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Standard Guide for Irradiation of Pre-packaged Processed Meat and Poultry Products to Control Pathogens and Other Microorganisms[1]

This standard is issued under the fixed designation E2449; 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 for eliminating or reducing the number of pathogenic microorganisms and parasites and for reducing the number of spoilage microorganisms on Processed Meat and Poultry. Information on the handling of processed meat and poultry prior to and after irradiation is also provided.

This guide is intended to serve as a set of recommendations to be followed when using irradiation technology where approved by an appropriate regulatory control 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) 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 pre-packaged refrigerated and frozen processed meat and poultry products.

NOTE 1—The Codex Alimentarius Commission defines "meat" (including poultry and game) as "the edible part of any mammal slaughtered in an abattoir," and "poultry meat" as "the edible part of slaughtered domesticated birds, including chicken, turkeys, ducks, geese, guineafowls, or pigeons." (CAC/RCP 13-1976)

NOTE 2—Current U.S. regulations limit the definition of livestock species to cattle, sheep, swine, goat, horse, mule, or other equine and poultry species to chicken, turkey, duck, goose, and guinea (**2, 3**).

1.2 This guide addresses all refrigerated and frozen meat and poultry products NOT covered by Guide F1356.

1.3 This guide provides information regarding absorbed doses used for inactivation of parasites and reduction of bacterial load. Such doses are typically less than 10 kilogray (kGy).

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E170 Terminology Relating to Radiation Measurements and Dosimetry

F1356 Practice for Irradiation of Fresh and Frozen Red Meat and Poultry to Control Pathogens and Other Microorganisms

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

E2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

2.2 *ISO/ASTM Standards:*[3]

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

51261 Guide for the Selection and Calibration of Dosimetry Systems for Radiation Processing

51431 Practice for Dosimetry in Electron and X-ray (Bremsstrahlung) Irradiation Facilities for Food Processing

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

[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.

51539 Guide for the Use of Radiation Sensitive Indicators

2.3 *Codex Alimentarius Commission Recommended International Codes of Practice and Standards:*[4]

CAC/RCP 13-1976, Rev. 1985 - Recommended International Code of Hygienic Practice for Processed Meat and Poultry Products

CAC/RCP 1-1969, Rev. 3-1997, Amd. 1999, A Recommended International Code of Practice, General Principles of Food Hygiene

CAC/RCP 19-1979, Rev. 2003 Recommended International Code of Practice for Radiation-processing of Food

CX STAN 1-1985, Rev. 1991, Amd. 2001 - General Standard for the Labelling of Prepackaged Foods

CX STAN 106 –1983, Rev. 2003 - General Standard for Irradiated Food

CAC/GL21-1997 Principles for the establishment and application of microbiological criteria for 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*—Quantity of ionizing radiation energy imparted per unit mass of a specified material. 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).

3.1.2.1 *Discussion*—A standard definition of absorbed dose appears in Terminology E170 .

3.1.3 D_{10}*-value* —absorbed dose required to reduce the microbial population in a given food by 90 % (1 $\log_{10}$).

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

3.1.5 *process load*—a 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 reduce the number of pathogenic bacteria, such as *Campylobacter, Escherichia coli* 0157:H7, *Listeria monocytogenes, Staphylococcus aureus* or *Salmonella* spp., in processed meats and poultry to make these foods safer for human consumption.

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

4.2 Irradiation treatment can extend the shelf life of processed meats and poultry by reducing the numbers of vegetative spoilage bacteria, such as *Pseudomonas* species and lactic acid bacilli.

4.3 Irradiation treatment also inactivates parasites such as *Trichinella spiralis* and *Toxoplasma gondii.*

4.4 Radiation processing of the final product in its packaging is a critical control point (CCP) of a Hazard Analysis of Critical Control Points (HACCP) concept for the production of Processed Meat and Poultry. It serves as an important measure to control any residual risk from pathogen microorganisms just before the product reaches the consumer.

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. Pre-Irradiation Product Handling

5.1 Product should be handled in an environment that does not increase the risk of contamination from physical, chemical, or biological hazards. Minimize microbial contamination and growth by following relevant standards of Good Manufacturing Practice (GMPs); see for example U.S. Food and Drug Administration (FDA) GMPs (**4**), U.S. Food Safety and Inspection Service (FSIS) Standard Sanitary Operating Procedures (SSOPs) (**5**), CAC Recommended International Codes of Practice, (CAC/RCP 13-1976 and CAC/RCP 1-1969)(see 2.3) and HACCP (**6, 7**).

5.2 *Pre-Irradiation Inspection*—Inspect packages and containers of processed meat and poultry upon receipt at the irradiation facility to ensure that the product is suitable for irradiation (see 5.2.1, 5.2.2, and 5.2.3). 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 product unsuitable for irradiation should be established.

5.2.1 *Product Temperature*—Upon receipt, using a calibrated temperature-sensing device, measure the temperature of the product at a pre-determined location and frequency as specified by HACCP and GMPs. Temperature should be between −2 and +4°C for refrigerated processed meat and poultry or −18°C or lower for frozen processed meat and poultry.

5.2.2 *Package Integrity*—Perform a visual inspection of the product packaging to ensure there is no evidence of compromised or damaged product.

5.2.3 *Product Inventory*—Count the number of containers and verify the description/identification of the product to be irradiated and compare 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.

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

5.3 *Pre-Irradiation Storage:*

5.3.1 *Refrigerated Processed Meats and Poultry*—the principal requirement for pre-irradiation storage is maintenance of

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

the product temperature between −2 and +4°C without freezing. Pre-irradiation storage at the irradiation facility should be minimized to approximately one day or less, whenever possible.

NOTE 4—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.

5.3.2 *Frozen Processed Meats and Poultry*—maintain the product temperature at or below −18°C at all times. The relatively short duration of frozen storage prior to irradiation is not particularly critical under normal commercial conditions. However, freezing does not provide an unlimited product life without loss of quality, and the pre-irradiation storage period should therefore be minimized.

5.4 *Product Separation*—It may not be possible to distinguish irradiated from un-irradiated product by visual inspection. It is therefore important that appropriate means integral to the facility design, such as physical barriers or clearly defined staging areas, be used to maintain un-irradiated product separate from irradiated product.

NOTE 5—Radiation-sensitive indicators undergo a color change when exposed to radiation in the pertinent dose range. These indicators may be useful within the irradiation facility as a visual check for determining whether or not a product has been exposed to the radiation source. They are not dosimeters intended for measuring absorbed dose and must not be used as a substitute for proper dosimetry. Information about dosimetry systems and the proper use of radiation-sensitive indicators is provided in ISO/ASTM Guides 51261 and 51539, respectively.

6. Packaging and Product Loading Configuration

6.1 *Packaging Materials:*

6.1.1 Use packaging materials suitable to the product considering any planned processing (including irradiation) and consistent with any regulatory requirements (see Guide F1640). Packaging materials should provide appropriate gas and moisture permeability to maintain product quality.

6.1.2 For frozen processed meats and poultry, the package should be as free as possible of voids or open spaces. Such spaces can cause a form of desiccation known as “freezer burn.”

6.2 *Product Loading Configuration:*

6.2.1 The size, shape, density and loading configuration of a process load to be irradiated should be determined primarily by considering design parameters of the irradiation facility. Critical design parameters include the characteristics of product transport systems and of the radiation source as they relate to the dose distribution obtained within the process load.

6.2.2 The dose distribution within the process load can often be optimized by using product packages that are geometrically well defined and uniformly loaded. With certain irradiation facilities, it may be necessary to limit use to particular package shapes and sizes depending on the density of the product and validation testing at known product densities. (see ISO/ASTM Practices 51204 and 51431).

6.2.3 Prescribed product dose specifications should be taken into account when determining the appropriate product-loading configuration (7.4).

7. Irradiation

7.1 *Standard Operating Procedures (SOPs)*—A standard operating procedure for food irradiation is a written procedure that is used to ensure that the absorbed dose range and irradiation conditions selected by the radiation processor are adequate under commercial processing conditions to achieve the intended effect on a specific product in a specific facility. The procedures shall be established by qualified persons having knowledge in irradiation requirements specific to the food and the irradiation facility (21 CFR 179.25).

7.2 *Radiation Sources*—The sources of ionizing radiation that may be employed in irradiating food products are limited to the following: (see CX STAN 106-1983)

7.2.1 *Isotopic Sources*—gamma rays from the radionuclides ^{60}Co (1.17 and 1.33 MeV) or ^{137}Cs (0.66 MeV);

7.2.2 *Machine Sources*—X-rays and accelerated electrons.

NOTE 6—The Codex Alimentarius Commission as well as regulations in some countries currently limit the maximum electron energy and nominal X-ray energy for the purpose of food irradiation (CX STAN 106-1983).

7.3 *Dosimetry System*—Select and calibrate a dosimetry system appropriate for the radiation source being used, the range of absorbed doses required, and the environmental conditions (e.g., product temperature, irradiation cell temperature) expected during irradiation (see ISO/ASTM 51204, 51261 and 51431) (**8**).

7.4 *Absorbed Dose—*

7.4.1 *Absorbed Doses Required to Accomplish Specific Effects:* The owner of the processed meat or poultry product shall provide required minimum and maximum absorbed dose limits (**9**): the lowest dose necessary to ensure the intended effect (e.g., microbial load reduction, pathogen inactivation), and the highest dose that does not negatively affect the product quality through the formation of off-flavors, aromas and color changes (**8,9**). One or both of these limits may be prescribed by government authorities for a given application. The sensitivity to irradiation of processed meat and poultry product varies with the type and product formulation, the packaging atmosphere, the product temperature during irradiation, and other factors. Experience indicates that a higher minimum dose may be required for frozen product than that for product irradiated in the refrigerated state to achieve the same intended objective.

7.4.2 *Absorbed Dose for the Control of Pathogenic Bacteria*—Pathogenic bacteria that may be present in or on processed meat and poultry products, include *Salmonella* species, *Campylobacter jejuni, Escherichia coli* O157:H7, *Staphylococcus aureus*, and *Listeria monocytogenes*. The absorbed dose required to reduce the numbers of these bacteria to levels commensurate with product that is safe for consumption depends on a number of criteria. The required absorbed dose range should be established on the basis of the microbial load in the un-irradiated product, the radiation sensitivity of the bacteria present, the temperature of the product during irradiation, the controlled atmosphere surrounding the packaged product during irradiation, and the regulatory or customer requirement for acceptable residual numbers of bacteria. Appendix X1 provides some information, taken from the scientific literature, about the radiation sensitivity (D_{10} values) of the

principal vegetative pathogenic bacteria found in processed meat and poultry products.

7.4.3 *Absorbed Dose for Inactivation of Parasites*—Most parasites will be rendered noninfectious by absorbed doses of less than 1 kGy. The minimum effective absorbed dose will depend on the specific parasite to be inactivated (**10-14**).

7.4.4 *Absorbed Dose for Shelf-Life Extension*—The absorbed dose that produces an extension of shelf life of processed meat and poultry products depends on the initial level of the bacterial load and the radiation sensitivity of the bacteria present.

7.4.5 The irradiation facility is responsible for delivering the required absorbed doses within the specified range (see ISO/ASTM 51204 and 51431).

7.5 *Routine Production Dosimetry*—The use of dosimetry is part of a verification process for establishing that the irradiation process is under control. Prior to performing routine production dosimetry, it is necessary to perform product absorbed-dose mapping (see ISO/ASTM 51204 and 51431, and ASTM E2232 and E2303).

7.5.1 Verify that the product routinely receives the required absorbed dose by using proper dosimetric measurement procedures, along with appropriate statistical controls and documentation.

7.5.2 Place dosimeters in or on the process load at locations of maximum and minimum absorbed dose (D_{min} and D_{max}). These locations are identified in the product absorbed-dose mapping exercise.If the D_{min} and D_{max} locations are not accessible, place dosimeters at reference locations where the dose values have known and quantifiable relationships to the dose extremes (see ISO/ASTM 51204 and 51431)

7.6 *Product Temperature:*

7.6.1 Measure and document the temperature of the product as it enters and exits the irradiator to ensure that requirements of the facility SOPs have been met.

7.6.2 If the temperature of the irradiation area and the time required to achieve the desired absorbed dose result in a temperature rise outside the specified limits, conditions of the process are not being met. Appropriate changes to the process are needed and could include insulation of the process load or refrigeration of the irradiation area. If the product is insulated during irradiation, the addition of the insulating material might require the process load to be re-characterized for absorbed-dose distribution.

NOTE 7—Temperature control of the product is critical in irradiation as a food safety intervention because bacteria multiply more rapidly as temperature rises. For example, the number of *Listeria* in a processed meat or poultry product can double much faster at ambient temperatures, than at refrigerated temperatures. (**15**)

7.7 *Re-irradiation*—Re-irradiation generally is not recommended because of the possibility of exceeding the maximum recommended absorbed dose. Incremental application of the specified absorbed dose is not considered to be re-irradiation. Keep product that has received a portion of the total specified dose separate from non-irradiated product and product for which the dose requirements have been met.

8. Post-Irradiation Labeling, Handling and Storage

8.1 *Post-Irradiation Inspection*—Inspect packages or containers of processed meat and poultry after irradiation to ensure that the product meets written acceptance criteria (package integrity, counts, etc.).

8.2 *Post-Irradiation Labeling*—Some consumers and food processors may wish to choose between irradiated and non-irradiated products, thus many governments have adopted labeling requirements (see 5.2 of CX STAN 1-1985). Labeling will identify the product as irradiated and can inform the consumer of the purpose and benefits of the treatment as well as handling or storage requirements (8.3, 8.4).

NOTE 8—Labeling requirements differ among different national authorities. Users should always contact such authorities before designing labeling materials. An increasing number of countries are adopting the internationally recognized "Radura" symbol as a means of labeling (see Fig. 1). In some countries, for example the U.S. (21 CFR 179.26), the symbol must be accompanied by a statement, such as "Treated with Radiation" or "Treated by Irradiation."

8.3 *Post-Irradiation Handling*—Handling of processed meat and poultry product in an irradiation facility should be in accordance with relevant and current GMPs. Measures should be in place for ensuring separation of irradiated and non-irradiated product. It may not be possible to distinguish irradiated from non-irradiated product by visual inspection. It is therefore important that appropriate means, such as physical barriers, or clearly defined staging areas, be used to maintain non-irradiated product separate from irradiated product.

8.4 *Post-Irradiation Storage*—Store irradiated products in the same manner as un-irradiated products. For refrigerated product, the temperature should be maintained between –2 and +4°C at all times during storage. For frozen product, the temperature should be maintained below –18°C at all times during storage.

9. Criteria for Assessing Irradiation Efficacy in Controlling Pathogenic Bacteria, Parasites and Spoilage Organisms (see CAC/GL 21–1007 (16))

9.1 Some local authorities have mandatory upper limits for pathogens, which, if exceeded, render the product unusable.

9.2 The criteria for total standard plate count are established by customer requirements based on the end use of the product and any applicable government requirements.

9.3 Failure to meet the criterion in 9.1 and 9.2 should direct attention to the manufacturing process and the re-establishment, if necessary, of GMPs. Radiation processing shall not serve to re-establish initial total plate counts; the

FIG. 1 Radura Logo (usually printed in green)

pre-requisite for using radiation processing to eliminate the residual risk of a load with pathogenic microorganisms are that the total plate count is at or below the pre-established acceptable levels.

10. Documentation

10.1 *Pre-Irradiation*—see 5.2

10.2 *Post-Irradiation:*

10.2.1 Record and document the date the product is irradiated, the starting and ending times of the irradiation process, the temperature rise during irradiation, the temperature and condition of the lot after irradiation, the date the lot leaves the facility, the name of the operator, and any special conditions that could have affected the irradiation process or the irradiated product.

10.2.2 Record and document all dosimetry data associated with product absorbed-dose mapping and routine processing (see ISO/ASTM Practices 51204 and 51431) (**8, 17**).

10.2.3 Record and document any deviation from the scheduled process in order to assess the validity of the process.

10.2.4 Audit all documentation prior to product release to ensure that records are accurate and complete. The person making the audit should sign the documentation. Make all deficiencies the subject of a separate file available for examination by a regulatory authority.

10.3 *Record Retention*—Retain all records about each lot irradiated at the facility for the period of time specified by relevant authorities and have them available for inspection as needed (**10**).

11. Keywords

11.1 bacteria; cattle; chicken; duck; equine; food; goat; goose; guinea; HACCP; horse; irradiation; labeling; meat; microorganisms; mule; packaging; parasites; pathogens; pigeons; poultry; processing; sheep; swine; turkey

APPENDIX

(Nonmandatory Information)

X1. RADIATION SENSITIVITY OF BACTERIA FOUND IN MEAT AND POULTRY PRODUCTS

Table X1.1 provides some information, taken from the scientific literature, about the radiation sensitivity (D_{10} values) of the principal vegetative pathogenic bacteria found in meat and poultry products.

TABLE X1.1 D_{10} Values (kGy) for Foodborne Pathogens in Meat and Poultry at Irradiation Temperatures of 5 and –20°C

Pathogen	D_{10} value (kGy) @ 0-5°C	D_{10} value (kGy) @ ≤–20°C	References
Campylobacter jejuni	0.18 ± 0.00	0.24 ± 0.02	A
Escherichia coli O157:H7	0.30 ± 0.02	0.57	B, C
	0.24 ± 0.01	0.31 ± 0.24	A
	0.54 ± 0.01		D
Listeria monocytogenes	0.45 ± 0.03	1.21 ± 0.06	C, D
	0.59 ± 0.06	0.61 ± 0.04	E
	0.61 ± 0.06		F
Salmonella species	0.41 ± 0.00	0.63 ± 0.00	G
	0.70 ± 0.04	0.92	C, H
	0.62 ± 0.09	0.80 ± 0.05	A
	0.64 ± 0.02		D
Staphylococcus aureus	0.46 ± 0.02	0.74	C, I, J
	0.45 ± 0.04	0.45 ± 0.04	G
	0.66 ± 0.01		D
Yersinia enterocolitica	0.19 ± 0.01	0.40 ± 0.01	K
	0.25 ± 0.01	0.25 ± 0.01	L

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(2) United States Code of Federal Regulations, Title 9, Section 301.2(qq), Washington, DC.

(3) United States Code of Federal Regulations, Title 9, Section 381.1(b)(40), Washington, DC.

(4) United States Code of Federal Regulations, Title 21, Part 110 *Current Good Manufacturing Practices in Manufacturing, Packaging, or Handling Human Food*, Washington, DC.

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