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

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INTRODUCTION

This guide provides information on the selection and use of contact materials for packaging intended to hold food during 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). 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. Substances 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 substance 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."[2] 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 in selecting food 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 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 food contact 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 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 document is one of a set of standards that provides recommendations for properly implementing and utilizing radiation processing. It is intended to be read in conjunction with ISO/ASTM 52628.

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

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the*

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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] Information on Food Contact Materials and the associated definitions can be found on the FDA website, (https://www.fda.gov/food/food-ingredients-packaging).

Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

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)[4]

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

2.2 *ISO/ASTM Standards:*[3]

ISO/ASTM 52628 Practice for Dosimetry in Radiation Processing

3. Terminology

3.1 *Definitions:*

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

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

3.1.1.1 *Discussion*—The SI unit of absorbed dose is the gray (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* ($\dot{D}$)—[ICRU-85a, 5.2.6]—quotient of dD by dt where dD is the increment of absorbed dose in the time interval dt, thus

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

3.1.2.1 *Discussion*—

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

(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**)[5]

3.1.6 *modified-atmosphere packaging (MAP)*—packaging system for maintaining an environment around the product that is different from the gaseous composition of air.

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 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 pathogens, as well as their impact on foods irradiated for other purposes, such as for phytosanitary treatment, delay of ripening, or 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 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 contact material to

[3] 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.

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

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

hold food during its irradiation. Typically, the requirements for 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 contact materials that are permitted to hold food during irradiation. Other countries, in general, do not provide a specific list of 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). (**5**)

6. Fitness for Use

6.1 *Chemical Effects*—The irradiation of contact materials will lead to the formation of free radicals or ions, formation of unsaturated molecular bonds and scission or cross-linking of polymeric chains. These reactions may modify the physical properties of 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 contact material and to ensure that the nature and quantity of any substances that may migrate from the 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. In general, the absorbed dose ranges used to irradiate foods for pasteurization or disinfestation (**3**, **6**) are not likely to affect the functional and protective behavior characteristics of contact materials.

6.3 *Sensorial Effects*—Foods packaged prior to irradiation may become tainted with volatile compounds from the contact materials during and following irradiation. The significance of this effect should be determined with appropriate sensory tests. Odor intensity of irradiated contact material alone is not always an adequate measure of potential tainting of the food. Appropriate methods for evaluating these effects are described in Practice E460, Test Method E462, and Ref (**7**). Recently, the use of regression modeling has been proposed to analyze the results of these sensory tests in a more objective way (see Ref (**8**)).

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 undesirable microorganism and subsequent development of an inferior 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 (**9**). 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 including flaws and micro-cracks in contact 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 (**9**).

8. Sensory Changes in Food

8.1 Irradiation conditions, product formulation, contact materials, and cooking conditions can affect the sensory attributes of food. Irradiation should be conducted under appropriate conditions such that it does not result in unacceptable sensory changes. 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 and the contact material, product temperature at the time of irradiation, and other factors. The effects of radiation-induced changes can be minimized by controlling these factors.

NOTE 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, higher absorbed dose and irradiation temperature increase 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 (**10**).

8.2 *Other Sensory Changes*—In general, the packaging provides a barrier that minimizes moisture loss and prevents re-infestation by insects or re-inoculation with microorganisms