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# Food irradiation: Standards, regulations and world-wide trade

# Peter B. Roberts\*

Radiation Advisory Services, Lower Hutt, New Zealand

#### HIGHLIGHTS

• International standards and national regulations for food irradiation are well-established.

• There are increasing numbers of bi-lateral agreements for trade.

• Phytosanitary irradiation for fresh produce trade is expanding.

• There are many variations to regulations on labelling.

#### ARTICLE INFO

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#### 1. Introduction

## Commercial trade in irradiated foods requires a framework of international standards and national regulations. For trade between countries, either multi- or bi-lateral agreements should be in place. This article will review this framework. It also provides a brief overview of consumer acceptance and present trade in irradiated food, details of which are found elsewhere in this volume.

#### 2. International standards

The key international standards can be sub-divided into those dealing with human health, plant protection, labelling, dose delivery, quality assurance and facility management.

E-mail address: radservices@xtra.co.nz

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#### ABSTRACT

There is an established framework of international standards for food irradiation covering human health, plant protection, labelling, dose delivery, quality assurance and facility management. Approximately 60 countries permit irradiation of one or more food or food classes. National regulations are briefly reviewed. Decontamination of spices, herbs and condiments remains the single largest application of irradiation. However, in recent years the market for irradiated fresh and processed meat has become firmly established in several countries including China and the USA. At least 10 countries have recently established bi-lateral agreements for trade in irradiated fresh fruits and vegetables using phytosanitary irradiation. Irradiated fresh produce volumes now exceed 20,000 t per year. Rationalization and greater consistency in labelling regulations would be advantageous to the future growth of applications of food irradiation.

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#### 2.1. Human Health

The Codex Alimentarius Commission (Codex) is the body responsible for standards related to human health. Food irradiation must be conducted according to good management practice and comply with the Codex Alimentarius General Principles of Food Hygiene (CAC, 2003a). The cornerstone of food irradiation was set with the adoption of the Codex World-wide General Standard for Irradiated Foods in 1983 (CAC, 1983) and a significant revision in 2003 (CAC, 2003b). This standard defines the radiation sources that may be used and elaborates general practices for hygiene, process control and technological requirements. It deals with reirradiation and post-irradiation verification.

The General Standard (CAC, 2003b) states that the minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose should be less than that which would compromise consumer safety, wholesomeness or would adversely affect structural integrity, functional properties, or sensory attributes. The maximum dose absorbed by a food should not exceed 10kGy except when necessary to achieve a legitimate technological purpose.

It is notable that the absorbed dose recommendations apply to

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<sup>\*</sup> Correspondence to: Radiation Advisory Services, 31 Wyndrum Avenue, Lower Hutt 5011, New Zealand.

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any food and imply that any food may be safely treated within the dose limits set.

## 2.2. Labelling

The General Standard also requires irradiated food to be labelled in accordance with the Codex General Standard for the Labelling of Pre-packaged Food (CAC, 2010). This Standard requires the label of a food which has been treated with ionizing radiation to carry a written statement indicating that treatment in close proximity to the name of the food. The use of the international food irradiation symbol, Radura, is optional, but when it is used, it shall be in close proximity to the name of the food. When an irradiated product is used as an ingredient in another food, this shall be so declared in the list of ingredients. When a single ingredient product is prepared from a raw material which has been irradiated, the label of the product shall contain a statement indicating the treatment. Labelling is discussed further in Sections 3 and 7.1.

## 2.3. Plant protection

The International Plant Protection Convention (IPPC) is the recognised international authority for standards and measures to prevent the introduction and spread of plant pests. It has issued several International Standards for Phytosanitary Measures (ISPM) related to phytosanitary use of irradiation.

ISPM 18, "Guidelines for the Use of Irradiation as Phytosanitary Measure" (FAO, 2003) provides technical guidance on the specific procedures for the application of ionizing radiation that countries should adopt when trading in irradiated fresh fruit and vegetables. ISPM 28 "Phytosanitary Treatments for Regulated Pests" sets out minimum doses for a range of regulated pests (FAO, 2009). ISPM 28, in a ground-breaking development, also recognises 150 Gy as a generic dose that will prevent the emergence of all adult Tephritid fruit flies in any host commodity.

# 2.4. Facilities

Any processing facility using irradiation for any purpose must operate within the safety standard set down by the International Atomic Energy Agency (IAEA, 2008). This applies to any facility using Gamma, Electron or X-Ray sources. Food irradiation facilities should also be guided by the Codex Code of Practice for the Radiation Processing of Food (CAC, 2003c). More detail is provided by the International Organisation for Standardization in its standard ISO 14,470 (ISO, 2011). An important recent step was the recognition of quality management in radiation facilities and these are formalised in ISO 9001 (ISO, 2008).

Although not an international standard, a Manual of Good Practice in Food Irradiation is a comprehensive guide for facility operators (IAEA, 2015). The American Society for Testing and Materials (now ASTM International) is widely recognised for its standards, some of which are issued jointly with ISO. A guide for facilities treating agricultural produce for a phytosanitary purpose was issued in 2014 (ASTM, 2014). A common feature of the standards and guidelines is that Good Manufacturing Practice for food production and handling must be followed.

## 2.5. Dosimetry

Accurate knowledge of the dose delivered to food is essential. Absorbed dose measurement (dosimetry) requires the use of dosimeters and a dosimeter system that provide a well-defined chemical or physical response that can be measured and related to the absorbed dose via the system's calibration curve. Proper calibration and traceability to reference standards is fundamental. Dosimeters are used prior to commercial application to confirm that a scheduled dose or dose range can be applied to a specific food and food package. A dose mapping operation is conducted to define the positions of maximum and minimum dose for a specified configuration of food packages and then a routine dose checking system is established to verify that specified dose limits are being met in commercial operation. The statistical accuracy of the system must be defined.

A number of international standards are available for good dosimetry practice. These include standards produced by the IAEA (2002) and ISO/ASTM (2004, 2005, 2013, 2015).

### 2.6. Packaging

Food to be irradiated must be packed in material that maintains its integrity and that will not cause the diffusion of any toxic materials into the food during or after the process. An updated website is available with details of an extensive list of suitable materials based mainly on USA research (USFDA 2015a, b). The list of packaging materials is usually accepted by other countries but ASTM has independently produced a standard guide to packaging material (ASTM, 2003).

#### 3. National regulations

#### 3.1. Regulations for human health

Approximately 60 countries have approved the use of food irradiation in their health or food regulations for at least one, and usually more, food or food class. The IAEA keeps a Food Authorizations Database (IAEA, 2012). However, there is no obligation only a request for countries to lodge approvals with the agency and it is doubtful whether it is completely up to date.

Most countries would claim that their regulations are based on the Codex General Standard (CAC, 2003b). However, the Standard does not name specific foods that may or may not be irradiated. All food may be irradiated to the maximum approved absorbed dose. Very few countries have a regulation which allows the irradiation of any food subject only to compliance with the Codex Standard. Brazil (ANVISA, 2001) and Singapore (AFVAS, 2014) are two such countries. Brazil, for example, decided on an 'any, food, any dose, any purpose' regulation provided only that the food tolerates the treatment. Most countries still opt to give approvals to a specified food or food class for a nominated purpose on a case-by-case basis. In countries such as the USA, Canada, Australia and New Zealand, approval can only be given in response to a petition to change the existing regulation. The relevant agency can initiate approval but it is more usual for an industry body to make a petition.

#### 3.2. Regulations for labelling

Within their regulations most countries adopt the Codex General Standard on Labelling of Pre-packaged Foods (CAC, 2010). However, interpretation and enforcement of labelling provisions is variable. The EU, Australia and New Zealand require all whole foods to be labelled with text indicating the food has been irradiated on the food package, the individual item or in close proximity to the food. All irradiated ingredients must be labelled without any lower concentration limit and irradiated food and ingredients must labelled within the restaurant and catering trades. In the EU, the labelling text but not the Radura logo is specified (EU, 1999). In Australia and New Zealand the wording of text is suggested but not mandatory and the use of the logo is optional (ANZFSC, 2016).

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