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Standard ~~Practice~~Guide for Irradiation of ~~Fresh and Frozen Red~~ 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 ~~practice~~guide is to present information on the use of ionizing radiation in treating ~~fresh or frozen red~~ 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 ~~vegetative~~ spoilage microorganisms.

This ~~practice~~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 ~~practice~~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 practice outlines procedures for the irradiation of fresh or frozen 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 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 practice covers absorbed doses used for inactivation of parasites and reduction of bacterial load in fresh and frozen red meat and poultry. Such doses are typically less than 10 kGy.~~

~~1.3 This practice 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.~~

~~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~~

~~E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities~~

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[1] This ~~practice~~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 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.

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]
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
51539 Guide for the Use of Radiation-Sensitive Indicators
2.3 *Codex Alimentarius Commission Recommended International Codes and Standards:*[4]
CAC/RCP 1-1969, Rev. 4-2003, A Recommended International Code of Practice—General Principles of Food Hygiene (Including Annex): Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Application
CAC/RCP 19-1979, Rev-2003, Recommended International Code of Practice for the Radiation Processing of Food
CX STAN 1-1985, Rev. 1991, Amd. 2001, 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)

3. Terminology

3.1 *Definitions:*
3.1.1 Other terms used in this practice 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).

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

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*—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 control (reduce the number of) pathogenic bacteria in fresh or frozen red meat and poultry to ensure the safety of these foods for human consumption. Irradiation significantly reduces the numbers of vegetative pathogenic bacteria such as *Campylobacter*,*Escherichia coli*,*Listeria*,*Salmonella*,*Staphylococcus aureus*, or *Yersinia enterocolitica*.

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 red meat and poultry by reducing the numbers of viable, vegetative spoilage bacteria, such as *Pseudomonas* species.

4.4 Radiation processing of fresh and frozen red 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.

5. Criteria for Assessing Irradiation Efficacy

5.1 *Irradiation for Control of Pathogenic Bacteria*—The numbers of pathogenic bacteria that can result in an infectious product vary with the specific bacterium and the susceptibility of the consumers involved. The adoption of criteria, such as those used in the U.S. for the pasteurization of milk or in scheduled processes for low-acid canned food, is the most reasonable in the absence of microbiological end product criteria for expected pathogenic bacteria (**4**, **5**).

5.2 *Irradiation for Inactivation of Parasites*—The criterion should be that the parasites in uncooked, irradiated product are noninfectious or noninvasive, as appropriate. (This does not necessarily require the parasite to be killed by the irradiation process.)

5.3 *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 customer.

5.4 Failure to meet these criteria should direct attention to the scheduled process (see 8.1) and the reestablishment, if necessary, of Good Manufacturing Practice (GMPs). The hazard analysis and critical control point (HACCP) system or another similar process control system should be 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 (**6**, **7**).

5.4.1 Implementation of a process control system to assess radiation-processing efficacy should include bacteriological examination of the product before and immediately after irradiation, use of time/temperature indicators throughout the processing chain (see Guide F1416), and testing of package integrity. Bacteriological testing should reveal a significant reduction in relevant bacterial counts compared to those of the non-irradiated product. Temperature monitoring should alert observers of any product abuse that could result in increases in bacterial counts after irradiation.

6. Pre-Irradiation Product Handling

6.1 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 GMPs; see for example U.S. Food and Drug Administration (FDA) GMPs (**8**), U.S. Food Safety and Inspection Service (FSIS) Standard Sanitary Operating Procedures (SSOPs) (**9**), CAC Recommended International Codes of Practice, (CAC/RCP1 (see 2.3) and HACCP) (**10**).

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 3—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 and frozen red 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 red meat and poultry or −18°C or lower for frozen red 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 For fresh red meat and poultry, the principal requirement for pre-irradiation storage is maintenance of the product temperature between −2 and +4°C without freezing.

NOTE 4—U.S. poultry regulations presently require that the temperature of fresh poultry be maintained at or below 4.4°C (**10**).

NOTE 5—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 A second requirement is that the pre-irradiation storage period at the irradiation facility be minimized, approximately one day or less, whenever possible.

6.5.3 For frozen red meat and poultry, the product temperature should be maintained 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.

6.6 *Product Segregation*—Distinguishing irradiated from non-irradiated product by inspection might not be possible. Therefore, the use of appropriate means integral to the facility design, such as physical barriers or special segregation in clearly defined staging areas, to maintain non-irradiated product separate from irradiated product is important.

NOTE 6—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.

7. Packaging and Product Loading Configuration

7.1 *Packaging Materials:*

7.1.1 Use packaging materials suitable to the product, taking into account planned processing (including irradiation) and consistent with regulatory requirements (see Guide F1640).

7.1.2 Packaging materials should provide appropriate gas and moisture permeability to maintain product quality.

7.2 *Product Loading Configuration:*

7.2.1 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.

7.2.2 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 the use of particular package shapes and sizes depending on the density of the product and facility Operational Qualification (OQ) data (see ISO/ASTM 51204 and 51431).

7.2.3 Prescribed product dose specifications should be taken into account when determining the appropriate product-loading configuration (see 8.4).

8. Irradiation

8.1 *Standard Operating Procedures (SOPs)*—A standard operating procedure, or scheduled process, for food irradiation is a written procedure that is used to ensure that the technologically advisable 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 (**11**). The procedures shall meet the requirements of CX STAN 106 and should follow the recommendations of CAC/RCP 19.

8.2 *Radiation Sources*—The sources of ionizing radiation that may be employed in irradiating fresh and frozen red meat and poultry products are limited to the following (see CX STAN 106):

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

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

NOTE 7—For electron beam processes, the depth of penetration of electrons in a material is dependent on the energy of the electrons and the density of the material.

NOTE 8—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).

8.3 *Absorbed Dose:*

8.3.1 *Absorbed Doses Required to Accomplish Specific Effects*—The owner of the fresh and/or frozen meat or poultry product shall provide required minimum and maximum absorbed dose limits: the lowest dose necessary to ensure the intended effect (for example, 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 (**12**). One or both of these limits may be prescribed by government authorities for a given application. The sensitivity of red meat and poultry to irradiation varies with the type of product, the packaging atmosphere, the product temperature during irradiation, and other factors. A higher minimum dose may be required for frozen product than for product irradiated in a refrigerated state to achieve the same intended objective because bacterial resistance to radiation damage is higher at sub-freezing temperatures (**13**, **14**).

8.3.2 *Absorbed Dose for the Control of Pathogenic Bacteria*—Pathogenic bacteria that may be present in or on fresh or frozen red meat and poultry products include *Salmonella* species, *Campylobacter jejuni*,*Escherichia coli* O157:H7, *Staphylococcus aureus*,*Listeria monocytogenes*, and *Yersinia enterocolitica*. 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 red meat and poultry products.

8.3.3 *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 (**15-19**).

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

8.3.5 The irradiation facility is responsible for delivering the required absorbed doses within the technically advisable dose range (see ISO/ASTM 51204 and 51431).

8.4 *Dosimetry*—Dosimetry is a major component of a total quality assurance program for adherence to good manufacturing practices used in the production of safe and wholesome food. CX STAN 106 and CAC/RCP 19 strongly emphasize the role of dosimetry for ensuring that irradiation will be properly performed.

8.4.1 Dosimetry shall be performed following the requirements of ISO/ASTM Practice 51204 for gamma irradiation facilities for food processing or ISO/ASTM Practice 51431 for electron beam and X-ray (bremmstrahlung) irradiation facilities for food processing.

8.4.2 Guidance on dose mapping is given in Guide E2303.

8.5 *Product Temperature:*

8.5.1 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.

8.5.2 If the temperature of the irradiation area and the time required to achieve the desired absorbed dose result in a rise in product temperature 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 product load or refrigeration of the irradiation area. If the product is insulated during irradiation, the addition of the insulating material will require the process load to be re-characterized for absorbed-dose distribution.

NOTE 9—Temperature control of the product is critical as a food safety intervention during irradiation because bacteria multiply more rapidly as temperature rises. For example, the number of *Listeria* in a red meat or poultry product can double much faster at ambient temperatures, than at refrigerated temperatures (**20**).

8.6 *Packaging Atmosphere:*

8.6.1 Irradiation can improve the shelf-life of meat 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 10—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 meat and for poultry, the color change resulting from vacuum packaging is less significant.

8.6.2 Irradiation at absorbed doses of less than 10 kGy may NOT be sufficient to reduce the number of *Clostridium botulinum* spores to a safe level. A considerably higher dose would be required to produce a sterile, shelf stable product equivalent to that produced by thermal retorting. Moreover, in the absence of oxygen, irradiation could significantly inhibit 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 11—*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 (**21**). Therefore, a 10 kGy absorbed dose would destroy 2.5 to 3 log colony forming units (cfu) of *C. botulinum* spores. A12 log cfu reduction is generally required for commercial sterilization using a thermal treatment.

8.7 *Incremental Irradiation*—Incremental irradiation is the application where the technically advisable dose range is achieved in multiple irradiation exposures. 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. In addition, the product should be maintained in the required temperature range and the time interval between irradiation exposures should be kept to a minimum.

9. Post-Irradiation Handling and Storage

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

9.2 *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). 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 (see 9.3 and 9.4).

NOTE 12—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. (**22**), the symbol must be accompanied by a statement, such as "Treated with Radiation" or "Treated by Irradiation."

FIG. 1 Radura Logo

9.3 *Post-Irradiation Handling*—Handling of fresh or frozen red meat and poultry product in an irradiation facility should be in accordance with relevant and current GMPs. Measures should be in place for ensuring segregation of irradiated and non-irradiated product. Distinguishing irradiated from non-irradiated product by visual inspection might not be possible. Therefore, the use of appropriate means, such as physical barriers, or clearly defined staging areas to maintain non-irradiated product separate from irradiated product is important.

9.3.1 *Product Temperature*—Bring fresh product to a temperature between −2 and +4°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.

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

9.3.3 *Product Integrity*—Attention should be given to all aspects affecting product quality, in addition to those associated with microbial content. For example, pigment changes can cause product discoloration, and lipid oxidation can affect flavor. If vacuum packaging or oxygen-free modified atmosphere packaging is used, particular care must be taken to ensure that the storage temperature is controlled at or below 4°C in order to prevent abuse of the product and subsequent outgrowth of *C. botulinum*.

9.3.4 *Product Inventory*—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.

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

10. Documentation

10.1 Ensure that each lot of product to be processed carries an identification number or other code that will distinguish it from other lots of product in the facility. Use this identification on all lot documents.

10.2 Establish a record of the operation of the irradiation facility.

10.2.1 Record and document the number of containers in the lot and the condition of the lot, the date it arrives at the facility, the temperature and condition of the lot upon receipt, the date it is irradiated, the starting and ending times of the irradiation, 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 affect 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 Practices ISO/ASTM 51204 and 51431) (**23**, **24**).

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

10.3 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.

10.4 Retain all records for each lot irradiated at the facility for the period of time specified by relevant authorities and have them available for inspection as needed.

11. Keywords

11.1 bacteria; cattle; chicken; duck; electron beam; equine; gamma radiation; goat; goose; guinea; HACCP; horse; irradiation; labeling; meat; microorganisms; mule; packaging; parasites; pathogens; pigeons; poultry; processing; sheep; swine; turkey; X-radiation; X-ray