteristics of packaging materials should not be adversely affected by the absorbed-dose ranges used to irradiate foods for pasteurization or disinfestation **(2, 4)**.

6.3 The risk of tainting foods with volatile compounds from packaging materials by irradiation 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 evaluating the fitness of packaging materials, see Practice E 460, Test Method E 462, and Ref **(7)**.

6.4 Packaging systems and irradiation treatments that collectively 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. Attention should be given to foods that may harbor spores of *Clostridium botulinum*, particularly when the product environment is anaerobic 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 bacterial but is 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 **(6)**.

7. Packaging Applications

7.1 *Requirements for Protecting Food*— It is generally a requirement to package food before it is irradiated to prevent recontamination or reinfestation of the food with pests or microorganisms following the irradiation treatment. Splits or punctures in packaging material or seal failure can compromise protection.

7.2 *Requirements for Preserving Food*—Modified Atmosphere Packaging (MAP) of foods is often used to complement other preservation techniques to minimize the rate of product deterioration. The effects of irradiation on foods does not necessarily remove the reliance on packaging as a food preservation technique. Food products intended for irradiation should be of good initial quality and should have been processed and held under 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 system used for a food.

8. Sensory Considerations

8.1 Irradiation should not result in unacceptable sensory changes in the food. The sensitivity of a food to radiation-induced changes can be affected by irradiation conditions, the availability of oxygen, product composition, and product temperature at time of irradiation. The effects of radiation-induced changes can be minimized by controlling irradiation conditions, the availability of oxygen, product composition, and irradiation temperature. The effects of irradiation on sensory attributes are also dependent on methods of product formulation and packaging and cooking conditions.

8.2 *Fatty Foods*— Special attention should be given to assessing flavor, odor, and color changes of fresh or frozen fatty foods (for example, meat, poultry, seafood, and dairy products). Irradiation, through the generation of free radicals, can promote the oxidation of foods, particularly fatty 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 **(5)**.

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

9. Keywords

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

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