

codex alimentarius commission



FOOD AND AGRICULTURE
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JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 10(a)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-fifth Session

Arusha, Tanzania, 17 - 21 March 2003

DRAFT REVISED CODEX GENERAL STANDARD FOR IRRADIATED FOODS

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 1 January 2003** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl, with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org).

BACKGROUND

1. The 34th Session of the Codex Committee on Food Additives and Contaminants requested a drafting group led by the Philippines to revise the Codex General Standard for Irradiated Foods based on the written comments submitted and the Committee's discussions for circulation, additional comment and further consideration at its next meeting (ALINORM 03/12, para. 81).

SUMMARY OF MAJOR AND MINOR ISSUES FOR THE DRAFTING COMMITTEE IN REVISING THE DRAFT CODEX GENERAL STANDARD FOR IRRADIATED FOODS

A) Section 2.2, Absorbed Dose

2. The recommendation made to the 34th CCFAC was to delete the upper dose limit for the overall average absorbed dose of a food at 10 kGy based on the report of a Joint FAO, IAEA and WHO Study Group (1999) on the wholesomeness of foods irradiated above 10 kGy. At the 34th CCFAC, some countries recommended that a decision on this matter be postponed until the EC Scientific Committee on Foods had provided an opinion on the implications to human health of the results of an EC-funded study on the toxicological effects of pure compounds of 2 alkyl cyclobutanones (2-ACB's), specifically 2-dodecylcyclobutanone, which is found in irradiated fat containing foods.

3. The EC Scientific Committee on Foods commented on the above studies on July 3, 2002. In a final statement they stated that "as the adverse effects noted refer almost entirely to *in vitro* studies, it is not appropriate, on the basis of these results, to make a risk assessment for human health associated with the consumption of 2-ACB's present in irradiated fat-containing foods." The Committee also stated that "reassurance as to the safety of irradiated fat-containing foods can be based on the large number of feeding studies carried out with irradiated foods which formed the basis for the wholesomeness assessments of irradiated foods published hitherto by WHO/FAO/IAEA" (WHO Technical Report Series No. 659).

4. The WHO recently issued a statement to the 19th Meeting of the International Consultative Group on Food Irradiation (ICGFI), a body of government-designated experts on food irradiation operating under the aegis of the FAO/WHO/IAEA on November 11-14, 2002 in Vienna, that “In view of the growing body of evidence, including negative Ames tests with 2-dodecylcyclobutanone, that these compounds pose no health risk to consumers, WHO has no basis to question the conclusions of several Joint FAO/IAEA/WHO expert groups as well as many national expert advisory bodies that irradiated foods are safe and nutritionally adequate.”

5. Countries in the drafting group that continue to recommend the deletion of the 10 kGy limit on the basis of the scientific evidence and technological need based on the requirements of some country regulations, are Australia, the Philippines, Thailand, the United States and the International Consultative Group on Food Irradiation (ICGFI). On the other hand, Japan, Korea, UK and the Netherlands for the same reasons as the EC, and Consumers International, continue to disagree with the deletion of the 10 kGy limit on the basis of the lack of or weak evidence of technological need, current non-use of doses above 10 kGy, consumer perceptions and the need for more complementary studies on 2 ACB's.

6. The new text in Section 2.2 is recommended to achieve compromise on this issue.

B) Section 4.1, General Requirements.

- Members of the drafting committee were divided on the use of the term “technological need” vs “technical objective” in this paragraph. The term “technological requirement” is proposed as a compromise as it could be perceived as less restrictive than “technological need” in the application of the technology.
- There was also objection to the use of the statement “of benefit to consumers” as it opens the door to trade disagreements based on the existence or lack of consumer benefits perceived differently between countries. As Codex standards are expected to specifically protect consumer health, a compromise phrase to define the expected consumer benefit (i.e that of health protection) is recommended.

C) Issues which were recommended by one member of the drafting committee but which were not included in the proposed new text for the reasons indicated below:

- Objection to the use of the term “overall average dose” in Section 2.2 as it has little value in assessing the absorbed dose delivered to the product. This is true and is also the reason why the 10 kGy limit as “overall average dose” absorbed should be deleted. However as consensus could not be obtained on the deletion, the statement as originally contained in the standard has to remain.
- Inclusion of a footnote on measures to prevent the contamination of food by radioactivity in the use of Cs 137 as a radiation source. There is likely no need for this as the Joint FAO/IAEA Division on Food and Agriculture of the IAEA as Secretariat to ICGFI, provided information that there should be no apprehensions that Cesium-137 is difficult to handle. Cesium chloride pellets are doubly encapsulated in stainless steel and absorbed into an appropriate configuration such as a plaque or cylinder made up of pencils or rods of the radionuclide pellets.

7. Keeping the 10 kGy limit in Section 5.3 on RE-IRRADIATION, as dependency on re irradiation may result in an increase in microbiological risk. This may not appear necessary as changes in bacterial flora of dry products at low doses, as that required for insect disinfestation or other applications for which re-irradiation will be necessary, would be minimal as these low doses have little effect on microorganisms.

DRAFT REVISED CODEX GENERAL STANDARD FOR IRRADIATED FOODS

1. SCOPE

This standard applies to foods processed by ionizing radiation that is used in conjunction with applicable hygienic codes, food standards and transportation codes. It does not apply to foods exposed to doses imparted by measuring instruments used for inspection purposes

2. GENERAL REQUIREMENTS FOR THE PROCESS

2.1 Radiation Sources

The following types of ionizing radiation may be used:

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

2.2 Absorbed Dose

For the irradiation of any food, 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 wholesomeness or would adversely affect structural integrity, functional properties, or sensory attributes.¹ In any case, the overall average dose absorbed by a food should not exceed 10 kGy except for dried aromatic herbs, vegetable seasonings and spices which require a maximum dose of 30 kGy. It is recognized that high dose irradiation has no effect on product safety. ¹

2.3 Facilities and Control of the Process

2.3.1 Radiation treatment of foods should be carried out in facilities licensed and registered for this purpose by the competent authority.

2.3.2 The facilities shall be designed to meet the requirements of safety, efficacy and good hygienic practices of food processing.

2.3.3 The facilities should be staffed by adequate, trained and competent personnel.

2.3.4 Control of the process within the facility should include the keeping of adequate records including quantitative dosimetry.

2.3.5 Facilities and records should be open to inspection by appropriate authorities.

2.3.6 Control should be carried out in accordance with the Recommended International Code of Practice for Radiation Processing of Foods (CAC/RCP 19-1979, **under revision**).

1.High Dose Irradiation: Wholesomeness of Food Irradiated with Doses above 10kGy, Report of a Joint FAO/IAEA/WHO Study Group, Technical Report Series 890 WHO, Geneva, 1999; Safety and Nutritional Adequacy of Irradiated Foods, WHO, Geneva, 1994; and Wholesomeness of Irradiated Food, Report of Joint FAO/IAEA WHO Expert Committee, Technical Report Series 659, WHO, Geneva, 1981.

3. HYGIENE OF IRRADIATED FOODS

3.1 The irradiated food should be prepared, processed, and transported hygienically in accordance with the provisions of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.3-1997), including the application of the seven principles of Hazard Analysis and Critical Control Point (HACCP) system where applicable for food safety purposes. Where appropriate, the technical requirements for the raw materials and end product should comply with applicable hygienic codes, food standards, and transportation codes.

3.2 Any relevant national public health requirement affecting microbiological safety and nutritional adequacy applicable in the country in which the food is sold should be observed.

4. TECHNOLOGICAL REQUIREMENTS

4.1 General Requirement

The irradiation of food is justified only when it fulfils a technological requirement and/or is beneficial for the protection of consumer health. It should not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices.

4.2 Food Quality and Packaging Requirements

The doses applied shall be commensurate with the technological and public health purposes to be achieved and shall be in accordance with good radiation processing practice. Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this purpose and shall be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the technology of the process.

5. RE-IRRADIATION

5.1 Except for foods with low moisture content (cereals, pulses, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect reinfestation, foods irradiated in accordance with Sections 2 and 4 of this standard should not be re-irradiated.

5.2 For the purpose of this standard, food is not considered as having been re-irradiated when: (a) the irradiated food is prepared from materials which have been irradiated at low dose levels for purposes other than food safety, e.g. quarantine control, prevention of sprouting of roots and tubers; (b) the food, containing less than 5% of irradiated ingredient, is irradiated; or when (c) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one increment as part of processing for a specific technological purpose.

5.3 The cumulative overall average dose absorbed should not exceed 10 kGy as a result of re-irradiation except for dried aromatic herbs, vegetable seasonings and spices which require a maximum dose of 30 kGy.

6. LABELLING

6.1 Inventory Control

For irradiated foods, whether prepackaged or not, the relevant shipping documents shall give appropriate information to identify the registered facility which has irradiated the food, the date(s) of treatment and lot identification.

6.2 Prepackaged Foods Intended for Direct Consumption

The labelling of prepackaged irradiated foods should indicate the treatment and in all aspects should be in accordance with the relevant provisions of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev.2-1999).

6.3 Foods in Bulk Containers

The declaration of the fact of irradiation should be made clear on the relevant shipping documents. In case of products sold in bulk to the ultimate consumer, the international logo and the words “irradiated” or “treated with ionizing radiation” should appear together with the name of the product on the container in which products are placed.

6.4 Post Irradiation Verification

When required and where applicable, analytical methods for the detection of irradiated foods may be used to enforce authorization and labeling requirements. The analytical methods used should be those adopted by the Codex Commission.