CODE OF PRACTICE FOR RADIATION PROCESSING OF FOOD (CAC/RCP 19-1979)

INTRODUCTION

Food irradiation is the processing of food products by ionizing radiation in order to, among other things, control foodborne pathogens, reduce microbial load and insect infestation, inhibit the germination of root crops, and extend the durable life of perishable produce. Many countries are using industrial irradiators for processing of food products for commercial purposes.

The regulatory control of food irradiation should take into consideration the *General Standard for Irradiated Foods* (CODEX-STAN 106-1983) and this Code.

The purpose of regulatory control of irradiated food products should be:

a) to ensure that radiation processing of food products is implemented safely and correctly, in accordance with all relevant Codex standards and codes of hygienic practice;

b) to establish a system of documentation to accompany irradiated food products, so that the fact of irradiation can be taken into account during subsequent handling, storage and marketing; and

c) to ensure that irradiated food products that enter into international trade conform to acceptable standards of radiation processing and are correctly labelled.

The purpose of this Code is to provide principles for the processing of food products with ionizing radiation that are consistent with relevant Codex Standards and codes of hygienic practice. Food irradiation may be incorporated as part of a HACCP-plan where applicable; but a HACCP-plan is not required for the use of radiation processing of food processed for purposes other than for food safety. The provisions of this Code will provide guidance to the radiation processor to apply the Hazard Analysis and Critical Control Point (HACCP) system, as recommended in the *General Principles of Food Hygiene* (CAC/RCP 1-1969), where applicable for food safety purposes, to foods processed by ionizing radiation.

1. OBJECTIVES

This Codex Code of Practice for Radiation Processing of Food identifies the essential practices to be implemented to achieve effective radiation processing of food products in a manner that maintains quality and yields food products that are safe and suitable for consumption.

2. SCOPE, USE and DEFINITIONS

2.1 Scope

This Code is concerned with food products processed by gamma rays, X-rays or accelerated electrons for the purpose of, among other things, control of foodborne pathogens, reduction of microbial load and insect infestation, inhibition of the germination of root crops, and extension of durable life for perishable foods.

This Code covers the requirements of the irradiation process in a facility; it also considers other aspects of the process as primary production and/or harvesting, post-harvest treatment, storage and shipment, packaging, irradiation, labelling, post-irradiation storage and handling, and training.[1]

2.2 Use

The *General Principles of Food Hygiene* (CAC/RCP 1-1969) and its annex on application of the HACCP system, as well as other relevant Codex Standards and codes of hygienic practice should be used with this document. Of particular relevance are the *General Standard for Irradiated Foods* (CODEX STAN 106-1983) and the *General Standard for the Labelling of Pre-Packaged Foods* (CODEX STAN 1-1985).

[1] Codes of good irradiation practice, compilations of technical data for the authorization and control of the irradiation of several food classes and also training manuals for facility operators and control officials have been produced by the International Consultative Group on Food Irradiation (ICGFI), available through the International Atomic Energy Agency, PO Box 100, A-1400 Vienna, Austria.

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2.3 Definitions

For purposes of this Code, the terms below are defined as follows:

Food Irradiation: Processing of food products by ionizing radiation, specifically gamma rays, X-rays or accelerated electrons as specified in the Codex General Standard for Irradiated Food**s**.

Irradiated Food: Food products processed by ionizing radiation in accordance with the *General Standard for Irradiated Foods* (CODEX-STAN 106-1983). Such food is subject to all relevant standards, codes and regulations applicable to the non-irradiated counterpart.

Dosimetry: The measurement of the absorbed dose of radiation at a particular point in a given absorbing medium.

Dose (absorbed): The absorbed dose**,** sometimes referred to simply as 'dose', is the amount of energy absorbed per unit mass of irradiated food product.

Dose Uniformity Ratio: The ratio of maximum to minimum absorbed dose in the production lot.

Dose Distribution: The spatial variation in absorbed dose throughout the production lot with extreme values being the maximum absorbed dose and the minimum absorbed dose.

Dose Limit: The minimum or maximum radiation dose absorbed by a food product prescribed in regulations as required for technological reasons. Such dose limits are expressed as ranges or as single lower or upper values (i.e.**,** no part of the food product shall absorb less than or more than a specified amount).

3. PRE-IRRADIATION TREATMENT

3.1 Primary production and/or harvesting

Primary food products intended for radiation processing should comply with the *General Principles of Food Hygiene* (CAC/RCP 1-1969) with reference to the hygienic requirements as well as other relevant Codex standards and codes of practice for primary production and/or harvesting, which ensure that food is safe and suitable for human consumption.

3.2 Handling, storage and transport

The intent to process food products by irradiation poses no unique requirements regarding handling, storage and transport of the food products prior to and subsequent to irradiation. All stages of the processing, i.e., pre-irradiation, irradiation and post-irradiation, should be in accordance with good manufacturing practices to maximize quality, to minimize contamination, and, if packaged, to maintain package integrity.

Radiation is applied to food products in forms in which they are normally prepared for processing, commercially traded or otherwise used. Food intended for radiation processing should conform to handling, storage and transport requirements of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) as well as relevant Codex standards and codes of practice for specific food products.

4. PACKAGING

In general, in order to avoid contamination or infestation after irradiation, food products should be packaged in materials that provide an effective barrier to re-contamination and re-infestation. Packaging must also meet the requirements of the importing country.

The size and shape of containers that may be used for irradiation are determined, in part, by the operating characteristics of the irradiation facility. These characteristics include the product transport systems and the irradiation source, as they affect the dose distribution within the container.

5. ESTABLISHMENT: DESIGN, FACILITIES and CONTROL

Authorization of a facility to irradiate food is granting approval to a facility licensed for radiation processing in general to irradiate food products. Authorization may be general in nature or issued for specific classes or groups of food products.

Facilities which carry out irradiation of food products should meet appropriate standards of occupational safety and good hygiene conditions, including:

- Regulations regarding design, construction and operation of radiation facilities
- *General Principles of Food Hygiene* (CAC/RCP 1-1969)
- *General Standard for Irradiated Foods* (CODEX-STAN 106-1983) and this Code.

5.1 Design and layout

This section is concerned with the areas in which food products are stored and irradiated. Prevention of contamination requires that all measures be taken to avoid direct or indirect contact of the food product with sources of potential contamination and to minimize growth of microorganisms.

Irradiation establishments are laid out to provide storage for irradiated and non-irradiated food products (under ambient, refrigerated and/or freezing temperature conditions), an irradiator, and the normal accommodation and infrastructure for staff and plant services including record maintenance. In order to achieve inventory control there should be provision in both the design and operation of the establishment to keep irradiated and non-irradiated food products separate. This separation can be accomplished by controlled single-direction movement of the food products through the plant and by separated storage areas for irradiated and non-irradiated food products.

Radiation facilities must be designed to provide an absorbed dose in the food product within minimum and maximum limits in accordance with process specifications and government regulatory requirements. For economic and technical reasons (e.g. maintaining product quality), various techniques are used to minimize the ratio, which is termed the dose uniformity ratio.

The following factors largely govern the selection of irradiator design:

a) Means of transporting food products: The mechanical design of the irradiation and transport systems, including the source-to-product geometry in a given process, as required by the form of the product, e.g. bulk or packaged, and its properties.
b) Range of doses: The range of doses needed to process a wide variety of products for various applications.
c) Throughput: The amount of product to be processed within a defined period of time.
d) Reliability: The property of providing correct performance as needed.
e) Safety-systems: The systems intended to protect operating personnel from hazards posed by radiation.
f) Compliance: The adherence to good manufacturing practices and relevant government regulations.
g) Capital and operational costs: The basic economic considerations necessary for sustainable operation.

5.2 Radiation sources

As described in the *General Standard for Irradiated Foods* (CODEX-STAN 106-1983), the following sources of ionizing radiation may be used in food irradiation**:**

a) Gamma rays from radionuclides ^{60}Co or ^{137}Cs**;**
b) X-rays generated from machine sources operated at or below an energy level of 5 MeV**;** and
c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

5.3 Control of operation

5.3.1 Legislation

Food processing establishments are constructed and operated in accordance with regulatory requirements in order to ensure safety of the processed foods for consumption and occupational safety of the plant personnel and the environment. A food irradiation facility, like any other food processing plant, is also subject to such regulation and should be designed, constructed and operated in compliance with relevant regulations.

5.3.2 Requirements for staff

The staff at an irradiation facility is subject to relevant sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) for personal hygiene recommendations and to the General Standard for Irradiated Foods for recommendations regarding the need for an adequate, trained and competent personnel.[2]

5.3.3 Requirements for process control

Requirements for process control are included in the *General Standard for Irradiated Foods* (CODEX-STAN 106-1983). Measuring the dose and monitoring of the physical parameters of the process are essential for process control. The need for adequate record keeping, including records of quantitative dosimetry**,** is emphasized in the General Standard. As for other physical methods of food processing, records are essential means for the regulatory control of processing by ionizing radiation. Evidence for correct processing, including adherence to any legal or technological dose limits, depends on the maintenance of full and accurate records by the irradiation facility. The facility's records link all the information from several sources to the irradiated food products. Such records enable verification of the irradiation process and should be kept.

5.3.4 Control of applied dose

The effectiveness of the irradiation process depends on proper application of the dose and its measurement. Dose distribution measurements should be carried out to characterize the process for each food product; and thereafter dosimeters should be used routinely to monitor correct execution of the process in accordance with internationally accepted procedures.[3]

For certain public health or quarantine applications, there may be specific requirements to regulate the minimum absorbed dose in order to ensure that the desired technological effect is achieved.

5.3.5 Product and inventory control

An adequate system should be in place so that specific consignments of food products can be traced back both to the irradiation facility and the source from which they were received for processing.

Plant design and administrative procedures should ensure that it is impossible to mix irradiated and non-irradiated food products. Incoming products should be logged and given a code number to identify the packages at each step in its path through the irradiation plant. All relevant parameters such as date, time, source strength, minimum and maximum dose, temperature, etc. should be logged against the code number of the product.

It is not possible to distinguish irradiated from non-irradiated product by visual inspection. Therefore, it is essential that appropriate means, such as physical barriers, be employed for keeping the irradiated and non-irradiated product separate. Affixing colour change indicator label on each package, where applicable, provides another means of distinguishing irradiated and non-irradiated product.

6. IRRADIATION

6.1 General

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2 Training manuals for facility operators and control officials have been produced by ICGFI, available through the International Atomic Energy Agency, PO Box 100, A-1400 Vienna, Austria. ICGFI also, through its FIPCOS, provides such training.

3 Such procedures are specified, for example, by the American Society for Testing and Materials (ASTM) in their annual handbooks.

Refer to the *General Standard for Irradiated Foods* (CODEX-STAN 106-1983).

6.2 Process determination

It is important that all steps in the determination of process procedures are documented to:

a) ensure that the application of the process complies with relevant regulatory requirements;
b) establish a clear statement for the technological objectives of the process;
c) estimate the dose range to be applied to achieve the technological objective based on appropriate knowledge of the food product;
d) demonstrate that irradiation of test samples has been carried out to confirm the estimated dose range under practical production conditions;
e) ensure that it is possible to meet the technological requirements, e.g**.** dose range and effectiveness of treatment, under practical production conditions; and
f) establish the process parameters under practical production conditions.

6.3 Dosimetry

Successful radiation processing practice depends on the ability of the processor to measure the absorbed dose delivered to each point in the food product and in the production lot.

Various techniques for dosimetry pertinent to radionuclide and machine sources are available for measuring absorbed dose in a quantitative manner. Relevant ISO/ASTM Standard Practices and Guides for dosimety in food irradiation facilities have been developed and should be consulted.[4]

In order to implement these irradiation practices, facilities should be adequately staffed by competent personnel trained in dosimetry and its application in radiation processing.

The calibration of the dosimetry system used in radiation processing should be traceable (i.e.**,** calibrated) to national and international standards.

6.4 Dosimetry systems

Dosimeters are devices that are capable of providing a quantitative and reproducible measurement of dose through a change in one or more of the physical properties of the dosimeters in response to the exposure to ionizing radiation energy. A dosimetry system consists of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use. Selection of appropriate dosimetry system for radiation processing of food will depend on a variety of factors, including the dose range needed to achieve a particular technological objective, cost, availability, and ease of use. A variety of dosimetry systems are available.[5]

6.5 Dosimetry and process control

In food irradiation, the key quantity that governs the process is the absorbed dose. It is influenced by various parameters, such as: radiation source type, strength and geometry; conveyor speed or dwell time; food product density and loading configuration; and carrier size and shape.[6] Their overall influence on dose distribution must be taken into account to ensure that the intended technological objective is achieved throughout the production lot.

The application of radiation processing is mainly governed by the minimum absorbed dose achieved in the dose distribution within a given product. If the required minimum is not applied, the intended technical effect may not

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4 ISO/ASTM 51204 – Standard Practice or Dosimetry in Gamma Irradiation Facilities for Food Processing; ISO/ASTM 51431 – Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing; ISO/ASTM 51261 – Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing.

5 ISO/ASTM 51261 – Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

6 ISO/ASTM 51204 – Standard Practice or Dosimetry in Gamma Irradiation Facilities for Food Processing and ISO/ASTM 51431 – Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing

be achieved (e.g. sprout inhibition, pathogen reduction). There are also situations where the application of too high a dose would impair the quality of the treated food (e.g. off flavours or odours). [7]

6.6 Records of irradiation

Radiation processors should maintain adequate records showing the food processed, identifying marks if packaged or, if not, the shipping details, the bulk density of the food, the dosimetry results, including the type of dosimeters used and details of their calibration, the date of irradiation and the type of radiation source. All documentation should be available to authorized personnel and accessible for a period of time established by food control authorities.

6.7 Control of hazards

Controls of microbiological hazards are described in the *General Principles of Food Hygiene* (CAC/RCP 1-1969).

The radiation processor should apply HACCP principles, as described in the *General Principles of Food Hygiene* (CAC/RCP 1-1969), as appropriate. In the overall HACCP context, irradiation is a means of reducing hazards associated with infectious parasites and microbial contamination of foods and may be used as a method of control.

7. POST-IRRADIATION STORAGE AND HANDLING

Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969) for general storage and handling guidance.

8. LABELLING

The *General Standard for Irradiated Foods* (CODEX STAN 106-1983) and the *General Standard for the Labelling of Pre-Packaged Foods* (CODEX STAN 1-1985) contain provisions for labelling of irradiated foods, including the internationally recognized symbol (logo) and the inclusion of information in shipping documents**,** and for the labelling of prepackaged irradiated foods, respectively. All food labelling must meet any additional requirements established by the competent authorities.

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[7] Codes of good irradiation practice and compilations of technical data for the authorization and control of the irradiation of several food classes have been produced by ICGFI, available through the International Atomic Energy Agency, PO Box 100, A-1400 Vienna, Austria.