codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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TO: - Codex Contact Points
- Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy.

SUBJECT: **Proposed Draft Revised General Standard for Irradiated Foods at Step 3**

DEADLINE: **15 JANUARY 2000**

COMMENTS:

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1. The 31st Session of the Committee on Food Additives and Contaminants noted that the Joint FAO/WHO/IAEA Study Group on High Dose Irradiation had considered the wholesomeness of food irradiated with doses above 10 kGy, the current limit in the Codex General Standard for Irradiated Foods (CODEX STAN 106-1983), and had concluded that food irradiated to any dose appropriate to achieve the technological objective was both safe and nutritionally adequate. In view of this recommendation, the Committee considered the need for a revision of the current Standard. As there was general support for the revision, the Committee agreed to propose the revision of the General Standard as new work (ALINORM 99/12A, paras. 6-7). The 23rd Session of the Codex Alimentarius Commission approved the revision as new work (ALINORM 99/37, para. 210 and Appendix VIII). The final report *High-Dose Irradiation: Wholesomeness of Food Irradiated with Doses above 10k Gy* is available on the WHO website (http://www.who.int/fsf/high1.pdf). The section including the conclusions of the report is attached as Annex 1 for ease of reference.

2. The 16th Meeting of the FAO/IAEA/WHO International Consultative Group on Food Irradiation (ICGFI) (Antalya, Turkey, 25-27 October 1999) considered this question and proposed an amended wording for inclusion in the Standard, reflecting the conclusions of the Study Group. This amendment has been incorporated into the attached Proposed Draft Revised General Standard for Irradiated Foods, which is hereby circulated at Step 3 for government comments.

3. The ICGFI Meeting also noted that the revision of the standard might entail an amendment of the current *Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods* (CAC/RCP 19-1979) which refers to the absorbed dose and provides specific examples for several commodities in the Annexes. The Committee is therefore invited to consider the opportunity of revising the Code in the light of the revision of the Standard.

4. Governments and international organizations wishing to submit comments on the Proposed Draft at Step 3 should do so in writing to the above addresses **before 15 January 2000.**

PROPOSED DRAFT REVISED GENERAL STANDARD FOR IRRADIATED FOODS
(At Step 3 of the Procedure)

1. SCOPE

This standard applies to foods processed by irradiation. 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

~~The overall average dose absorbed by a food subjected to radiation processing should not exceed 10 kGy~~[1] [2].

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 adversely affect functional properties or compromise sensory attributes[3]

2.3 Facilities and Control of the Process

2.3.1 Radiation treatment of foods shall be carried out in facilities licensed and registered for this purpose by the competent national 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 shall be staffed by adequate, trained and competent personnel.

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

2.3.5 Premises and records shall be open to inspection by appropriate national authorities.

2.3.6 Control should be carried out in accordance with the Recommended International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods (CAC/RCP 19-1979, Rev. 1).

3. HYGIENE OF IRRADIATED FOODS

3.1 The food should comply with the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3- 1997).

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[1] ~~For measurement and calculation of overall average dose absorbed, see Annex A of the Recommended International Code of Practice for the Operation of Radiation Facilities Used for Treatment of Foods (CAC/RCP 19-1979, Rev. 1)~~

[2] ~~The wholesomeness of foods, irradiated so as to have absorbed an overall average dose of up to 10 kGy, is not impaired. In this context the term "wholesomeness" refers to safety for consumption of irradiated foods from the toxicological point of view. The irradiation of foods up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems (Wholesomeness of Irradiated Foods, Report of a Joint FAO/IAEA/WHO Expert Committee, Technical Report Series 659, WHO, Geneva, 1981).~~

[3] **Foods irradiated in accordance with good manufacturing practice are wholesome in that they are safe to consume and nutritionally adequate (*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 a Joint FAO/IAEA/WHO Expert Committee, Technical Report Series 659, WHO, Geneva, 1981)**

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 Conditions for Irradiation

The irradiation of food is justified only when it fulfils a technological need or where it serves a food hygiene purpose[4] and should not be used as a substitute for good manufacturing 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 shall not be re-irradiated.

5.2 For the purpose of this standard food is not considered as having been re-irradiated when: (a) the food prepared from materials which have been irradiated at low dose levels, e.g., about 1 kGy, is irradiated for another technological purpose; (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 instalment 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.~~

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 shall 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 or irradiation shall be made clear on the relevant shipping documents.

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[4] The utility of the irradiation process has been demonstrated for a number of food items listed in Annex B to the Recommended International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods.

ANNEX 1

High-Dose Irradiation: Wholesomeness of Food Irradiated with Doses above 10k Gy[5]

9. Conclusions

9.1 Wholesomeness: safety and nutritional adequacy

The Study Group concluded that food irradiated to any dose appropriate to achieve the intended technological objective is both safe to consume and nutritionally adequate. This conclusion is based on extensive scientific evidence that this preservation process can be used effectively to eliminate spores of proteolytic strains of Clostridium botulinum and all spoilage microorganisms, that it does not compromise the nutritional value of the foods, and that it does not result in any toxicological hazard. Recognizing that, in practice, the doses applied to eliminate the biological hazards would be below those doses that might compromise sensory quality, the Study Group concluded that no upper dose limit need be imposed. Accordingly, irradiated foods are deemed wholesome throughout the technologically useful dose range from below 10 kGy to envisioned doses above 10 kGy.

9.2 Substantial equivalence

In assessing risk, the Study Group concluded that irradiation to high doses is essentially analogous to conventional thermal processing, such as the 161canning of low-acid foods, in that it eliminates biological hazards (i.e. pathogenic and spoilage microorganisms) from food materials intended for human consumption, but does not result in the formation of physical or chemical entities that could constitute a hazard. Abundant and convincing data indicate that high-dose irradiated foods do not contain either measurable levels of induced radioactivity or significant levels of any radiolysis products distinct from those found in unirradiated foods. The theoretical maximum levels that might be formed would be so low as to be of no toxicological consequence. Accordingly, none of the toxicological data derived from extensive animal feeding studies reveals any teratogenic, carcinogenic, mutagenic or other harmful effects that are ascribable to high-dose irradiated foods. For these reasons, the application of ``risk assessment'' in the currently accepted sense (1) is not appropriate to the toxicological assessment of foods preserved by high-dose irradiation. In this context, the concept of ``substantial equivalence'' may be more appropriate. High-dose irradiated foods are indeed as safe as food materials sterilized by thermal processing, which humans have been eating for more than a century.

9.3 Applications

The Study Group concluded that high-dose irradiation, conducted in accordance with good manufacturing practices and good irradiation practices, could be applied to several types of foods to improve their hygienic quality, to make them shelf-stable, and to produce special products. These foods are envisaged to include, but not be limited to: spices and other dry food ingredients; prepackaged precooked foods that could be stored at ambient temperature for extended periods; and sterilized meals for specific target groups (such as disaster victims, outdoor enthusiasts, and the immunocompromised). Components of all classes of foods whose sensory qualities are not compromised could be irradiated to high doses, either singly or in any combination. Packaging materials that are technically applicable and approved should be used as appropriate.

9.4 Global standardization

The Study Group concluded that appropriate steps need to be taken to establish the technological guidelines implied by these conclusions and to communicate them through Codex Alimentarius standards.

(1) In 1997, the Codex Alimentarius Commission adopted, on an interim basis, the following definition for risk assessment: ``A scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; (iv) risk characterization.''

[5] Report of a Joint FAO/IAEA/WHO Study Group, WHO Technical Report Series 890, Geneva 1999