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Standard Guide for Irradiation of Fresh and Frozen Red Meat and Poultry to Control Pathogens and Other Microorganisms¹

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INTRODUCTION

The purpose of this guide is to present information on the use of ionizing energy (radiation) in treating fresh or frozen red 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 vegetative spoilage microorganisms.

This guide is intended to serve as a recommendation when using irradiation technology where approved by an appropriate regulatory authority. It is not to be construed as a requirement for the use of irradiation, nor as a rigid code of practice. 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 fresh or frozen meat and poultry as defined by the Codex Alimentarius Commission (CAC), (CAC/RCP 11-1976 and CAC/RCP 14-1976). Codex defines meat as "the edible part of any mammal slaughtered in an abattoir," and poultry as" the edible part of slaughtered domesticated birds, including chicken, turkeys, ducks, geese, guinea-fowls, or pigeons."

NOTE 1—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 covers absorbed doses used for inactivation of parasites and reduction of bacterial load. Such doses are typically less than 10 kiloGray (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.

2. Referenced Documents

- 2.1 ASTM Standards:
- E 170 Terminology Relating to Radiation Measurements and Dosimetry³
- **E 1204** Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing³
- **E 1261** Guide for the Selection and Calibration of Dosimetry Systems for Radiation Processing³
- **E 1431** Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing³
- E 1539 Guide for the Use of Radiation Sensitive Indicators³
- F 1416 Guide for the Selection of Time-Temperature Indicators⁴
- F 1640 Guide for Packaging Materials for Foods to Be $\rm Irradiated^4$

2.2 Codex Alimentarius Commission Recommended International Codes and Standards:⁵

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

CAC/RCP 1-1969, Rev. 3, (Annex) Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application

³ Annual Book of ASTM Standards, Vol 12.02.

⁴ Annual Book of ASTM Standards, Vol 15.09.

⁵ Available from the Joint FAO/WHO Food Standards Programme, Joint Office, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy.

- CAC/RCP 11-1976 Recommended International Code of Hygienic Practice for Fresh Meat
- CAC/RCP 14-1976 Recommended Code of Hygienic Practice for Poultry Processing
- CAC/Vol A Recommended International Code of Practice, General Principles of Food Hygiene, Edition 2
- STAN 1-1985 General Standard for the Labelling of Prepackaged Foods

STAN 106-1983 General Standard for Irradiated Food

3. Terminology

3.1 *Definitions*—Other terms used in this guide may be defined in Terminology E 170.

3.1.1 *absorbed dose*, n—the quantity of energy from ionizing radiation imparted to a unit mass of a specified material (food). The special name for the unit of absorbed dose is the Gray (Gy). One Gy is equal to one joule of absorbed energy per kilogram. Formerly, the unit of absorbed dose was the rad (1 rad = 0.01 Gy).

3.1.1.1 *Discussion*—A standard definition of absorbed dose appears in Terminology E 170.

3.1.2 D_{10} -value, *n*—absorbed dose required to reduce the microbial population in a given food by 90 % (1 log₁₀).

3.1.3 *dose distribution*, *n*—the variation in absorbed dose within a process load exposed to ionizing radiation.

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

3.1.5 *transport system*, *n*—the 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 control (reduce the number of) pathogenic bacteria in fresh or frozen red meats and poultry to make these foods safer for human consumption. Irradiation significantly reduces the numbers of viable, vegetative bacteria such as *Campylobacter, Escherichia coli, Listeria*, or *Salmonella*.

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

4.3 The process may extend the shelf-life of fresh red meats and poultry by reducing the numbers of viable, vegetative spoilage bacteria, such as *Pseudomonas* species.

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. Take measures at all times to minimize microbial contamination and growth by following relevant standards of Good Manufacturing Practice (GMP); see for example U.S. Food and Drug Administration (FDA) GMP (4), U.S. Food Safety and Inspection Service (FSIS) Standard Sanitary Operating Procedures (SSOP) (5), and CAC Recommended International Codes of Practice, (CAC/RCP 11-1976, CAC/RCP 14-1976, and CAC/Vol A)(see 2.2).

5.2 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 2—An operating environment with high moisture or air flow may contribute to the risk of bacterial contamination. Moisture provides a growth medium for bacteria and air flow 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.

5.3 *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 may not be applicable for facilities handling only pre-packaged product. Obtain information on applicable requirements from the appropriate regulatory authorities before starting operations.

5.4 *Pre-Irradiation Inspection*—Inspect packages and containers of red meat and poultry upon receipt at the irradiation facility to ensure that the product is suitable for irradiation. (see 5.4.1, 5.4.2, and 5.4.3). Written acceptance criteria for inspection frequency, product temperature and package integrity, as applicable, should be established by the product owner and agreed to by management of the irradiation facility prior to accepting product from an owner. Also, disposition of product unsuitable for irradiation should be among the criteria established.

5.4.1 *Product Temperature*—Using a calibrated temperature-sensing device, measure the temperature of the product upon receipt. Temperature should be between -2 and $+4^{\circ}C$ for fresh red meat or poultry or $-18^{\circ}C$ or lower for frozen red meat or 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 packaging materials in direct contact with the product.

5.4.2 *Package Integrity*—Perform a sensory inspection of the product. No leakage of fluids or odor indicative of product spoilage should be evident upon inspection.

5.4.3 Count the number of containers to be irradiated and compare that count with documentation from the product owner. A comparison of this pre-irradiation count with a count performed after irradiation provides a check that all product received has been irradiated.

5.5 Pre-Irradiation Storage:

5.5.1 For fresh meats and poultry, the principal requirement for pre-irradiation storage is maintenance of the product temperature between -2 and $+4^{\circ}$ C without freezing.

Note 3—U.S. poultry regulations presently require a maximum temperature of $40^{\circ}F$ (4.4°C) for fresh poultry.(6)

5.5.2 A second requirement is that the pre-irradiation storage period at the irradiation facility be minimized, approximately one day or less, whenever possible.

5.5.3 For frozen 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.

5.6 Handling of red meats and poultry differently from the procedures described in 5.5 violates the principles of GMP,

which constitute the total of all measures taken to produce meat and poultry products containing as low a level of contaminants as possible. Holding product under refrigeration for an unduly long time would violate these principles because such treatment may result in excessive bacterial growth and undesirable changes in products. Radiation processing can neither reverse these undesirable changes nor replace GMP.

5.7 *Product Separation*—It may not be possible to distinguish irradiated from unirradiated product by 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 unirradiated product separate from irradiated product.

6. Packaging

6.1 Packaging meat or poultry products prior to irradiation reduces the risk of contaminating the product and the irradiation facility. Prepackaging may not be necessary in the case of irradiation for inactivation of parasites or if other control procedures (for example, aseptic processing) are in place to maintain the intended effect of the treatment.

6.2 If products are packaged, use materials suitable to the product considering any planned processing (including irradiation) and consistent with any regulatory requirements (see Guide F 1640).

6.2.1 Packaging materials should provide appropriate gas and moisture permeability to maintain product quality. (see 7.6)

6.2.2 For frozen red 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."

6.3 To achieve a more uniform dose distribution within a process load, the product packages or containers should be geometrically well defined and uniform in shape and size. With certain irradiation facilities, it may be necessary to limit use to particular package shapes and sizes based on the density of the product and validation testing at known product densities in the irradiation facility. See Practices E 1204 and E 1431.

7. Irradiation

7.1 Scheduled Process—Irradiation of food should conform to a scheduled process. A scheduled process for food irradiation is a written procedure that is used to ensure that the absorbed dose range and irradiation conditions (for example, product temperature) are adequate under commercial processing conditions to achieve the intended effect on a specific product in a specific facility. The procedure should also address disposition of improperly irradiated product and corrective actions to be taken if the irradiation process is not adequately controlled. The scheduled process should be established and validated by qualified persons having expert knowledge in irradiation requirements specific for the food and the processor's irradiation facility. See, for example, FDA regulations (7).

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

7.2.1 Gamma rays from the radionuclides ⁶⁰Co or ¹³⁷Cs,

7.2.2 X-rays generated from machine sources operated at or below an energy level of 5 MeV, and

7.2.3 Electrons generated from machine sources operated at or below an energy level of 10 MeV.

Note 4—The depth of penetration of electrons in a material is dependent on the energy of the electrons and the density of the material.

7.3 Radiation Process Parameters:

7.3.1 Absorbed Dose—Food irradiation specifications from the owner of the product should include minimum and maximum absorbed dose limits (see 7.4): a minimum necessary to ensure the intended effect; and a maximum to prevent product degradation. One or both of these limits may be prescribed by regulation for a given application. See, for example, FDA regulations (8). It is necessary to configure irradiation parameters to ensure that processing is carried out within these limits. Once this capability is established, it is necessary to monitor and record absorbed dose values during routine processing (see 11.2.2).

7.3.1.1 Routine dosimetry is part of a verification process for establishing that the irradiation process is under control.

7.3.1.2 Select and calibrate a dosimetry system appropriate to the radiation source being used, the environmental conditions, and the range of absorbed doses required (see Guide E 1261).

7.3.1.3 Verify that the product receives the required absorbed dose by using proper dosimetric measurement procedures, along with appropriate statistical controls and documentation. Place dosimeters in or on the process load at locations of maximum and minimum absorbed dose. If those locations are not accessible, place dosimeters at reference locations that have a known and quantifiable relationship to the maximum and minimum absorbed dose locations (see Practices E 1204 and E 1431)

NOTE 5—Radiation sensitive indicators (RSIs), such as labels, papers, or inks, that undergo a color change or become colored when exposed to irradiation in the pertinent dose range are commercially available. The purpose of RSIs is to determine visually whether or not a product has been irradiated, rather than to measure the absorbed dose received by the product. RSIs are not dosimeters and must not be used as a substitute for proper dosimetry (see Guide E 1539).

7.3.2 *Process Load Design*—The size and shape of the process load are determined partly by certain design parameters of the irradiation facility. Critical design parameters include the characteristics of the transport system and of the radiation source as they relate to the dose distribution obtained within the process load. The size and shape of the product and minimum and maximum dose limits may also affect the loading configuration of the process load.

7.4 Absorbed Doses Required to Accomplish Specific Effects—The minimum absorbed dose that has been shown to achieve the intended objective of the process should be used. Too high an absorbed dose can cause the formation of an off-flavor in the product. The sensitivity to this off-flavor formation varies with the type and cut of meat, the packaging atmosphere, the product temperature during irradiation, and other factors. In addition, excessive absorbed doses may cause discoloration in some meats (9,10). Care should therefore be taken to control the absorbed dose and other irradiation conditions that may affect the intended process objective and product quality. Experience indicates that a higher minimum

dose may be required for frozen product than that for product irradiated in the fresh state to achieve the same intended objective. The owner of the product is responsible for specifying for each lot the required absorbed dose range to achieve the intended objective. Historical information on previously processed lots may be useful for determining the appropriate range. The irradiation facility is responsible for delivering the specified dose range (see Practices E 1204 and E 1431).

7.4.1 Absorbed Dose for the Control of Pathogenic *Bacteria*—A number of pathogenic bacteria may be present in red meats and poultry, including 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 unirradiated product, the radiation sensitivity of the bacteria present, the temperature of the product during irradiation, the atmosphere surrounding the 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 meat and poultry products.

7.4.2 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 (11-15).

7.4.3 Absorbed Dose for Shelf-Life Extension—The absorbed dose that produces shelf-life extension of fresh meats and poultry depends on the initial level of contamination, the radiation sensitivity of the bacteria present, and the customer requirement for acceptable residual numbers of bacteria.

7.5 Product Temperature—Measure and document the temperature of the product as it exits the irradiator to ensure that requirements of the scheduled process have been met (See 5.4 and 7.1). Irradiation at absorbed doses less than 10 kGy should result in a temperature rise of not more than 5°C above that recorded during pre-irradiation inspection. (see 5.4.1) If the temperature of the irradiation area and the time required to achieve the desired absorbed dose result in a greater temperature rise, conditions of the scheduled process are not being met. Appropriate changes to the scheduled process could include insulation of the product load or refrigeration of the irradiation area.

NOTE 6—Temperature control is critical in irradiation as a food safety intervention because bacteria multiply more rapidly as temperature rises. For example, at temperatures above 5°C, the number of salmonella in a meat or poultry product can double every 20 min.

7.6 Environmental Effects:

7.6.1 As with other pathogen reduction processes, irradiation at absorbed doses of less than 10 kGy may reduce the number of *Clostridium botulinum* spores. A considerably higher dose would be required, however, to produce a sterile, shelf stable product equivalent to that produced by thermal retorting. Especially in the absence of oxygen, irradiation, like other pathogen reduction processes, may significantly retard the growth of spoilage microorganisms that compete with *C. botulinum*. Proper storage temperatures (see 5.4.1) minimize the potential for production of botulinum toxin without sensory evidence of spoilage.

NOTE 7—*C. botulinum* spores have radiation D_{10} values ranging from 3.45 to 3.85 kGy depending on their serotype and the temperature at which they are irradiated (16). Therefore, a 10 kGy absorbed dose would destroy 2.5 to 3 log colony forming units (cfu) of *C. botulinum* spores. A 12 log cfu reduction is generally required for commercial sterilization using a thermal treatment.

7.6.2 Irradiation can improve the shelf-life of meats and poultry only by its action on their microbial load. There are mechanisms other than bacterial action that cause meat spoilage. These are largely chemical in nature and generally involve oxidation of the product, resulting in discoloration and rancidity. Other measures in addition to irradiation may be necessary to obtain a satisfactory product. Where applicable, a package providing a reduced oxygen environment (for example, vacuum packaging) minimizes such effects.

NOTE 8—Fresh red meats, especially the more highly pigmented ones such as beef, ordinarily require the presence of oxygen in order to maintain their normal red color. The use of vacuum packaging and oxygen-impermeable films causes meat to darken in the package, although the normal red color will return when the package is opened. For the less pigmented red meats and for poultry, the color change resulting from vacuum packaging is less significant.

7.7 *Reirradiation*—Reirradiation generally is not recommended because of the possibility of exceeding the maximum recommended absorbed dose (STAN 106–1983). Incremental application of the specified absorbed dose is not considered to be reirradiation provided that the maximum recommended or permitted absorbed dose is not exceeded and that preirradiation handling requirements are met. (see 5.5) Keep product that has received a portion of the total specified dose separate from either unirradiated or irradiated product.

8. Post-Irradiation Handling and Storage

8.1 *Post-Irradiation Inspection*—Inspect packages or containers of red meat and poultry again after irradiation to ensure that the product meets written acceptance criteria (see 5.4).

8.1.1 *Product Temperature*—Bring fresh product to a temperature between -2 and $+4^{\circ}$ C within the time necessary to prevent growth of any surviving bacteria. Bring frozen product to a temperature at or below -18° C as soon as possible after irradiation.

8.1.2 *Package Integrity*—No leakage of fluids or odor indicative of product spoilage should be evident upon inspection.

8.1.3 Count the number of containers irradiated. A comparison of this information with a count performed before irradiation provides a check that all product received has been irradiated or otherwise accounted for and so documented.

8.2 *Post-Irradiation Storage*—Store irradiated products in the same manner as unirradiated products. For fresh product, the temperature should be maintained between -2 and $+4^{\circ}C$ at all times during storage. For frozen product, the temperature should be maintained below $-18^{\circ}C$ at all times during storage.