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

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INTRODUCTION

This guide provides information on the selection and use of ~~packaging~~contact materials for packaging intended to hold food during ~~irradiation~~treatment 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 F1355, F1356, F1736, and F1885). ~~Packaging~~ Food contact 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. Molecules from food contact materials can migrate to the food when these materials are in contact with the food. Because of this, in many countries regulations are made to ensure food safety. The amended FD&C Act (United States, 1998a) defined a food contact material as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food." Common types of food contact materials include coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging.

1. Scope

1.1 This guide provides a format to assist producers and users of food ~~packaging materials~~ in selecting contact materials that have the desirable characteristics for their intended use and that comply with applicable standards or government authorizations. It outlines parameters that should be considered when selecting ~~food-contact packaging~~food contact 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~~contact materials for holding foods during ~~irradiation;~~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 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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

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[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. Referenced Documents

2.1 *ASTM Standards:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E460 Practice for Determining Effect of Packaging on Food and Beverage Products During Storage

E462 Test Method for Odor and Taste Transfer From Packaging Film (Withdrawn 1998)[3]

F1355 Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment

F1356 Guide for Irradiation of Fresh, Frozen or Processed Meat and Poultry to Control Pathogens and Other Microorganisms

F1736 Guide for Irradiation of Finfish and Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms

F1885 Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose—dose (D)—*quantity of ionizing[ICRU-85a, 5.2.5] — quotient of $d\bar{\varepsilon}$ radiation by d*m*, where $d\bar{\varepsilon}$ energy imparted per unit mass of specified material. is the mean incremental energy imparted by ionizing radiation to matter of mass d*m*, The thus

SI

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

unit for absorbed dose is the gray (Gy), where one gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1Gy = 1 J/kg).

[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.

[3] The last approved version of this historical standard is referenced on www.astm.org.

3.1.1.1 *Discussion—*

A standard definitionThe SI unit of absorbed dose appears in Terminologyis the gray E170.(Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy=1 J/kg).

3.1.2 *absorbed-dose rate—absorbed dose rate (**Ḋ**)—*the absorbed dose in a material per incremental time interval; ie., the quotient of [ICRU-85a, 5.2.6]—quotient of d*dD*D by d*dt*t (D =where d*D* disD/dt). The SI unit for absorbed-dose rate is Gy·s the increment of absorbed dose in the time^{-1}: interval d*t,* thus

$$\dot{D} = dD/dt$$

3.1.2.1 *Discussion—*

A standard definition of absorbed dose appears in Terminology E170.

(1) The SI unit is Gy-s^{-1}. However, the absorbed-dose rate is often specified in terms of its average value over longer time intervals, for example, in units of Gy·min^{-1} or Gy·h^{-1}.

(2) In gamma industrial irradiators, dose rate may be significantly different at different locations.

(3) In electron-beam irradiators with pulsed or scanned beam, there are two types of dose rate: average value over several pulses (scans) and instantaneous value within a pulse (scan). These two values can be significantly different.

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 *food contact material (also referred to as 'contact material'*—any material (not only packaging) that is expected to come into contact with food.

3.1.4.1 *Discussion—*

Food contact materials are either intended to be brought into contact with food, are already in contact with food, or can reasonably be brought into contact with food which could lead to the transfer of their constituents to the food under normal or foreseeable use. Food contact materials can be constructed from a variety of materials like plastics, rubber, paper, coatings, metal, etc. In many cases a combination is used; for example, a carton box for juices can include (from the inside to the outside): plastic layer, aluminum, paper, printing and top coating.

3.1.5 *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.

3.1.5.1 *Discussion*—

In the United States, the GMP regulations, which deal primarily with sanitation, are CFR, Title 21, Part 110. (**1**)[4]

3.1.6 *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 or by gas flushing, and may be maintained by use of gas scavengers.~~

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

3.1.6.1 *Discussion*—

The modified atmosphere can be obtained by application of a vacuum or by gas flushing, and may be maintained by use of gas scavengers.

4. Significance and Use

4.1 The judicious selection of a ~~packaging~~contact 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~~ 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~~ shelf-life extension.

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

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~~contact material to hold food during its irradiation. Typically, the requirements for ~~packaging~~contact 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~~contact materials that are permitted to hold food during irradiation. Other countries, in general, do not provide a specific list of ~~packaging~~contact 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~~contact 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~~contact 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~~contact material and to ensure that the nature and quantity of any substances that may migrate from the ~~packaging~~contact 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.