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Food irradiation — Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

Ionisation des aliments — Exigences pour l'élaboration, la validation et le contrôle de routine du procédé d'irradiation utilisant le rayonnement ionisant dans le traitement des aliments

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14470 was prepared by Technical Committee ISO/TC 34, *Food products*.

Introduction

Food irradiation is the process where food is exposed to ionizing radiation in order to improve its safety and quality. It is intended to be used only on food that has been produced under good manufacturing practice (GMP) principles. Many countries are using irradiation as a technological choice at some stage in food processing, making relevant the establishment of standards to assist customers, irradiator operators, and consumers.

The irradiation of food can be used for different purposes including control of pathogenic microorganisms and parasites, reduction of the number of spoilage microorganisms, inhibition of the sprouting of bulbs, tubers and root crops, extension of product shelf life or phytosanitary treatment.

When applicable, food irradiation should be incorporated as part of a food safety management system (ISO 22000). The irradiation of food is a critical control point (CCP) of a Hazard Analysis and Critical Control Points (HACCP) programme, contributing to the minimization of risks from the transmission of pathogenic microorganisms to consumers.

The main purposes of this International Standard are to:

a) provide requirements for the irradiation of food consistent with current standards and practices;

b) provide directions for a technical agreement between the customer and the irradiator operator;

c) establish a documentation system to support the controls on the food irradiation process.

To facilitate the application of this International Standard, it has been constructed in a form that can be used by internal and external parties, including certification bodies, for auditing an irradiator operator to assess its ability to fulfil all requirements for the irradiation of food.

Food irradiation — Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food

1 Scope

This International Standard specifies requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food, and establishes guidelines for meeting the requirements.

NOTE 1 Requirements in this International Standard are consistent with those developed by the Codex Alimentarius Commission (CAC/RCP 19-1979, Rev. 2-2003[21], and CODEX STAN 106-1983, Rev. 1-2003[22]).

This International Standard covers irradiation processes using the radionuclides ^{60}Co or ^{137}Cs, electron beams or X-ray generators.

The requirements given in this International Standard are the minimum necessary to control the food irradiation process.

NOTE 2 The requirements can be addressed by a food safety management system (see ISO 22000).

This International Standard does not specify requirements for the primary production and/or harvesting, post-harvest treatment, storage and shipment, and packaging for foods that are to be irradiated. Only those aspects of the food production directly related to the irradiation process that may affect the safety or quality of the irradiated food are addressed.

This International Standard does not specify requirements for occupational safety associated with the design and operation of irradiation facilities.

This International Standard does not cover measuring or inspection devices that utilize ionizing radiation.

The application of this International Standard does not exempt the user from compliance with current and applicable legislation.

IMPORTANT Attention is drawn to regulatory and legal requirements that possibly exist for the irradiation and sale of irradiated food and the requirement for authorization to irradiate food.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
absorbed dose
quantity of ionizing radiation energy imparted per unit mass of a specified material

NOTE 1 The unit of absorbed dose is the gray (Gy) where 1 Gy is equivalent to the absorption of 1 J/kg.

NOTE 2 For the purposes of this International Standard, the term dose is used to mean “absorbed dose”.

[ISO 11137-1:2006[4], 3.1]

3.2
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[ISO/IEC Guide 99:2007[16], 2.39]

3.3
correction
action to eliminate a detected non-conformity

NOTE A correction can be made in conjunction with a corrective action.

[ISO 9000:2005[2], 3.6.6]

3.4
corrective action
action to eliminate the cause of a detected non-conformity or other undesirable situation

NOTE 1 There can be more than one cause of non-conformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

NOTE 3 There is a distinction between correction and corrective action.

[ISO 9000:2005[2], 3.6.5]

3.5
cross-contamination
contamination of a material or of a product with another material or product

[ISO 15378:2011[7], 3.15]

NOTE Cross-contamination occurs when a product and/or raw material is contaminated directly or indirectly from another product and/or raw material through physical contact or the environment.

3.6
customer
organization or person that receives a product

[ISO 9000:2005[2], 3.3.5]

NOTE In the context of this International Standard, the “product” is irradiation treatment supplied by an irradiator operator under specified conditions.

3.7
dose distribution
spatial variation in absorbed dose throughout a defined region and material, integrated over a complete treatment

3.8
dose mapping
measurement of dose distribution and variability in material irradiated under defined conditions

[ISO 11137-1:2006[4], 3.10]

3.9
dose uniformity ratio
ratio of the maximum to the minimum absorbed dose

3.10
dosimeter
device having a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given system

[ISO 11137-1:2006[4], 3.11]

3.11
dosimetry
measurement of absorbed dose by the use of dosimeters

[ISO 11137-1:2006[4], 3.12]

3.12
dosimetry system
interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards and procedures for their use

[ISO 11137-3:2006[5], 3.1]

3.13
food irradiation
processing of food by ionizing radiation

3.14
food safety
concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use

[ISO 22000:2005, 3.1]

3.15
good manufacturing practice
GMP
combination of manufacturing and quality procedures aimed at ensuring that products are consistently manufactured to their specifications, and to avoid contamination of the product by internal or external sources

3.16
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[ISO 11137-1:2006[4], 3.16]

3.17
irradiation container
holder in which product is transported through the irradiator

NOTE The holder can be a carrier, cart, tray, product carton, pallet or other container.

[ISO 11137-1:2006[4], 3.17]

3.18
irradiation facility
establishment where the irradiation process is performed

NOTE 1 Irradiation facilities can consist of an irradiator, shipping and receiving docks, storage zones for irradiated and non-irradiated food, conveyor system, safety systems and the infrastructure for personnel and facility services including record control (generation, updating, control and file).

NOTE 2 There are different types of irradiation facilities depending on the irradiator type, the conveyor system, the radiation source, the operating mode, among others.

3.19
irradiator
assembly that provides for safe and reliable irradiation processing, including the source of radiation, conveyor and source mechanisms, safety devices, and biological shield

3.20
irradiator operator
company or body responsible for irradiation of product

[ISO 11137-1:2006[4], 3.18]

3.21
non-conformity
non-fulfillment of a requirement

[ISO 9000:2005[2], 3.6.2]

3.22
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[ISO 11137-1:2006[4], 3.22]

3.23
performance qualification
PQ
process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

[ISO 11137-1:2006[4], 3.23]

3.24
preventive action
action to eliminate the cause of a potential non-conformity or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential non-conformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

[ISO 9000:2005[2], 3.6.4]

3.25
process interruption
intentional or unintentional stoppage of the irradiation process

[ISO 11137-1:2006[4], 3.26]