

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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

CX/FAC 03/12-Add. 1  
February 2003

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-fifth Session

Arusha, United Republic of Tanzania, 17 - 21 March 2003

#### DRAFT REVISED CODEX GENERAL STANDARD FOR IRRADIATED FOODS COMMENTS

The following comments have been received from New Zealand, Canada, USA, ICGFI:

#### **NEW ZEALAND:**

##### **Section 2.2**

New Zealand prefers that the proposed second sentence be deleted. The reasons are that:

- The scientific advice available to CCFAC from WHO and the EC Scientific Committee on Foods is that previous recommendations by WHO Study Groups on the safety and nutritional adequacy of irradiated foods remain valid. This includes the 1999 conclusion of a WHO Study Group concerning wholesomeness at doses above 10 kGy.
- The key irradiation parameter relevant to human health is the minimum dose received by part of the food package, since this sets the microbiological performance criteria that can be achieved in any specific situation. The Codex Standard should therefore facilitate the ability of processors to meet the minimum dose required to meet microbiological objectives.
- Under some practical conditions, an overall average dose maximum of 10 kGy may place unnecessary restrictions on the ability of processors to achieve an intended benefit through failure to achieve the minimum dose requirement.
- Several countries have already assessed that a Dmax above 10kGy is prudent for herbs and spices despite the existing Codex Standard.
- Other foods and uses of irradiation may arise in future for which a maximum limit of 10 kGy is inappropriate.

##### **Section 2.3.5**

New Zealand agrees with the proposed wording

##### **Section 4.1**

New Zealand agrees with the proposed wording. “*Technological requirement*” is a less subjective term than “*technological need*”, and fits better with the context in which a Codex Standard should be placed. This context is that it must be demonstrated that even under best present GMP, situations may arise in which a

further process is required to ensure the protection of consumer health. The process should then be assessed only for its ability to achieve the level of protection required in a safe manner. Considerations such as alternative methods and existing usage are not appropriate considerations for Standard setting for relatively new commercial technologies.

### **Section 6.3**

New Zealand agrees with the proposed wording.

### **Section 6.4**

New Zealand agrees with the proposed wording.

## **CANADA:**

Canada has an established pre-clearance procedure for extended or new applications of the irradiation process. At this time, petitioners offering food irradiation submissions have not requested the use of irradiation above a total overall average absorbed dose of 10 kGy. Canada considers the adequacy of existing pertinent toxicological data when dealing with food irradiation submissions of any new food commodity or food class, irrespective of the absorbed dose involved. As such, Canada has no real objection to the proposal to delete the upper dose limit for the overall average absorbed dose of a food at 10 kGy. This should not be construed as Canada accepting foods irradiated at doses higher than 10 kGy without prior toxicological review and subsequent positive listing in the Table to Division 26 of the *Food and Drug Regulations*.

## **USA:**

The United States of America appreciates the opportunity to provide comments in response to CX/FAC 03/12 dated November 2002, on the Draft Revised Codex General Standard for Irradiated Foods for consideration at the forthcoming Thirty-fifth Session of the Codex Committee on Food Additives and Contaminants.

### **General Comments**

#### **2.2 Absorbed dose**

First, irradiation processors must ensure that the minimum absorbed dose delivered to the product is adequate to accomplish the technical objective. Processors must also ensure that the maximum dose will not damage the product or exceed any national regulatory limits. This is accomplished by using standard dosimetric procedures (see ALINORM 03/12, App. V, Code of Practice). The “overall average dose,” as used in the current standard (CX/STAN 106-1983) and defined in the current Annex, has limited practical value in assessing the absorbed dose delivered to a product and of necessity must be calculated from the direct dosimetry measurements. In addition, the proposed text for aromatic herbs, vegetable seasonings and spices sets a limitation on the *maximum dose* to which such products may be exposed, rather than an overall average dose. The use of these two different quantities to set absorbed dose limitations is confusing.

Second, the U.S. recognizes the current lack of consensus regarding this section of the revised draft standard. We also recognize that a maximum dose of 10 kGy will be adequate for most applications and, moreover, will result in an overall average dose that can only approach but never exceed 10 kGy. However, legitimate technological objectives exist for which maximum doses higher than 10 kGy are appropriate. In the U.S., for example, an absorbed dose not to exceed 30 kGy is permitted for microbial control in dried or dehydrated spices and seasonings. Also, doses higher than 10 kGy would be necessary to ensure that *C. botulinum*

spores that may be present in packaged foods can be reduced to the levels achieved using traditional thermal retorting protocols. We believe, therefore, that the standard should be sufficiently flexible to acknowledge all current legitimate applications of irradiation requiring absorbed doses above 10 kGy, as well as future applications without requiring further revision. Therefore, we propose the following for 2.2:

“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 compromise wholesomeness or would adversely affect structural integrity, functional properties, or sensory attributes. The maximum absorbed dose delivered to a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose.”

In sum, the U.S. proposes to eliminate reference to the ill-defined and impractical overall average dose, to establish a maximum dose of 10 kGy, and to acknowledge current and future legitimate technological objectives requiring deliveries of absorbed doses above 10 kGy. This proposal is consistent with the conclusions of the 1999 Joint FAO/IAEA/WHO report (Section 9.1) that “ irradiated foods are deemed wholesome throughout the technologically useful dose range from below 10 kGy to envisioned doses above 10 kGy” and that such food “is both safe to consume and nutritionally adequate.”

#### **4.1 General Requirements**

The U.S. concurs with the sense of the proposed text. However, the use of the term “technological requirement” is somewhat unclear and we recommend using the term “technological purpose.” Therefore, we recommend that the 4.1 General Requirement be further revised to read:

“The irradiation of food is justified only when it fulfils a technological purpose 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.”

#### **Section 5.3**

Consistent with the above comment on section 2.2, and noting that spices and seasonings do not necessarily require a maximum dose of 30 kGy, we recommend the following revised text:

“The cumulative maximum absorbed dose delivered to a food should not exceed 10 kGy, as a result of re-irradiation, except when it is necessary to achieve a legitimate technological purpose, such as the elimination of microbial pathogens in dried or dehydrated aromatic herbs, vegetable seasonings and spices.”

### Section 6.3

The U.S. concurs with the general sense of the proposed text. However, as currently written, this section would require both the international logo for irradiation and informative text to appear with the name of the product when sold in bulk to the ultimate consumer. We recommend that either the international logo or informative text is adequate. Therefore, we propose substituting “or” for “and” in this section. The revised section would then read:

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 or 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.

The U.S. supports all other proposed revisions contained in the draft revised Codex General Standard for Irradiated Foods, CX/FAC 03/12 dated November 2002.

### **ICGFI** (The International Consultative Group on Food Irradiation)

The International Atomic Energy Agency, Vienna, at the request of the International Consultative Group on Food Irradiation (ICGFI), established under the aegis of FAO, IAEA and WHO in 1984 and of which 29 governments are current members, is forwarding the comments of ICGFI on the above matter for the consideration of the 35<sup>th</sup> Session of the CCFAC.

#### **Subsection 2.1.(a):** agreed

The 34<sup>th</sup> Session of CCFAC agreed to amend the statement in subsection 2.1(a) to include Cesium 137 as radiation source. ICGFI agrees to this. The purpose is to retain the four types of radiation sources permitted in the existing Standard as all of them are suitable for treating foods on the grounds of their inability to induce radioactivity in the treated food as recognized in the Report of a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods, Technical Report Series 659, World Health Organization, Geneva, 1981. It is also recognized that encapsulation, handling, transport and installation of Cesium-137 source in industrial irradiation facilities is well standardised and Safety Guides have been published by the International Atomic Energy Agency. Environmental or occupational safety concerns regarding sources of ionising radiation are the responsibility of the competent national authorities for the licensing and registration of radiation facilities and sources generally.

#### **Subsection 2.2 Absorbed Dose**

The ICGFI recommends retention of the first sentence “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”.

The ICGFI recommends deletion of the second sentence “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”.

#### **Rationale:**

1. The ICGFI believes it would be useful to explain the concept and terminology of overall average dose of 10 kGy in the existing Standard (CODEX STAN 106-1983).

The terminology of ‘overall average absorbed dose of 10 kGy’ in the existing Standard (CODEX STAN 106-1983) was adopted from the conclusions of a FAO/IAEA/WHO Joint Expert Committee on the Wholesomeness of Irradiated Food (Technical Report Series 659, WHO, Geneva 1981), based on wholesomeness and safety considerations, the level at which toxicological safety has been established at that point of time.

It is the considered view of ICGFI that in practice this concept of overall average absorbed dose of 10 kGy lacks clarity and introduces ambiguity, since all foods cannot be subjected to an overall average dose of 10 kGy. For instance, there are many applications requiring much lower doses for achieving the intended technological objective such as sprout inhibition in tubers and bulbs, delay of ripening and/or maturation in

fruits and vegetables, control of insect infestation in grains, as a quarantine measure for fresh fruits and vegetables, shelf-life enhancement and elimination of foodborne pathogens and parasites in meat, poultry, sea foods and fresh produce, etc. The more important parameters are the minimum absorbed dose to ensure efficacy of the process and the maximum dose to ensure the product is not damaged.

In the case of spices, which require higher doses for microbial decontamination, an overall average dose of 10 kGy and a maximum to minimum ratio of 3:1 under commercial processing conditions implies a minimum absorbed dose of 5 kGy and a maximum absorbed dose of 15 kGy resulting in an overall average absorbed dose of 10 kGy. In products with higher naturally occurring initial microbial load, despite good agricultural practices (GAP), the required level of microbial reduction may not be achieved at these dose ranges, therefore, many countries (Argentina, Australia, New Zealand, USA) have regulations permitting maximum doses up to 30 kGy to ensure effective microbial decontamination.

2. The ICGFI proposal to remove the upper dose limit of 10 kGy in the Codex General Standard for Irradiated Foods is based on the Report of a Joint FAO/IAEA/WHO Study Group (High-Dose Irradiation: Wholesomeness of Food Irradiated with Doses above 10 kGy, Technical Report Series, WHO, Geneva 1999), which establishes the safety of foods irradiated to doses above 10 kGy.

3. The Designated Experts of Member States of ICGFI at its 19<sup>th</sup> Annual Meeting, 12-14 November 2002 reaffirmed that the safety of high dose irradiated foods, particularly the concerns regarding the safety of cyclobutanones formed in irradiated fat containing foods, has been resolved in the light of:

(i) Position Statement of WHO at the 19<sup>th</sup> ICGFI Meeting that “ In view of the growing body of evidence, including negative Ames tests with 2-DCB, 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”, and,

(ii) Statement of the European Commission Scientific Committee on Food on a report on 2-alkylcyclobutanones expressed on 3 July 2002.

4. The ICGFI wishes to make the submission that absence of international trade or no current application above the average 10 kGy dose should not be a criteria for removal of the upper dose limit of 10 kGy as contended by some countries. On the contrary ICGFI is of the firm belief that removal of the upper dose limit in the Codex General Standard would facilitate the adoption of the same by more countries in their national regulations and eventual trade in such products. This is more than exemplified by the rapid increase in the number of countries approving food irradiation following the adoption of the Codex General Standard for Irradiated Foods by the Codex Alimentarius Commission at its 13<sup>th</sup> Session in 1979, when virtually no commercial application or trade in irradiated foods existed.

5. In several countries hospital patients, in particular immuno-compromised patients are supplied with radiation-sterilized meals and meal components because of their superior sensory qualities in comparison to thermally sterilized foods. For almost 30 years NASA has been using radiation-sterilized foods for the US astronauts, while in South Africa till recently, military units, sailing enthusiasts, and mountain climbers have been consuming similar products. It can be foreseen that food industry and consumer interest in radiation-sterilized shelf stable convenience foods that could be stored for longer periods without refrigeration, and trade in such foods would grow in the near future. The removal of the upper dose limit of 10 kGy would therefore facilitate practical application and international trade.

**Sub-section 2.3.5:** agreed

**Sub-section 4.1:** agreed

The ICGFI agrees to the text. However, ICGFI recommends addition of the sentence “The range of doses needed to process a wide variety of products for various applications should be in accordance with the Codes of good irradiation practice referred to in the Recommended International Code of Practice for Radiation Processing of Foods (CAC/RCP 19-1979, **under revision**).

**Sub-section 5.3:**

The ICGFI recommends deletion of this subsection. The purpose is to be consistent with the recommended Subsection 2.2 and give effect to the findings of the FAO/IAEA/WHO Study Group on High Dose Irradiation (High Dose Irradiation: Wholesomeness of Food Irradiated with Doses Above 10 kGy, Report of a Joint FAO/IAEA/WHO Study Group, WHO Technical Report Series 890, World Health Organization, Geneva 1999). These findings remain valid.

**Sub-section 6.3:** agreed

**Sub-section 6.4:** agreed