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Standard Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment[1]

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INTRODUCTION

The purpose of this guide is to present information on the use of ionizing energy (radiation) in treating fresh agricultural produce to control insects and other arthropod pests, in order to meet phytosanitary requirements.

This guide is intended to serve as a recommendation to be followed 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 required 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 provides procedures for the radiation processing of fresh agricultural produce, for example, fruits, vegetables, and cut flowers, as a phytosanitary treatment. This guide is directed primarily toward the treatment needed to control regulated pests commonly associated with fresh agricultural produce.

1.2 This guide covers gamma, electron beam and X-radiation treatment.

1.3 The typical absorbed dose range used for phytosanitary treatments is between 60 gray (Gy) and 600 gray (Gy). The practical minimum or maximum dose of a treatment may be higher or lower than this range, depending on the type of pest to be controlled and the radiation tolerance of a particular type of produce. If the minimum effective dose necessary to achieve the desired phytosanitary effect is greater than the radiation tolerance of the produce, then irradiation is not an appropriate treatment (see 5.2).

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 This document is one of a set of standards that provides recommendations for properly implementing and utilizing radiation processing. It is intended to be read in conjunction with ISO/ASTM Practice 52628.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

F1640 Guide for Selection and Use of Contact Materials for

[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.

Foods to Be Irradiated
E3083 Terminology Relating to Radiation Processing: Dosimetry and Applications

2.2 *ISO/ASTM Standards:*
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) 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
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 of Practice and Standards:*[4]
CX STAN 1-1985, Rev. 1991, and 2001 General Standard for the Labeling of Prepackaged Foods
CX STAN 106-1983, Rev. 2003 General Standard for Irradiated Food
CAC/RCP 19-1979, Rev. 2003 Recommended International Code of Practice for the Radiation Processing of Food

2.4 *ISO Standards:*[5]
ISO 873 Peaches — Guide to Cold Storage
ISO 931 Green Bananas — Guide to Storage and Transport
ISO 1134 Pears — Guide to Cold Storage
ISO 1212 Apples — Guide to Cold Storage
ISO 1838 Fresh Pineapples — Guide to Storage and Transport
ISO 2168 Table Grapes — Guide to Cold Storage
ISO 2826 Apricots — Guide to Cold Storage
ISO 3631 Citrus Fruits — Guide to Cold Storage
ISO 3659 Fruits and Vegetables — Ripening After Cold Storage
ISO 6660 Mangoes — Guide to Storage
ISO 6661 Fresh Fruits and Vegetables — Arrangement of Parallelpipedic Packages in Land Transport Vehicles
ISO 6664 Bilberries and Blueberries — Guide To Cold Storage
ISO 6665 Strawberries — Guide to Cold Storage
ISO 6949 Fruits and Vegetables — Principles and Techniques of the Controlled Atmosphere Method of Storage
ISO 7558 Guide to the Prepacking of Fruits and Vegetables
ISO 12749-4 Nuclear energy, nuclear technologies, and radiological protection — Vocabulary — Part 4: Dosimetry for radiation processing

2.5 *U.S. Food and Drug Administration, Code of Federal Regulations:*[6]
CFR Title 21, Part 110 Current Good Manufacturing Practices in Manufacturing, Packaging, or Handling Human Food
CFR Title 21, Section 179.25 General Provisions for Food Irradiation
CFR Title 21, Section 179.26 Irradiation in the Production, Processing and Handling of Food
CFR Title 7, Part 305.31 Irradiation treatment of imported regulated articles for certain plant pests

2.6 *International Commission on Radiation Units and Measurements (ICRU) Report:*[7]
ICRU 85a Fundamental Qualities and Units for Ionizing Radiation

2.7 *Joint Committee for Guides in Metrology (JCGM) Reports:*[8]
JCGM 200:2012, (JCGM 200:2008 with minor revisions) VIM, International vocabulary of metrology – Basis and general concepts and associated terms

3. Terminology

3.1 *Definitions:*

3.1.1 *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

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

3.1.1.1 *Discussion*—the SI unit of absorbed dose is the gray (Gy), where one gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg).

3.1.2 *absorbed dose mapping*—measurement of absorbed dose within an irradiated product to produce a one-, two-, or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed dose values.

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

3.1.4 *good manufacturing practice (GMP)*—procedure established and exercised throughout the production, manufacturing processing, packing, and distribution of foods, encompassing maintenance of sanitation system, quality control and assurance, qualification of personnel and other relevant activities, to ensure the delivery of commercially acceptable and safe product.

3.1.5 *pest*—any species, strain or bio type of plant, animal or pathogenic agent injurious to plant or plant products (**2**).

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

[4] Available from Joint FAO/WHO Food Standards Programme Joint Office, FAO, Viale delle Terme di Caracalla 00100 Rome, Italy.
[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.
[6] Available from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402-9328.
[7] Available from the International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814 USA.
[8] Document produced by Working Group 2 of the Joint Committee for Guides in Metrology (JCGM/WG 2). Available free of charge from at the BIPM website (http://www.bipm.org).

3.1.7 *quarantine pest*—a pest of potential economic importance to an endangered area and not yet present there, or present but not widely distributed and being officially controlled **(3)**.

3.1.8 *quarantine treatment*—pertaining to the killing, removal, or rendering infertile of regulated plant pests on host material that has been placed in quarantine (or seized and detained) by regulatory authorities because of the potential or actual presence of a quarantine pest **(4)**.

3.1.9 *regulated non-quarantine pest*—non-quarantine pest whose presence in plants for planting affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the importing contracting party **(3)**.

3.1.10 *regulated pest*—quarantine pest or a regulated non-quarantine pest **(3)**.

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

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ISO/ASTM 52628, Terminology E3083, and ISO Terminology 12749-4. Definitions in these documents are compatible with ICRU Report 85a, and therefore, may be used as alternative references. Where appropriate, definitions used in this standard have been derived from, and are consistent with, general metrological definitions given in the VIM.

4. Significance and Use

4.1 The purpose of radiation treatment, as discussed in this guide, is to minimize the pest risk and to maximize the safety associated with the movement and use of fresh agricultural produce.

4.2 Irradiation as a phytosanitary treatment can prevent development or emergence of the adult stage where adults are not present in the agricultural produce (for example, fruit flies) or sterilize the adult where that stage is present (for example, weevils). **(4)**

5. Selection of Fresh Agricultural Produce for Irradiation

5.1 Most fresh agricultural produce is not adversely affected at the minimum doses indicated in 8.5.2. In particular, the following fruits have been found to be tolerant of those minimum doses: apple, cantaloupe, carambola, cherry, citrus, currant, date, fig, grape, guava, honeydew melon, kiwi, lychee, mango, muskmelon, nectarine, papaya, peach, prune, raspberry, strawberry, and tomato.

5.2 Some fresh agricultural produce may be damaged or exhibit unacceptable changes in shelf-life, color, taste, or other properties at the minimum doses indicated in 8.5.2, making it necessary to evaluate the effects of irradiation on the fruit at the required dose level. Differences among varieties, origins, growing and harvest conditions, and elapsed time between harvest and processing should be considered.

5.3 Irradiation of product will result in a distribution of absorbed dose in a process load, which is characterized by a maximum and minimum absorbed dose. Thus, in addition to evaluating the suitability of treating product at the minimum dose necessary to inactivate pests, tolerance of the product to the expected maximum dose should be evaluated.

6. Packaging and Product Loading Configuration

6.1 *Packaging*

6.1.1 Guide F1640 provides guidance on packaging materials in contact with food during irradiation.

6.2 Appropriate packaging materials should be used for safeguarding the produce as part of the effort to ensure phytosanitary integrity (for example, see 7 CFR 305.31).

6.3 *Product Loading Configuration*

6.3.1 The size, shape, and loading configuration of a process load for the commodities to be irradiated should be determined primarily by considering design parameters of the irradiation facility (see ISO/ASTM Practices 51608, 51649, and 51702). Critical irradiation 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. These parameters and product dose specifications should be taken into account in determining the size, shape and loading configuration of a process load (8.3).

7. Pre-Irradiation Product Handling and Treatment

7.1 Fresh agricultural produce intended to be irradiated should be of good overall quality and reflect the results of good agronomic practices.

7.1.1 Upon receipt at the irradiation facility, inspect packages and containers of the commodities according to relevant Good Manufacturing Practices (GMPs) to ensure that their integrity has not been compromised. See for example 21 CFR 110.

7.2 Radiation can be applied to these commodities in bulk, in-line prior to packaging, or in commercial packages. However, some countries may require that pest-proof packaging be in place prior to irradiation.

7.3 Fresh agricultural produce should be appropriately segregated or otherwise safeguarded prior to irradiation as part of the effort to ensure phytosanitary integrity.

7.4 Normal storage procedures should be used prior to radiation treatment. Pre-irradiation storage should include appropriate temperature and atmospheric conditions. Information on storage conditions is provided in ISO Standards (see 2.4).

7.5 Handling of the commodities in an irradiation facility should be in accordance with relevant and current GMPs. There are no special requirements for handling of the commodities prior to irradiation except for providing control measures to prevent post-irradiation re-contamination in storage facilities and for ensuring separation of irradiated and non-irradiated product.

7.6 *Product Separation*—It may not be possible to distinguish irradiated from non-irradiated product by inspection. It is therefore important that appropriate means, such as physical barriers, or clearly defined areas, be used to maintain non-irradiated product separate from irradiated product.

NOTE 1—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.

8. Irradiation

8.1 *Standard Operating Procedures (SOPs)*—Standard operating procedures for food irradiation are documented procedures that are used to ensure that the technologically established dose range and irradiation conditions selected by the radiation processor are achievable on a specific product in a specific facility. These procedures should be established and validated by qualified persons having knowledge in irradiation requirements specific for the food and the irradiation facility (see CAC/RCP 19).

8.1.1 Installation qualification, operational qualification, performance qualification and process control should be performed following the requirements of ISO/ASTM Practices 51702, 51608, or 51649.

8.2 *Radiation Sources*—The sources of ionizing radiation that may be employed in irradiating fresh agricultural produce 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) (see ISO/ASTM Practice 51702);

8.2.2 *Machine Sources*—X-rays and accelerated electrons (see ISO/ASTM Practices 51608 and 51649).

NOTE 2—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 and 21 CFR, 179.26).

8.3 *Absorbed Dose:*

8.3.1 *Absorbed Doses Required to Accomplish Specific Effects*—Food irradiation specifications provided by the owner of the product should include minimum and maximum absorbed dose limits: 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 and USDA regulations 7 CFR 305.31 and 21 CFR 179.25. The irradiation process must be configured to ensure that the absorbed dose achieved is within these limits throughout each process load. Once this capability is established, the absorbed dose values for each production run must be monitored and recorded (see 11.1.3).

8.3.2 *Doses to Control Various Pests*—Appendix X1 lists the many quarantine pests of fresh agricultural produce. Additional information on the use of irradiation as a quarantine treatment for pests on fresh agricultural produce can be found in the International Database on Commodity Tolerance on the IAEA website (**5**) or the USDA website (**6**). The sensitivity of a pest to radiation varies with the life stage of the pest at the time of irradiation (see Note 3). The effect of irradiation at one stage may carry over to, and be more apparent in, a later stage.

NOTE 3—Infestation of a fruit with fruit flies occurs when the adult female lays eggs in the agricultural produce. Later, these eggs hatch and larvae emerge. These larvae feed and develop in the fruit and in this manner damage it. The larvae leave the fruit upon maturation and undergo pupation in the ground. In packaged agricultural produce, pupation may occur in the container. Seed weevils can infest fresh agricultural produce at an early stage and upon emergence as adults, damage the seed and the fruit. One should concentrate on developing a treatment against the most radiation-tolerant stage, that can be reasonably expected to be in, on, or with the fresh agricultural produce. The most tolerant stage is usually the one closest to the adult if the adult itself is not present in the agricultural produce.

8.3.3 *Dosimetry*—Dosimetry is a major component of a total quality assurance program for adherence to Good Manufacturing Practices used in radiation processing of food. CX STAN 106 and CAC/RCP 19 strongly emphasize the role of dosimetry for ensuring that irradiation is properly performed, since dosimetry is part of a verification process for establishing that the irradiation process is under control.

8.3.4 *Dosimetry System*—Dosimetry used in the development, validation and routine control of the irradiation process shall have measurement traceability to national or international standards and shall have a known level of uncertainty. The selected dosimetry system should be appropriate for the radiation source being used, the range of absorbed doses required, and the environmental conditions (for example, product temperature, irradiation temperature) expected during irradiation (see ISO/ASTM Practices 51261 , 52628, and Guide 52701). (**7**)

8.3.5 *Absorbed-dose Mapping*—Prior to performing routine irradiation, it is necessary to characterize the dose distribution in the volume of product being irradiated through absorbed dose mapping. Dosimeters placed throughout the product provide dose measurements to identify the magnitude and location of minimum and maximum dose. The absorbed dose map depends on the product based on what the product is, how the product is packaged and oriented in the package, the packaging material, and presentation to the irradiation source. Guidance on dose mapping is given in ISO/ASTM Guide 52303.

8.4 *Routine Production Dosimetry*—The irradiation facility is responsible for delivering the absorbed doses within the specified dose range. Dosimetry should be performed following the requirements of ISO/ASTM Practices 51702, 51608, or 51649.

8.4.1 Once the radiation facility has demonstrated the ability to deliver the absorbed dose, it is necessary to monitor, and record absorbed dose values during routine processing. (See 11.1.3.)

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

8.4.3 Select and calibrate a dosimetry system appropriate to the radiation source being used, the environmental conditions, and the range of absorbed doses required (see ISO/ASTM Practice 51261 and Refs (**8**) and (**9**)).

8.4.3.1 Verify that the product routinely receives the required absorbed dose by using proper dosimetry procedures, with appropriate statistical controls and documentation.

8.4.3.2 Place dosimeters in or on the process load at regions of minimum and maximum absorbed dose. These locations are identified in the product absorbed-dose mapping exercise. If