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## Standard Guide for Packaging Materials for Foods to Be Irradiated<sup>1</sup>

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 approval. A superscript epsilon ( $\epsilon$ ) 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<sup>2</sup>

E 460 Practice for Determining Effect of Packaging on Food and Beverage Products During Storage<sup>3</sup>

E 462 Test Method for Odor and Taste Transfer from Packaging Film<sup>3</sup>

F 1355 Guide for Irradiation of Fresh Fruits for Disinfestation as a Quarantine Treatment<sup>3</sup>

F 1356 Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry (to Control Pathogens)<sup>3</sup>

#### 2.2 Other Standards:

Canada Food and Drug Act, Division 23, Sec. B23.001<sup>4</sup>  
Relatif aux dossiers de demande d'autorisation d'emploi des constituants de matériaux et objets mis ou destinés à être

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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 15.09.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 15.07.

<sup>4</sup> Available from Canada Communications Group, Supply & Service, Publishing Centre, 45 Sacre-Coeur Blvd., Hull, Quebec, K1A 0S9, Canada.

tre mis au contact des denrees, produits et boissons alimentaires (Journal officiel du 4 Decembre 1986)<sup>5</sup>

### 2.3 Federal Standards:

Code of Federal Regulations (CFR), Title 21, § 171.1 Petitions<sup>6</sup>

21CFR, Part 110, Current Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food<sup>6</sup>  
CFR, Title 21, § 179.45 Packaging materials for use during the irradiation of prepackaged foods<sup>6</sup>

## 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)<sup>7</sup>. It is advisable that the country where irradiated foods are to be produced or sold be consulted for specific regulations.

<sup>5</sup> Available from Journal Officiel, 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.

<sup>6</sup> Available from U.S Government Printing Office, Superintendent of Documents, Washington, DC 20402-9328.

<sup>7</sup> The boldface numbers given in parentheses refer to a list of references at the end of the text.