

codex alimentarius commission



FOOD AND AGRICULTURE
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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INFORMATION PAPER ON REQUIREMENTS IN INTERNATIONAL TRADE FOR CERTIFICATES FOR FOODS IRRADIATED FOR NON-PHYTOSANITARY PURPOSES

**(Submitted by the Secretariat of the
International Consultative Group on Food Irradiation)**

BACKGROUND

1. The International Consultative Group on Food Irradiation (ICGFI) was established on 9 May 1984 under the aegis of FAO, IAEA and WHO. ICGFI is composed of experts and other representatives designated by their member governments, which have accepted the terms of the declaration establishing ICGFI.
2. As of November 2001, the following countries are members of ICGFI: Argentina, Australia, Bangladesh, Belgium, Brazil, Bulgaria, Canada, Chile, Costa Rica, Cote d'Ivoire, Croatia, Cuba, Czech Republic, Ecuador, Egypt, France, Germany, Ghana, Greece, Hungary, India, Indonesia, Iraq, Israel, Italy, Libya, Republic of Korea, Malaysia, Mexico, Morocco, Netherlands, New Zealand, Pakistan, Peoples Republic of China, Peru, Philippines, Poland, Portugal, South Africa, Syrian Arab Republic, Thailand, Tunisia, Turkey, Ukraine, United Kingdom, United States of America, Vietnam and Yugoslavia.
3. It is becoming widely recognised that irradiation is beginning to play an important role as a sanitary and phytosanitary treatment for international trade in food and agricultural commodities. In December 2000 in Sydney, Australia and July 2001 in Rio de Janeiro, Brazil, workshops on Certification of Irradiation as a Sanitary and Phytosanitary treatment for food and agricultural commodities were held either in co-operation with or under ICGFI auspices.
4. The outcome of these workshops was agreement of the criteria needed for the certification of irradiated foods for international trade, and the described principles and guidelines for the preparation and issuance of certificates for irradiated foods. The guidelines encompass certification for all applications of food irradiation (e.g reduction of foodborne pathogens, sprout inhibition, delay of ripening, shelf life enhancement and insect disinfestation) except applications of irradiation for phytosanitary purposes, which are covered by another certificate issued under the procedures of the International Plant Protection Convention (IPPC).

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5. Recognising the existence of the *Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates*, adopted by the last Session of the Codex Alimentarius Commission, Geneva, Switzerland, July 2001, ICGFI revised its guidelines and model certificate to comply with the Codex Guidelines as requested by ICGFI members at its 18th Meeting held at FAO, Rome 21-23 October 2001.

6. At the Rome meeting, the Codex Secretariat representative suggested "the ICGFI work related to the certification of irradiated food could be presented as a matter of interest to the forthcoming 10th Session of the CCFICS under its agenda item concerning other business". ICGFI therefore prepared this discussion paper accordingly, for the consideration of delegates attending the Committee of Food Import and Export Inspection and Certification Systems (CCFISC) meeting.

ISSUES FOR INTERNATIONAL TRADE IN IRRADIATED FOOD

7. The World Health Organisation (WHO) has endorsed the safety and wholesomeness of irradiated food and encouraged its appropriate use as a sanitary treatment of food for various applications;

- Irradiation is a useful technology for the reduction of pathogens of public health significance as part of overall GMP and HACCP.
- It also has other useful applications of significance to the food trade, such as delay of ripening and insect control.

8. Irradiation as a food process is increasingly recognised by a number of countries as a method of meeting strict sanitary and phytosanitary regulations in food trade. Global production of irradiated foods, while small in volume has increased steadily in the past five years. Over 30 countries are producing one or more irradiated foods, mainly for their own requirements, including meat, poultry, seafood, fresh fruits and vegetables and spices. The total volume of irradiated foods produced in different countries in 2000 exceeded 300,000 metric tonnes and the production trends are increasing.

9. North and South American, Asian, Oceania and the ASEAN countries have recently experienced a large increase in food irradiation activities and approvals of commercial irradiation facilities due to various factors, including the increasing awareness of health risks from the consumption of food of animal and plant origin, especially those consumed raw or minimally processed. These countries are interested in using irradiation for treating food both for domestic and international trade. The total volume of irradiated food produced in different countries in 2000 exceeded 300,000 metric tonnes and the production trend is increasing.

10. Certification systems for irradiated foods will help and assist the facilitation of trade in these commodities. However, it is recognised internationally that certificates should only be required where declarations are necessary relating to product safety or suitability for consumption or to otherwise facilitate fair trade.

CONCLUSION

11. The *Draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates* sets a broad framework for the format of official certificates. It is hoped that the specific example offered of the ICGFI guidelines and model certificate for trade in irradiated foods will enable such a certificate to be used by importing countries for international trade and result in a consistent approach to certification and improved trade for this type of foods.

GUIDELINES FOR THE CERTIFICATION OF FOODS IRRADIATED OTHER THAN FOR PHYTOSANITARY PURPOSES

SECTION 1: PREAMBLE

1. These guidelines recognise that importing country authorities may as a condition of clearance of consignments require importers to present certification issued by, or with the authority of, exporting country authorities. These guidelines do not mandate a need to use such certification or in any way diminish the trade facilitatory role of commercial or other types of certificates, including third party certificates, not issued by, or with the authority of, exporting country authorities. These guidelines are based on the presumption that the commercial parties engaged in international trade in food are responsible for complying with the regulatory requirements of the exporting and importing country.

SECTION 2: SCOPE

2. These guidelines concern the design and use of official and officially recognised certificates that attest to attributes of foods treated by irradiation presented for international trade. Hereafter, in these guidelines, the term "certificates" means official and officially recognised certificates.
3. These guidelines do not deal with matters of animal or plant health unless directly related to food quality or safety. However it is recognised that a single certificate may contain information relevant to several matters.
4. These guidelines are equally applicable to the use of paper or electronic forms of certification.

SECTION 3: OBJECTIVES

5. These guidelines provide criteria for the certification of irradiated foods produced, handled and processed in according to relevant Codex Codes of Practice/GMP, and subject to proper irradiation treatment based on procedures of the Codex General Standard for Irradiated Foods and the relevant guidelines and recommendations of the International Consultative Group on Food Irradiation (ICGFI).
6. These guidelines aim to assist national food control authorities or other competent certifying organisations with the preparation and issuance of certificates for irradiated foods. A model certificate is attached to the guidelines for reference (Appendix 1)
7. Certificates are issued to indicate that consignments of irradiated foods or food products meet the regulatory requirements of the importing country and are in conformity with a certifying statement based on that contained in the attached model certificate. Certificates should contain a clear reference to any requirements to which the certified product is required to perform.

SECTION 4: DEFINITIONS

Certificates are those paper or electronic documents which describe and attest to attributes of consignments of food moving in international trade.

Certification is the procedure by which official certification bodies or officially recognised certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

Certifying bodies are official certification bodies and officially recognised certification bodies.

Certifying officers are employees of certifying bodies authorised to complete and issue certificates.

Commodities are a type of food or food product being moved for trade or other purposes.

Consignment is the quantity of food or food products being moved from one country or another and covered by a single certificate.

Consignment in transit is a consignment that passes through a country without being imported, and without being exposed to conditions that increase the risk of contamination from biological, chemical or physical hazards. The consignment may not be split up, combined with other consignments or have its packaging changed.

Country of Origin is the country where the food or food products originate and /or are processed.

Food or food products are any commodities of animal or plant origin such as meats, poultry, eggs, fishery products; fruits and vegetables, including seeds, sprouts and juices; dried species and vegetables seasonings, dried fruits, nuts and grains.

Foodborn pathogen is any organism carried on or by a food product that can result in human disease. They include but are not limited to bacteria, protozoa and other parasites and fungi.

Gray (Gy) is the SI unit of ionizing radiation absorbed by an irradiated product. (eg usually measure in 1000's, ie 1.0 Kilogray (1 kGy))

Import permits are official documents authorising importation of a commodity in accordance with specified regulations.

Inspection (at the port of entry) official examination of irradiated food products including their packaging integrity and the accompanying certification to determining compliance with regulations.

Ionizing radiation is any type of radiation consisting of charged particles (such as electrons) or photons (such as gamma or x-rays) or both, that as a result of physical interaction create ions by either primary or secondary processes.

Irradiation source are gamma rays from the radionuclides Cobalt 60 or Cesium 137, X-rays generated from machine sources operated at or below an energy of 5 million electron volts (MeV), and electrons generated from machine sources operated at or below an energy of 10 MeV.

Irradiation purpose is the intended objective of an irradiation treatment of the food or food product (eg, reduction of foodborn pathogens of public health significance, insect disinfestation, sprout inhibition, delay of ripening, shelf life enhancement.)

Min/Max absorbed dose indicates the minimum absorbed dose and the maximum absorbed dose received in kGy's in a particular lot or batch of food or food product verified using proper dosimetric measurement practices in accordance with internationally accepted standards such as those published by ASTM or similar standards organisations.

Megaelectronvolt (MeV) is one million electronvolts

Official certificates are certificates issued by an official certification body of an exporting country, in accordance with the requirements of an importing country or exporting country.

Officially recognised certificates are certificates issued by an officially recognised certification body of an exporting country, in accordance with the conditions of that recognition and in accordance with the requirements of an importing or exporting country.

Sanitary requirements are officially prescribed conditions to be met in order to prevent the introduction and/or spread of pathogenic organisms. Sanitary requirements should be specified in advance by the certifying bodies of importing countries in legislation, regulations, or elsewhere (eg import permits and bilateral agreements and arrangements).

Scheduled process is a written procedure that is used to ensure that the absorbed dose range and other irradiation conditions (eg product temperatures) are adequate under commercial processing conditions to achieve the intended effect on a specific product in a specific facility. The procedure should also address disposition of improperly irradiated food product and corrective actions to be taken if the irradiation process is not adequately controlled.

SECTION 5: PRINCIPLES

8. Irradiation certificates are only required where declarations are necessary to provide information about product safety or suitability for consumption, or to otherwise facilitate fair trade. Multiple or redundant certificates should be avoided to the extent possible. The rationale and requirements for certification should be communicated in a transparent way and consistently implemented in a non-discriminatory manner.

SECTION 6: IRRADIATION CERTIFICATE CRITERIA

9. Each certificate should contain a declaration by the official, or officially recognised certification body which relates to the consignment described on that certificate. The certificate should clearly identify the certifying body with its letterhead and/or logo.
10. Each certificate has a unique identification number and should be presented in an unambiguous style in a language, or language fully understood by the certifying officers and the receiving authority. A record of unique identification numbers assigned to certificates should be maintained by the competent authority and be able to be related to the distribution of the certificates.
11. When the certificates are presented as a paper document, the original certificate should be uniquely identifiable and be printed with at least one copy for the use of the certifying body and retention by that body. Further copies may be officially printed copies or photocopies. In all cases the status of the certificate should be clear, for example, marked "original" or "copy" as appropriate.
12. Certificates should be designed to minimise the risk of fraud (for example, use of watermark paper or other security measures for paper certificates; use of secure lines and systems of electronic certificates.)
13. Where certificates are produced in physical form, they should occupy one sheet of paper, or where more than one page is required, in such a form that any two pages are part of an integrated whole and indivisible sheet of paper. Where this is not possible, each individual sheet should be separately initialled by the certifying officer and /or numbered so as to indicate it is a particular page in a finite sequence (for example page 2 of 4 pages) and should contain the unique identification number for that certificate.
14. The certificate should clearly describe the commodity and consignment to which it uniquely relates.
15. Certificates should contain a clear reference to any requirements to which the certified product is required to conform.
16. Certificates should be issued prior to the consignment, to which to certificate relates, leaving the control of the certifying body. Certificates may be issued while consignments are in transit to the country of destination only when appropriate systems of control are agreed by the competent authorities of the importing and exporting countries.
17. The use of electronic means for the issue or transfer of certificates should be accepted where the integrity of the certification system has been assured to the satisfaction of the relevant authorities of both the importing and export countries. A hard copy of an electronic certificate should be made available by the issuing authority on request of the importing country authorities. When electronic certificates are used, the importing country inspectors should have electronic access to the certification details.

RESPONSIBILITIES OF THE CERTIFYING BODY

18. The certifying body should be designated and adequately empowered by national legislation or regulation in a transparent manner to provide the particular attestation's required in a certificate or officially recognised certificate. Such designations/empowerment should be recognised as sufficient by governments, alleviating requirements for further identity or authority.
19. The certifying bodies should ensure that their procedures allow for the use of the certificate in a timely manner so as to avoid unnecessary disruptions to trade.
20. The certifying bodies should have in place an effective system, to the extent practicable, that eliminates any fraudulent use of official and officially recognised certificates.

21. The certifying body should ensure that the irradiation facility is suitable to irradiate food and food products in a proper and sanitary manner and that proper handling and process controls are practiced.
22. The certifying bodies should refer to the relevant Codex Codes of Hygienic Practice and Codex General Standard for Irradiated Foods and its associated Codes of Practice and other relevant documents. (See References section)

RESPONSIBILITIES OF THE CERTIFYING OFFICERS

23. Information and guidance notes to facilitate the correct completion of certificates should be available to all certifying officers and to the parties responsible for providing details for inclusion in a certificate.
24. The certifying officers should:
 - be appropriately designated by the certifying body;
 - have no conflict of interest in the commercial aspects of the consignment and be independent from the commercial parties;
 - be fully conversant with the requirements to which they are attesting;
 - have access to a copy of regulations or requirements that are referred to on the certificate or clear information and guidance notes issued by the competent authority explaining the criteria that the product must meet before being certified;
 - only certify matters which are within their own knowledge (or which have been separately attested to be another competent party); and
 - only certify in respect of the circumstance known at the time of signing the document including conformity with production requirements and any other specified requirements between the completion of production and the date of certification.

INSTRUCTIONS FOR COMPLETING PAPER CERTIFICATES

25. Certificates should always be issued and presented, to the exporter or their agent, as the original certificate (ie, this is an original printed paper form of the original certificate, issued once only.)
26. A copy of the original certificate (clearly marked as such) should be kept by the certifying body in the exporting country and provided to the competent authority in the importing country, on request.
27. When signing the paper certificate, the officer should ensure that;
 - The certificate contains no deletions other than those required by the text of the certificate;
 - Any alterations of the certified information are initialled and as required by the importing country, stamped by the certifying officer using the official stamp of the certifying body; when the certificate occupies more than one sheet of paper, each individual sheet is separately initiated by the certifying officer and numbered with the respective unique certificate number;
 - The certificate bears his/her signature, his/her name and official position of the certifying officer in clear lettering and where appropriate, his/her qualifications;
 - The certificate bears the date expressed unambiguously on which the certificate was signed and issued and, where appropriate, the time for which the certificate will remain valid;
 - After signature by the certifying officer, no portion of the certificate is left blank in a manner that will allow it to be amended.

INSTRUCTIONS FOR COMPLETING ELECTRONIC CERTIFICATES

28. The exporter or their agent should be notified when an electronic certificate has been authorised for a consignment.
29. Before authorising an electronic certificate, the certifying officer should ensure that all steps and checks established for the secure operation of the electronic system have been satisfactorily completed.

REPLACEMENT CERTIFICATES

30. Where, for any good and sufficient reason (such as loss or damage to the certificate in transit) a replacement certificate is issued by the certifying officer, it must be clearly marked "REPLACEMENT" before being issued. A replacement certificate should reference the number of the original certificate that it supersedes.

REVOCAION OF A CERTIFICATE

31. When, for good and sufficient reason, there is cause to revoke a certificate, the certifying authority should revoke the original certificate as soon as possible and notify the exporter or their agent in hard copy or by electronic means of the revocation. The notice should reference the number of the original certificate to which the revocation refers and provide all particulars regarding the consignment and the reasons(s) for the revocation. A copy of the revocation should be provided to the appropriate food control authority of the importing country if the export of the consignment has occurred.

DETAILS OF THE CONSIGNMENT

32. The details of the product being certified should be clearly documented on the certificate;
 - certificate identification number(a unique serial number allowing trace back)
 - name of the certifying body;
 - nature of the food;
 - name of the product;
 - quantity, in the appropriate units;
 - lot identifier or date coding;
 - identify, and as appropriate the location of the production establishment;
 - name and contact details of the importer or consignee;
 - name and contact details of the exporter or consignor;
 - country of dispatch;
 - country of destination.
33. Certificates may also contain details on relevant transport and handling requirements, including appropriate temperature controls.

ATTESTATIONS (GENERAL)

34. The particular attestation's included in a certificate will be determined by the requirements of the importing or exporting country. They should be clearly identified in the text of the certificate. Such attestation's include, but are not limited to;
 - Health status as it may effect the safety of the food;
 - Product conformity with particular standards, production or processing requirements;
 - The status (eg licensing details) or production, processing and/or packaging establishments in the exporting country; and
 - Reference to any associated bilateral/multilateral agreement.

ATTESTATIONS (IRRADIATION SPECIFIC)

- Name and address of the irradiation facility;
- Date of irradiation
- Irradiation source (see under definitions);

- Absorbed dose (see under definitions);
- Purpose of irradiation;
- Other relevant irradiation conditions;
- Additional information.

REFERENCES**Codex Alimentarius Commission Recommended International Codes of Practice**

STAN 1 -1985. *Codex General Standard for the Labelling of Prepackaged Foods*

STAN 106-1983. *Codex General Standard for Irradiated Foods*

CAC/RCP 1-1969. *Recommended International Code of Practice- General Principles of Food Hygiene*

CAC/RCP 3-1969. *Recommended International Code of Hygienic Practice for Dried Fruits*

CAC/RCP 5-1971. *Recommended International Code of Hygienic Practice for Dehydrated Fruits and Vegetables Including Edible Fungi*

CAC/RCP 6-1972. *Recommended International Code of Hygienic Practice for Tree Nuts*

CAC/RCP 8-1976. *Recommended International Code of Hygienic Practice for the Processing and Handling of Quick Frozen food*

CAC/RCP 9-1976. *Recommended International Code of Practice for Fresh Fish*

CAC/RCP 11-1976. *Recommended International Code of Hygienic Practice for Fresh Meat*

CAC/RCP 13-1976. Rev.1 (1985) *Recommended International Code of Hygienic Practice for Processed Meat and Poultry Products*

CAC/RCP 14-1976. *Recommended International Code of Hygienic Practice for Poultry Processing*

CAC/RCP 15-1976. *Recommended International Code of Hygienic Practices for Egg Products*

CAC/RCP 16-1978. *Recommended International Code of Practice for Frozen Fish*

CAC/RCP 17-1978. *Recommended International Code of Practice for Shrimps and Prawns*

CAC/RCP 18-1978. *Recommended International Code of Hygienic Practice for Molluscan Shellfish*

CAC/RCP 19-1979. (Rev.1) *Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods*

CAC/RCP 24-1979. *Recommended International Code of Practice for Lobsters*

CAC/RCP 25-1979. *Recommended International Code of Practice for Smoked Fish*

CAC/RCP 26-1979. *Recommended International Code of Practice for Salted Fish*

CAC/RCP 27-1983. *Recommended International Code of Practice for Minced Fish Prepared by Mechanical Separation*

CAC/RCP 28-1983. *Recommended International Code of Practice for Crabs*

CAC/RCP 30-1983. *Recommended International Code of Hygienic Practice for the Processing of Frog Legs*

CAC/RCP 32-1983. *Recommended International Code of Practice for the Production, Storage and Composition of Mechanically Separated Meat and Poultry Meat Intended for Further Processing*

CAC/RCP 37-1989. *Recommended International Code of Practice for Cephalopods*

CAC/RCP 42-1995. *Recommended International Code of Hygienic Practice for Spices and Dried Aromatic Plants*

CAC/RCP 44-1985. *Recommended International Code of Practice for Packaging and Transportation of Tropical Fresh Fruits and Vegetables*

ALINORM 01/03A Appendix II

Draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates (Step 8)

13. ASTM Standards

E1204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

E1261 Guide for the Selection and Calibration of Dosimetry Systems for Radiation Processing

E1431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing

E1539 Guide for the Use of Radiation Sensitive Indicators

F1556 Guide for Irradiation of Fresh and Frozen Red Meat and Poultry to Control Pathogens and Other Microorganisms

F1416 Guide for the Selection of Time-Temperature Indicators

F1640 Guide for Packaging Materials for Foods to be Irradiated

F1736 Guide for Irradiation of Finfish and Shellfish to Control Pathogens and Spoilage Microorganisms

F1885 Guide for Irradiation of Dried Spices, Herbs and Vegetable Seasonings to Control Pathogens and Other Microorganisms

14. ICGFI Documents

International Inventory of Authorised Food Irradiation Facilities (ICGFI Document No. 2)

Code of Good Irradiation Practice for Insect Disinfestation of Cereal Grains

(ICGFI Document No.3)

Code of Good Irradiation Practice for Prepackaged Meat and Poultry

(ICGFI Document No.4)

Code of Good Irradiation Practice for the Control of Pathogens and Other Microflora in Spices, Herbs and Other Vegetable Seasonings (ICGFI Document No.5)

Code of Good Irradiation Practice for Shelf Life Extension of Bananas, Mangoes and Papayas (ICGFI Document No.6)

Code of Good Irradiation Practice for Sprout Inhibition of Bulb and Tuber Crops

(ICGFI Document No.8)

Code of Good Irradiation Practice for Insect Disinfestation of Dried Fish and Salted and Dried Fish (ICGFI Document No.9)

Code of Good Irradiation Practice for the Control of Microflora in Fish, Froglegs and Shrimps (ICGFI Document No.10)

Code of Good Irradiation Practice for Dried Fruits and Tree Nuts

(ICGFI Document No.20)

15. International Organisation for Standardisation (ISO)

International Standard ISO 9004 Quality Management and Quality System Elements- Guidelines