Archived Content

VERSION: Nov 19, 2002

RECOMMENDED CANADIAN CODE OF PRACTICE FOR FOOD IRRADIATION

Prepared by Health Products and Food Branch,
Health Canada, in cooperation with
The Canadian Food Inspection Agency

This Code is based on the Codex "Draft Revised Recommended International Code of Practice for Radiation Processing of Food"

TABLE OF CONTENTS

PREFACE

This Code of Practice has been adapted directly from the *Codex Alimentarius* Recommended International Code of Practice for Radiation Processing of Food.[1]

This Code of Practice is intended as a guideline for a) food manufacturers/processors contemplating contract irradiation for their products; b) operators of irradiation facilities engaged in the commercial application of the irradiation of food products; and c) distributors of imported irradiated food. The Code will also be useful for government officers involved in the authorization or inspection of the application of irradiation to food products and the inspection of imported irradiated food products.

This Code is meant to be used in conjunction with, rather than to supersede, relevant legislation and regulations established by federal, provincial or municipal authorities.

INTRODUCTION

Food irradiation is the treatment of food products with ionizing radiation in order to 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 to treat food products for commercial purposes.

The purpose of regulatory control of irradiated food products is to ensure:

a) the safety and nutritional quality of the food for human consumption;
b) that radiation processing of food products is implemented safely and correctly, in accordance with all relevant legislation and regulations and codes of hygienic practice;
c) that records are maintained and available on irradiated food products to guide subsequent handling, storage and marketing of these products;
d) that irradiated food products that enter into trade conform to acceptable standards of radiation processing and are correctly labeled; and
e) that both domestic and imported irradiated food products meet Canadian regulatory requirements.

The purpose of this voluntary Code is to provide principles for the treatment of food products with ionizing radiation and subsequent processing that are consistent with the requirements of Canada's *Food and Drugs Act and Regulations* and other federal, provincial or municipal regulations and codes of practice that are concerned with the safety of food.

---

[1]This Code of Practice has not yet been adopted (October 11, 2002) by the Codex Alimentarius Commission. It is presently at Step 5/8 of the Codex Accelerated Procedure.

Consistent with Canadian regulatory requirements is the *Codex Recommended International Code of Practice - General Principles of Food Hygiene* (RCP 01-1969, Rev 3-1997, Amd 1-1999) and its annex on *Hazard Analysis and Critical Control Point (HACCP) System* and Guidelines For Its Application (which will be referred to as *Codex General Principles of Food Hygiene* in the rest of this document). These essential principles of hygiene, along with the use of a HACCP based approach for process control of safety hazards, provide the foundation for assuring the safety and nutritional quality of food from harvest to consumption. A food safety control program, such as HACCP, is not required for some irradiation applications such as the inhibition of sprouting in root crops, shelf-life extension of fruit and vegetables or quarantine treatments.

1 OBJECTIVES

This voluntary *Code of Practice for Radiation Processing of Food* identifies the essential practices to be implemented to achieve effective radiation treatment of food products in a manner that maintains nutritional quality and yields food products that are safe and suitable for consumption. In achieving the above goals, every effort should be made to use the lowest possible effective radiation dose, low oxygen environments and low product temperature during irradiation.

2 SCOPE, USE and DEFINITIONS

2.1 Scope

This Code of Practice applies to food products processed by gamma rays, X-rays or accelerated electrons for 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 outlines the required control of the irradiation process as applied to food products. It also considers other aspects of the overall process including primary production and harvesting, post-harvest treatment, storage and shipment, packaging, labeling, post-irradiation storage and handling, and training, and takes into account other relevant legislation.

The good irradiation practices described in this Code apply to irradiated food products of domestic and foreign origin.

2.2 Use

This document should be used with other relevant and applicable legislation (e.g., *Food and Drugs Act and Regulations, Consumer Packaging and Labelling Act, Nuclear Safety and Control Act, Meat Inspection Act and Regulations, Fish Inspection Act and Regulations*, etc.). Other relevant references are the *Codex General Principles of Food Hygiene*; commodity specific codes of hygienic practice established by Canadian food control agencies; and International Consultative Group on Food Irradiation (ICGFI) publications, particularly its codes of good

irradiation practice.[2]

2.3 Definitions

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

Food Irradiation: Treatment of food products by ionizing radiation, specifically gamma rays, X-rays or electron beams as specified in Division 26 of Part B of the *Food and Drug Regulations*.

Irradiated Food: Food products processed with ionizing radiation in accordance with the requirements of the *Food and Drugs Act and Regulations* as well as all other relevant legislation, regulations and codes applicable to the non-irradiated commodity.

Dosimetry: The measurement of the absorbed dose of radiation at particular points 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 to produce a specific technological effect. Such dose limits are expressed as a (maximum) total overall average absorbed dose, as ranges (minimum - maximum dose), 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).

Licensing of Facility: Approvals and certifications of an irradiation facility and equipment under the *Nuclear Safety and Control Act* and regulations of the Canadian Nuclear Safety Commission.

Authorization of Facility to Irradiate Food: Granting approval for the licensing of facilities

---

[2] 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, P.O. Box 100, A-1400 Vienna, Austria or its website http://www.iaea.org/icgfi.

under authority of the *Nuclear Safety and Control Act*.[3]

3 PRE-IRRADIATION TREATMENT

3.1 Primary production and harvesting

Irradiation cannot be used as a substitute for good manufacturing practice. Primary food production should still be managed in a way that ensures that food is safe and of suitable quality for human consumption. Compliance with the *Codex General Principles of Food Hygiene* and additional commodity specific codes of hygienic practice, established by Codex, requires producers to identify hazards and implement measures to protect food sources and control plant and animal health.

3.2 Handling, storage and transport

Post-harvest handling, storage and transport of product destined for irradiation treatment should conform to the requirements of the *Codex General Principles of Food Hygiene*, as well as relevant regulations and codes of practice for specific food products. Suitable practices should be implemented to maintain food safety and nutritional quality, minimize contamination and, if packaged, to retain package integrity.

4 PACKAGING

In order to avoid contamination or infestation after irradiation, food products should be pre-packaged in materials that provide an effective barrier to re-contamination and re-infestation. This practice does not apply to all applications of irradiation, such as bulk treatment of root crops to inhibit germination. In food safety applications where it is necessary to treat unpackaged product, the HACCP approach to process controls should be followed to ensure that re-contamination does not occur after irradiation and before packaging.

The size and shape of containers that may be used for irradiation treatment 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.

The safety of materials used for the packaging of foods is controlled under Division 23 of Part B of the *Food and Drug Regulations*. Packaging materials used for foods subjected to irradiation treatment should be assessed in advance for suitability. When the packaging material used for an irradiated food is not listed for this purpose within the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemicals* published by the

[3]This act came into force May 31, 2000 replacing the *Atomic Energy Control Act.* The primary concern of this act is the safety of the worker and the public.

Canadian Food Inspection Agency,[4] the processor should seek an advisory opinion on the acceptability of the material from Health Canada[5] prior to using the material.

5 ESTABLISHMENT: DESIGN, FACILITIES and CONTROL

5.1 General

5.1.1 Mandatory Requirements

Facilities which carry out the irradiation of food products must meet relevant standards for environmental and occupational safety and food hygiene conditions, including:

a) Legislation regarding the design, construction and operation of radiation facilities, i.e. *Nuclear Safety and Control Act* and regulatory authority of the Canadian Nuclear Safety Commission for Class II Nuclear Facilities and Prescribed Equipment.

b) Applicable legislation regarding the design, construction and operation of food processing facilities e.g., *Fish Inspection Act and Regulations*, *Meat Inspection Act and Regulations*, etc.

5.1.2 Voluntary Requirements

In addition, facilities should also meet the requirements of:

a) *Codex General Principles of Food Hygiene* and its annex on the application of HACCP.

b) *Codex General Standard for Irradiated Foods* (CX-STAN-106-1983, under revision) and this *Canadian Code of Practice for Irradiation Treatment of Food*.

5.2 Design and layout

Irradiation establishments comprise various components/areas:

a) provision of docking, loading and unloading facilities for transport vehicles;

b) storage for irradiated and non-irradiated food products (under ambient, refrigerated and/or freezing temperature conditions);

c) an irradiator; and

d) 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

---

[4]Canadian Food Inspection Agency (CFIA), 59 Camelot Drive, Ottawa, ON, K1A 0Y9, website www.inspection.gc.ca.

[5]Requests should be directed to Head, Food Packaging and Incidental Additives Section, Chemical Health Hazard Assessment Division, Bureau of Chemical Safety, Food Directorate, Postal Locator 2201B1, Health Products and Food Branch, Health Canada, Ottawa, ON, K1A 0L2, with a copy to the Program Officer, Hygienic Environment Program, CFIA.

segregation 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.

Just as retorts deliver an absorbed thermal energy range to batches of canned foods, industrial irradiators deliver an absorbed ionizing energy (dose) range to irradiated products. Radiation facilities should 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 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 accurate, dependable performance.
e) Safety-systems: The systems intended to protect operating personnel from hazards posed by radiation and overexposure of food.
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.

5.3 Radiation sources

In general, as described in the *Food and Drug Regulations*, the following sources of ionizing radiation may be used in food irradiation:

a) Gamma radiation from radionuclides Cobalt-60 or Cesium-137;
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.

Constraints on the sources that may be used and energy levels that may be employed may be established in the Table to Division 26 of the *Food and Drug Regulations* for specific food irradiation applications.

5.4 Control of operation

5.4.1 Legislation

Food processing establishments are constructed and operated in accordance with legislative and

regulatory requirements in order to ensure the safety of processed foods for consumption, occupational safety of the plant personnel and protection of the environment. A food irradiation facility is also subject to these requirements and should be designed, constructed and operated in compliance with relevant legislation and regulations. These include the licensing, certification or registration requirements under the *Nuclear Safety and Control Act* (administered by the Canadian Nuclear Safety Commission) and the registration requirements for establishments regulated by the Canadian Food Inspection Agency under the *Fish Inspection Act, Meat Inspection Act*, etc.

5.4.2 Requirements for staff

The staff at an irradiation facility is subject to relevant sections of the *Codex General Principles of Food Hygiene* for personal hygiene recommendations and also to the *Codex General Standard for Irradiated Foods* for recommendations regarding the need for an adequate, trained and competent personnel to control the radiation process. See Section 9, Staff Competency. The manager of a food irradiation facility should maintain records which document the training received by staff.

5.4.3 Requirements for process control

Requirements for process control are included in the *Codex General Standard for Irradiated Foods*. For example, procedures for 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 also emphasized in the Codex 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 are mandatory under the requirements of section B.26.004 of the *Food and Drug Regulations*, and enable verification of the irradiation process. These records must be kept for the 2-year period required by the *Regulations*.

5.4.4 Control of applied dose

Only foods listed in the Table to Division 26 of the *Food and Drug Regulations* may be irradiated subject to any constraints in that table opposite the entry for that food regarding permitted sources, dose, conditions, and purpose of irradiation.

The effectiveness of the irradiation process depends on proper application of the dose and on dose 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.[6]

For certain public health or quarantine applications, such as to control pathogens in poultry or for quarantine treatments to control insect infestation in imported fruits, there may be specific requirements to regulate the minimum absorbed dose in order to ensure that the desired technological effect is achieved.

5.4.5 Product and inventory control

Plant design and administrative procedures must 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 irradiated and non-irradiated product separate. Affixing colour change indicator labels on each package, where applicable, provides another means of distinguishing irradiated and non-irradiated product.

6 IRRADIATION

6.1 General

The irradiation of food is justified only when it fulfils a technological need or benefit to consumers or where it serves a food hygiene purpose and only those foods listed in the Table to Division 26 may be irradiated, subject to any constraints specified therein.

The process cannot be used to substitute for good manufacturing practices in the production and handling of food. Only top quality foods should be chosen for irradiation treatment.

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

[6]Such procedures are specified, for example, by the American Society for Testing and Materials (ASTM) in its annual handbooks.

f) establish the process parameters under practical production conditions.

6.3 Dosimetry

Successful irradiation 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, and to control the radiation process once production begins.

Various techniques for dosimetry pertinent to radionuclide and machine sources are available in an international publication.[7] Appropriate procedures have been developed by the American Society for Testing Materials (ASTM) and the International Standards Organization (ISO).[8]

The calibration of the dosimetry system used in irradiation treatment should be traceable (i.e., calibrated to a recognized standard such as those provided by ASTM or the International Dose Assurance Service operated by the International Atomic Energy Agency, Vienna).

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

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. The selection of an appropriate dosimetry system for irradiation 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.[9]

6.5 Dosimetry and process control

In food irradiation, the key measurement 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

---

[7] Manual of Food Irradiation Dosimetry, International Atomic Energy Agency, Vienna, 1977, under revision.

[8] See ASTM annual handbooks. Also see ISO published standards 51204:2002, 51431:2002 and 51702:2002.

[9] Manual of Food Irradiation Dosimetry, International Atomic Energy Agency, Vienna, 1977, under revision; and for example "Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing" ISO 15556 (1998) / ASTM E 1261-00.

and shape.[10] The overall influence of these latter parameters on dose distribution must be taken into account to ensure that the intended technological objective is achieved throughout the production lot.

The minimum and maximum radiation doses absorbed by a food product are important process controls. If the required minimum dose is not applied, the intended technical effect may not 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). In this regard, the process may be described as being self-regulating in a technological or economic sense.[11] In any case, any minimum and maximum doses specified in the Table to Division 26 of the *Food and Drug Regulations* should be respected.

6.6 Records of irradiation

Record requirements for the irradiation of food are specified in Section B.26.004 of the *Food and Drug Regulations*. Irradiation processors must maintain adequate records listing the type of food processed; the purpose and date of the treatment; the quantity and lot numbers of the food; the absorbed dose; the type of irradiator and radiation source; dosimetry results (including types of dosimeters and their calibration); and records of any previous radiation treatment. All product documentation shall be available to authorized personnel and accessible for at least two years after the date of irradiation by food control authorities.

6.7 Control of hazards

Measures to control hazards are described in the *Codex General Principles of Food Hygiene* including the application of the HACCP system where applicable for food safety purposes. For example, facilities irradiating products such as meat, poultry or seafoods for the purpose of reducing pathogens should operate in accordance with a recognized safety control program (e.g. HACCP). This plan should be consistent with the regulatory requirements for the commodity.

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, but not as a substitute for the essential principles of food hygiene and good manufacturing practices.

---

[10] "Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing" ISO 15554 (1998) / ASTM E 1204-97. "Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing" ISO 15562 (1998) / ASTM E 1431-098.

[11] Codes of good irradiation practice and compilations of technical data for use in the authorization and control of the irradiation of several food classes 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 or its website http://www.iaea.org/icgfi.

6.8 Re-irradiation

Re-irradiation of a food is mentioned twice in Part B of the *Food and Drug Regulations.* In subsection B.01.035(7), the *Regulations* state:

- "The label attached to a shipping container containing any food referred to in column I of the Table to Division 26 that has been subjected to the maximum permitted absorbed dose set out in column IV of that Table shall carry the statement required by subsection (3) and the statement "Do not irradiate again."
- In paragraph B.26.004(f), there is a requirement for "a statement indicating whether the food was irradiated prior to the irradiation by the manufacturer and, if so, the information referred to in paragraphs (a) to (e) in respect of that prior irradiation.

These two sections highlight the fact that re-irradiation is not allowed unless specifically authorized in the Table to Division 26. For instance, there might be situations where it is beneficial technologically to apply and authorize application of the irradiation in two or more stages and in such instances, specific authorization would be inscribed in the Table to Division 26.

7 POST-IRRADIATION STORAGE and HANDLING

In conformance with *Codex General Principles of Food Hygiene*, good storage and handling practices should be in place to maintain product quality and nutritional attributes and, where enhanced food safety is the objective, to protect against re-contamination or re-infestation.

Foods which are irradiated for the control of pathogenic micro-organisms (e.g., shrimp, poultry or ground beef) must not be re-packaged after having been irradiated. Damaged packages of these foods must not be sold.

8 LABELLING

The labelling requirements for irradiated food products are set out in section B.01.035 of the *Food and Drug Regulations*. Labeling provisions for prepackaged products, bulk retail units, shipping containers and the use of the internationally recognized radura symbol and label statement shall be followed. Information should be provided on the label which enables the tracking of individual lots of irradiated product sold to the consumer.

9 STAFF COMPETENCY

The Canadian Nuclear Safety Commission, under authority of the *Nuclear Safety Control Act*, ensures staff competency by requiring Class II facilities to have a staff training policy and confirmation that operators are competent in radiation safety.

Managers and staff should refer to the *Codex General Principles of Food Hygiene* for requirements regarding personnel awareness and responsibilities regarding food safety and the

need for training programs, instruction and supervision, and refresher training. The *Codex General Standard for Irradiated Foods* requires that irradiation facilities should be staffed by adequate, trained and competent personnel.

Training manuals for facility operators and control officials have been produced by ICGFI[12]. Operators and inspectors of food irradiation facilities should have successfully completed a course of instruction on irradiation processing and radiation health and safety.

[12] Available from the International Consultative Group on Food Irradiation, IAEA, P.O. Box 100, A-1400 Vienna, Austria.