Designation: F1356 – 16

Standard Guide for Irradiation of Fresh, Frozen or Processed Meat and Poultry to Control Pathogens and Other Microorganisms[1]

This standard is issued under the fixed designation F1356; 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

The purpose of this guide is to present information on the use of ionizing radiation in treating fresh, frozen, or processed meat and poultry products to eliminate or reduce the numbers of vegetative, pathogenic microorganisms and parasites, and to extend the refrigerated shelf-life of those products by reducing the numbers of spoilage microorganisms.

This guide is intended to serve as a set of recommendations to be followed when using irradiation technology where approved by an appropriate regulatory authority. It is not to be construed as setting forth rigid requirements for the use of irradiation. While the use of irradiation involves certain essential requirements to attain the objective of the treatment, some parameters can be varied in optimizing the process.

This guide has been prepared from a Code of Good Irradiation Practice published by the International Consultative Group on Food Irradiation (ICGFI) developed under the auspices of the Food and Agriculture Organization (FAO), the World Health Organization (WHO), and the International Atomic Energy Agency (IAEA) (**1**).[2]

1. Scope

1.1 This guide outlines procedures for the irradiation of fresh, frozen, or processed meat and poultry.

NOTE 1—The Codex Alimentarius Commission defines meat as "the edible part of any mammal" and poultry as "any domesticated bird, including chicken, turkeys, ducks, geese, guinea-fowls, or pigeons" (CAC/MISC 5).

NOTE 2—Current U.S. regulations limit the definition of meat and poultry as listed in 9 CFR Section 301.2 and 381.1, respectively. (**2, 3**).

1.2 This guide covers the use of ionizing radiation to eliminate or reduce the numbers of vegetative, pathogenic microorganisms and parasites, and to extend the refrigerated shelf-life of those products by reducing the numbers of spoilage microorganisms in fresh, frozen, or processed meat and poultry. The absorbed dose for this application is typically less than 10 kGy.

1.3 This guide addresses irradiation of pre-packaged product for retail sale or for use as an ingredient in other products. It also addresses the in-line irradiation of unpackaged product. Other specific ISO and ASTM standards exist for the irradiation of food. In those areas covered by ISO 14470, that standard takes precedence.

1.4 *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:*[3]

E170 Terminology Relating to Radiation Measurements and Dosimetry

F1416 Guide for Selection of Time-Temperature Indicators

F1640 Guide for Selection and Use of Packaging Materials for Foods to Be Irradiated

2.2 *ISO/ASTM Standards:*[3]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51539 Guide for Use of Radiation-Sensitive Indicators

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung)

[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.

Current edition approved Feb. 1, 2016. Published March 2016. Originally approved in 1991. Last previous edition approved in 2008 as F1356 – 08. DOI: 10.1520/F1356-16.

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

[3] For referenced ASTM and ISO/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.

Facility for Radiation Processing at Energies between 50 keV and 7.5 MeV
51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV
51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing
51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV
52303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities
52628 Practice for Dosimetry in Radiation Processing
52701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.3 *Codex Alimentarius Commission Recommended International Codes and Standards:*[4]
CAC/RCP 1-1969, Rev. 4-2003, Recommended International Code of Practice—General Principles of Food Hygiene including Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application
CAC/RCP 19-1979, Rev. 2003, Recommended International Code of Practice for the Radiation Processing of Food
CX STAN 1-1985, Rev. 2010, General Standard for the Labeling of Prepackaged Foods
CX STAN 106, Rev. 2003, General Standard for Irradiated Food
CAC/MISC 5-1993, Amd. 2003, Glossary of Terms and Definitions (Veterinary Drug Residues in Food)
CAC/GL21-1997, Rev. 2013, Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Food

2.4 *ISO Standard*[5]
ISO 14470-2011 Food irradiation-requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

3. Terminology

3.1 *Definitions:*

3.1.1 Other terms used in this guide may be defined in Terminology E170.

3.1.2 *absorbed dose*—quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm, thus

$$D = d\bar{\varepsilon}/dm \quad (1)$$

3.1.2.1 *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).

3.1.3 D_{10} *value*—absorbed dose required to reduce the microbial population in a given food by 90 %.

3.1.4 *dose distribution*—variation in absorbed dose within a process load exposed to ionizing radiation.

3.1.5 *process load*—volume of material with a specified loading configuration irradiated as a single entity.

3.1.6 *transport system*—conveyor or other mechanical system used to move the process load through the irradiator.

4. Significance and Use

4.1 The principal purpose of irradiation is to help ensure the safety of these foods for human consumption. Irradiation significantly reduces the numbers of pathogenic bacteria such as *Campylobacter*, *Shiga toxin-Producing E coli*, *Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus*, and *Yersinia enterocolitica*.

NOTE 3—Ionizing radiation doses below 10 kGy will reduce but may not eliminate spores of pathogenic bacteria uncluding those of *Clostridium botulinum*, *Clostridium perfringens*, and *Bacillus cereus*.

4.2 The process also inactivates parasites such as *Trichinella spiralis* and *Toxoplasma gondii*.

4.3 The process may extend the shelf life of fresh meat and poultry by reducing the numbers of viable, spoilage bacteria, such as *Pseudomonas* species and lactic acid bacilli.

4.4 Radiation processing of fresh, frozen, or processed meat and poultry is a critical control point (CCP) of a Hazard Analysis of Critical Control Points (HACCP) program. It serves as an important measure to control any residual risk from pathogenic microorganisms before the product reaches the consumer (**4**).

4.5 The "Recommended International Code of Practice for Radiation Processing of Food" (CAC/RCP 19-1979) of the Codex Alimentarius identifies the essential practices to be implemented to achieve effective radiation processing of food, in general, in a manner that maintains quality and yields food products that are safe and suitable for consumption.

5. Criteria for Assessing Process Control and Irradiation Efficacy

5.1 *Process Control System*—The criterion should be that hazard analysis and critical control point (HACCP) system or another similar process control system is applied to the entire processing and distribution chain. With this system, any point in the chain where a hazardous or critical situation could result is monitored and controlled to prevent unsafe and unwholesome product from reaching the consumer. See CAC/RCP 1 and (**4**, **5**). Failure to meet these criteria should be investigated, to assess the efficacy of standard operating procedures (see 8.1) and the re-establishment, if necessary, of Good Manufacturing Practice (GMPs).

5.1.1 Implementation of a process control system (see 4.4) to assess radiation-processing efficacy should include bacteriological examination of the product before and after irradiation, use of time/temperature indicators throughout the processing chain (see Guide F1416), and testing of package integrity. Irradiation efficacy has to be validated to ensure that the minimum absorbed dose delivered (see 8.3–8.4) to the product

[4] Available from the Joint FAO/WHO Food Standards Programme, Joint Office, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

[5] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

is able to achieve the minimum reduction in target microbial organisms that is expected. The target organism(s) have to be identified prior to this validation. Bacteriological testing after specific irradiation doses should yield a predicted decline in viable counts of the target pathogen(s). Temperature monitoring should provide an alert of any product abuse that could result in increases in bacterial counts after irradiation.

5.2 *Criteria for Irradiation Treatment:*

5.2.1 *Irradiation for Control of Pathogenic Bacteria*—The criterion should be that the irradiation treatment is able to reduce the number of pathogenic bacteria in the meat or poultry, such that they are no longer able to cause illness. Determining whether a specified irradiation treatment will reduce the likelihood of illness can only be based on a formal quantitative microbial risk assessment (QMRA) approach (**6, 7**). The numbers of pathogenic bacteria that can result in an infectious product vary with the specific bacterium.

NOTE 4—Susceptibility of a person to pathogenic bacteria varies and is based on the health of the individual and the virulence of the particular strain of the pathogen (**8, 9**).

5.2.2 *Irradiation for Inactivation of Parasites*—The criterion should be that the parasites in uncooked, irradiated product are noninfectious or noninvasive, as appropriate.

5.2.3 *Irradiation for Shelf-Life Extension*—The criterion should be the bacterial plate count using appropriate time, temperature, and media parameters. Reduction in bacterial counts as final criteria cannot be specified unless local regulations, customer specifications, or both, are known. Therefore, the final product specification regarding bacterial plate count should be established by the food producer or food processor.

6. Pre-Irradiation Product Handling

6.1 Product handling should be under conditions that protect the product against physical, chemical, or biological hazards. Microbial contamination and growth should be minimized by following relevant standards of GMPs; see for example U.S. Food and Drug Administration (FDA) GMPs (**10**), U.S. Food Safety and Inspection Service (FSIS) Standard Sanitary Operating Procedures (SSOPs) (**11**), CAC Recommended International Codes of Practice, (CAC/RCP 1 (see 2.3) and HACCP) (**4, 5, 12**).

6.2 *Unpackaged Product*—In facilities handling unpackaged product, the irradiation environment and equipment should be designed and constructed to be cleanable and durable to maintain a sanitary condition and, thereby, not increase the risk of contamination.

NOTE 5—An operating environment with high moisture or airflow may contribute to the risk of bacterial contamination. Moisture provides a growth medium for bacteria and airflow provides a means of transport for bacteria. Food contact surfaces may contribute chemical or physical contaminants to products unless such surfaces are fabricated from appropriate materials and properly maintained and cleaned. Also, employee hygiene and pest control should be closely monitored.

6.3 *Pre-Packaged Product*—For pre-packaged product, the package itself provides a barrier that helps to reduce the risk of recontamination. Thus, many of the requirements for the irradiation environment and equipment necessary for handling unpackaged product may not be applicable for facilities handling only pre-packaged product. Information on applicable requirements should be obtained from the appropriate regulatory authorities before starting operations.

6.4 *Pre-Irradiation Inspection*—Packages and containers of fresh, frozen, or processed meat and poultry should be inspected upon receipt at the irradiation facility to ensure that the product is suitable for irradiation. Written acceptance criteria for product temperature, package integrity and inspection frequency, as applicable, should be established by the product owner and agreed to by management of the irradiation facility prior to accepting product from the owner. Also, criteria for handling of product unsuitable for irradiation should be established.

6.4.1 *Product Temperature*—Upon receipt of product, its temperature should be measured using a calibrated sanitized temperature-sensing device, at a predetermined location and frequency as specified by HACCP and GMPs. Temperature should be between –2 and +4°C for refrigerated fresh or processed meat and poultry or –18°C or lower for frozen meat and poultry. For unpackaged product, insert the device directly into the product and sanitize the device between each measurement. For prepackaged product, use a device that can be placed between individual packages without puncturing them.

6.4.2 *Package Integrity*—A visual inspection of the product packaging should be performed to ensure there is no evidence of compromised or damaged product. Also, a sensory inspection should be performed. No leakage of fluids or odor indicative of product spoilage should be evident upon inspection.

6.4.3 *Product Inventory*—The number of containers should be counted and the description/identification of the product to be irradiated should be verified and compared with the documentation from the product owner. A comparison of this pre-irradiation count with a count performed after irradiation provides a check that all products received have been irradiated.

6.4.4 *Product Identification*—A unique identification number for tracking the product throughout the irradiation process should be issued and documented for the incoming product.

6.5 *Pre-Irradiation Storage:*

6.5.1 *Refrigerated Fresh or Processed Meats and Poultry*—The principal requirement for pre-irradiation storage is to maintain product temperature between –2 and +4°C without freezing. Whenever possible, the pre-irradiation storage at the irradiation facility should be minimized to one day or less.

NOTE 6—U.S.A. poultry regulations presently require that the temperature of fresh poultry be maintained at or below 4.4°C (**12**).

NOTE 7—Holding product under refrigeration for an unduly long time would violate principles of GMPs because such treatment may result in excessive growth of psychrotrophic bacteria and undesirable changes in products.

6.5.2 *Frozen Meats and Poultry*—The product temperature should be maintained at or below –18°C at all times.

6.6 *Product Segregation*—Distinguishing irradiated from un-irradiated product by visual inspection might not be possible. Therefore, it is important that appropriate means integral