codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 10 A **CX/FAC 02/11**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-fourth Session
Rotterdam, The Netherlands, 11-15 March 2002

DRAFT REVISED CODEX GENERAL STANDARD FOR IRRADIATED FOODS

The following comments have been received from Poland, USA, Argentina, IAEA, European Community and CI.

POLAND

Alinorm 01/12A, para. 85, Appendix VII

Add. 2.2 ***Absorbed dose***

In compliance with European Union legislation which Polish law is being harmonised with, the overall dose absorbed by a food subjected to radiation processing should not exceed 10 kGy.

Add. 5.1 ***Re-irradiation***

Poland is of an opinion that foodstuffs once processed by irradiation to required dose (which does not exceed 10 kGy) should not be irradiated once more, even foods with low moisture content (cereals, pulses, dehydrated foods and other such commodities).

Add. 6 ***Labelling***

In our opinion irradiated food whether pre-packaged or not need to be labelled in special manner. If foodstuffs intended for individual consumer and mass caterers are sold by number, the labelling should include a symbol of irradiated food and words: *"irradiated"* or *"treated with ionising radiation"*. Polish draft regulation provides that a label of irradiated foodstuffs should also contain date and number of official permission.

If foodstuffs are sold in the mass these words should be placed in the proximity of the product name on a board or in information close to the container with the product (above or next to it).

Irradiated ingredient of foodstuffs should be indicated in the manner mentioned above, notwithstanding its content in the final product.

USA

We believe that the revised draft standard reflects the discussion of the 33rd session of the CCFAC and are pleased to offer the following comments.

2.2 Absorbed Dose

The concept of "overall average dose" has little value in assessing the absorbed dose delivered to a product. The operator needs to know the maximum dose to ensure that the product is not damaged. The operator also needs to know the minimum dose to ensure efficacy. Combining these to provide an average does not provide any meaningful information and obscures the more useful parameters. Further, if the CCFAC

desires to specify absorbed-dose limits in this standard, references should be made to maximum or minimum values, as appropriate.

[5.3] – Consistent with the above comment on section 2.2, we recommend deletion of this bracketed statement.

2.3.5
We recommend the substitution of the term “facilities” in place of “premises” for consistency with the other sub-paragraphs of 2.3.

4.1 General Requirement
The purpose of the Codex Alimentarius is to protect the health of consumers and to ensure fair trade practices through the development of food standards and codes of practice. The Codex Alimentarius has adopted other standards and codes of practice for food processing. These include several commodity standards for frozen foods (e.g., Standard for Quick Frozen Spinach, Standard for Quick Frozen Peaches) and several codes of practice (e.g., Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods, Recommended International Code of Practice for the Processing and Handling of Quick Frozen Foods). The adopted Codex food processing standards and codes of practices are limited to provisions that protect consumer health and ensure fair trade practices. In contrast, Section 4.1 General Requirement of the revised draft standard includes a criterion that the use of a food process, such as food irradiation, must be justified on a technological need basis and on its use as “a benefit to consumers or where it serves a food hygiene purpose…"

The U.S. is concerned that the phrase "benefit to consumers" is subjective, ill defined and open to divergent interpretations. In our view, the concept of "benefit to consumers" is like beauty, which is in the eye of the beholder. Inclusion of this phrase provides an undesirable opportunity for establishment of national measures that do not advance consumer health protection, but do promote unfair trading practices.

The U.S. is also concerned that the phrase "technical need" is too restrictive and that the phrase "technical objective" is more appropriate. Technical need implies an essential requirement for which there are no alternatives but technical objectives may be accomplished in more than one way. The U.S. believes that the standard should not imply that irradiation can be applied only when there are no other alternatives. The standard should allow Codex member states to choose among several safe technologies using criteria that may vary with individual situations such as cost, feasibility, or efficacy to achieve a particular technical objective.

We agree, as stated in the paragraph, that food irradiation should never be used as a substitute for good manufacturing practices (or good agricultural practices). Therefore, we recommend that 4.1 General Requirement be revised to read:

The irradiation of food is justified only when it fulfills a technological objective or when it serves a food hygiene purpose. Food irradiation shall not be used as a substitute for good manufacturing practices or good agricultural practices.

7 Methods of Analysis and Sampling
The U.S. understands that the intent of this section is to address post-irradiation verification procedures to ensure that irradiated foods sold to consumers are properly labeled. The U.S. believes that this standard, which is a document on how to use irradiation for food processing, is not the appropriate vehicle for methods intended for enforcement of labeling provisions that are referenced in this standard (para. 6.2).

The Procedural Manual (11th ed, p. 72) states “The methods [of Analysis and Sampling] are primarily intended as international methods for the verification of provisions in Codex standards.” This standard does not contain provisions that may be subjected to verification through analytical methods and sampling. The Procedural Manual (11th ed., p. 96) also instructs

that, when methods of analysis are intended for general application to foods, the CCMAS is responsible for their elaboration and for carrying out the steps of the Procedure. Therefore, the U.S. recommends that Section 7 be deleted from the draft revised Codex General Standard for Irradiated Foods. Additionally, the U.S. believes it is appropriate for the CCFAC to request that CCMAS consider as new work the elaboration of methods of analysis for determining compliance with labeling provisions of this standard and those in Section 5.2 of the Codex General Standard for the Labelling of Prepackaged Foods.

ARGENTINA

English version of the Argentine comments will be sent out as soon as possible.

IAEA (INTERNATIONAL ATOMIC ENERGY AGENCY)

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 46 governments are members, is forwarding the comments of the ICGFI on the above matter adopted at its 18th Annual Meeting at the FAO Headquarters, 23-25 October 2001 for the consideration of the 34th Session of the CCFAC.

The 18th Annual Meeting of ICGFI considered the Draft Revised Codex General Standard for Irradiated Foods as adopted at Step 5 and advanced to Step 6 by the 49th (Extraordinary) Session of the Executive Committee of the Codex Alimentarius Commission and the related discussion by Member States of Codex (para 19 of the report of the 49th (Extraordinary) Session of the Executive Committee of the CAC and paras 72 – 85 of the Report of the 33rd Session of CCFAC).

The government designated experts of ICGFI reached consensus on recommended changes to the Draft Revised General Standard as follows:

Clause 1

Modify sentence 1 to read: "This standard applies to foods processed by ionising radiation that is used in conjunction with applicable hygienic codes, food standards and transportation codes". The purpose of the change is to clarify that the standard refers only to ionising radiation (and not, for example, UV or microwave radiation). It also brings to the immediate attention of the reader that the treatment must be used in conjunction with, and not be a substitute for good manufacturing practice.

Clause 2.1

Modify 2.1 (a) to read: "Gamma rays from the radionuclides ^{60}Co or ^{137}Cs". 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 product as recognized in the existing General Standard as well as 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 and the Report of a Joint FAO/IAEA/WHO Study Group on High Dose Irradiation: Wholesomeness of Food Irradiated With Doses Above 10 kGy, WHO Technical Report Series, World Health Organization, Geneva, 1999. 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.

Clause 2.2

The wording presently in brackets in draft Clause 2.2 should be deleted. The purpose is to 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.

Clauses 3 and 4

The requirement that irradiation should not be used as a substitute for good hygienic practice is clearly stated in the Draft Standard. However, there is no objection to a clear and suitable strengthening of the wording related to this requirement that Member States may wish to implement. It is agreed that irradiation must always be used in conjunction with all applicable Codes of Hygienic Practice, incorporating HACCP plans where relevant.

Clause 5.3

Delete Clause 5.3 (bracketed) concerning re-irradiation. The purpose is to be consistent with the recommended Clause 2.2.

Clause 6.1

Modify to read: "For irradiated food, whether prepackaged or not, the relevant shipping documents should give appropriate information to identify the registered facility which has irradiated the food, the date(s) and purpose of treatment, the maximum and minimum doses applied, and lot identification." The purpose is to provide more complete information within shipping documents.

Clause 7

Modify by deletion of a proposed Clause 7 and replace with a new Clause 6.4 as follows.

Clause 6.4

Add the following clause: "When required, and where applicable, analytical methods for the detection of irradiated foods may be used to enforce labelling requirements. The analytical methods used should be those adopted by the Codex Alimentarius Commission."

The purpose of the above changes is to draw attention to the use of standardised analytical methods within a system for the enforcement of labelling, where required by national authorities.

The proposal in the present Draft for a new Clause 7 on Methods of Analysis and Sampling relates solely to the capacity of competent authorities to enforce labelling requirements for the purpose of informing consumers. The best approach to regulate irradiated food moving within trade, including labelling requirements, is by a system of certification and documentation, as is recommended by Codex generally.

Where national authorities wish to verify the certification and documentation system, or to enforce labelling requirements, then there is a role for analytical methods. The 5 detection methods for irradiated food endorsed by the 23rd Session of the CCMAS and adopted by the 24th Session of the Codex Alimentarius Commission are suitable for the detection of some irradiated foods but the following points should be noted:

? As is the case for all analytical methods, the detection methods for irradiated foods have limits to their ability to detect irradiated foods. These limits may be the result of the amount of irradiated food to be detected or to the treatment that the food has received.
? The Codex General Standard for Irradiated Food and the Codex General Standard for the Labelling of Pre-packaged Food (CODEX STAN 1-1985, Rev 2-1999) require only that irradiated foods be labelled. Many national authorities place no lower limit on the amount of irradiated product in a compound food for the purpose of labelling.
? The inability of any standardised and approved detection method to detect whether a food has been irradiated in a specific situation should not be used as a trade barrier to irradiated foods.

- Many developing countries need assistance to build up the expertise and capacity to implement detection methods for irradiated food.
- Available detection methods are generally not suitable for the estimation of the absorbed dose received by foods.

Other Comment

The33rd Session of the CCFAC discussed the possible toxicity of 2-dodecylcyclobutanone. This was a reason for the retention of the bracketed clauses in clauses 2.2 and 5.3.

No scientific grounds have been established for 2-alkylcyclobutanones to be considered a public health risk. Information from a battery of tests for cytotoxicity and genotoxicity for a number of representative compounds is still undergoing review.

In this context, ICGFI would like to reproduce relevant text from the Conference Room Document, 49th Session (Extraordinary) of the CAC Executive Committee, "Comments from ICGFI on the Safety of 2-dodecylcyclobutanones".

At the XII International Meeting on Radiation Processing, 25-30 March 2001, Avignon, France, authors Henry Delincee, Christiane Soika and Erich Marchioni presented their preliminary findings of the ongoing cooperative research (Federal Research Centre for Nutrition, Karlsruhe, Germany and Faculty of Pharmacy, University of Strasbourg, France) on the safety of 2-alkylcyclobutanones in a paper titled "Genotoxicity of 2-alkylcyclobutanones, markers for an irradiation treatment in fat-containing food". In the extended abstract of their paper, the authors describe experiments performed on human colon tumor cell lines using well characterized 2- tetradecylcyclobutanone (2-TCB), a representative of the class of cyclobutanones, to test its cytotoxicity and genotoxicity using the DNA Comet assay.

The authors state, quote "A concentration-dependent damage of DNA could not be observed using the employed cell lines. Possibly would longer incubation times with 2-TCB induce DNA damage, but difficulties would then arise to discern these effects from the effects caused by cytotoxicity. The highest amount of 2-TCB tested in these experiments was 400 ?M, which corresponds to about 100 ?g/ml. If one recognizes that e.g. in chicken about 0.1 ?g 2-TCB/g lipid/kGy would be present following an irradiation treatment (Stevenson, 1996), these tested amounts of 2-TCB are very high compared with an assumed human intake", unquote.

In their conclusions the authors state that, quote "Employing human colon tumor cell lines HT 29 and HT 29 cl 19A as a model in *in vitro* experiments, neither cytotoxic nor genotoxic effects were induced by 2-TCB at an incubation time of 30 min at 37° C. After longer incubation times (1-2 days) at higher concentrations of 2-TCB (>50 ????cytotoxicity did, however, appear. Further toxicological studies with other endpoints will contribute to the knowledge about cyclobutanones", unquote. The full peer reviewed paper is yet to be published in the Proceedings

Don Thayer of the Agricultural Research Service, US Department of Agriculture has made the following calculation on the basis of the highest concentration used in the above study, which was 400 ?M. If it is assumed that the average fat content of hamburger is 20% then the person consuming ¼ pound (115g) irradiated to 2.5 kGy (the dose required for the elimination of *Escherichia coli* O157:H7 and other foodborne pathogens) would consume 0.17 ?M of cyclobutanone.

The preliminary results of the above experiments reinforce the existing scientific evidence that 2-alkylcyclobutanones do not pose an unacceptable public health risk.

No credible toxicological risk has been observed from a whole range of experiments testing the wholesomeness of many irradiated foods that must have contained amounts of 2-alkylcyclobutanones.

EUROPEAN COMMUNITY

Introduction

The proposed revision of the Codex General Standard for Irradiated Foods concerns in particular the replacement of the specific maximum overall average dose value of 10 kGy by a more general wording on minimum and maximum radiation dose. This proposal is based on results of the Joint FAO/IAEA/WHO Study Group on High Dose Irradiation of 1997 which concluded that food irradiated to any dose appropriate to achieve the intended purpose was both safe to consume and nutritionally adequate.

During the 33rd CCFAC meeting the WHO representative informed that scientific studies on cyclobutanones are being performed since concerns about their safety had been expressed. Cyclobutanones are created by irradiation of triglycerides and are the only molecules which have been so far exclusively detected in irradiated foods. The ICGFI representative informed that preliminary results of these studies were negative with regard to genotoxicity and cytotoxicity and that the studies would be completed by November 2001 (ALINORM 01/12A, para 73).

The final report of these studies has been submitted by the authors to the Scientific Committee on Food of the European Commission (SCF) in November 2001. The report indicates tumour promoting and genotoxic potential of purified cyclobutanones. The European Commission has requested the opinion of the SCF on the implications of these results concerning the wholesomeness of irradiated foods.

As long as this scientific advice is pending, the European Community considers it as prudent not to proceed with the proposed changes on the maximum dose.

Proposal

2.2 Absorbed Dose

? Delete square brackets in 1st paragraph.

? Delete footnote 1.

? Text of footnote 2 should be the text of footnote 2 of the existing Codex Standard, mentioning that the 'Code of Practice' is under revision.

? Delete 2nd paragraph.

4.1 General Requirement

? Replace by *"The irradiation of food is justified only when it fulfils a technological need and is of benefit to consumers, and it should not be used as a substitute for hygiene practices or for good manufacturing practices.***"**

5.3

? Delete square brackets.

6.2 Prepackaged Foods Intended for Direct Consumption

? The labelling of irradiated foods and food ingredients is covered by section 5.2 of the Codex Standard for the Labelling of Prepackaged Foods. The European Community interprets section 5.2.2 of this standard in this way that the irradiation of all ingredients, including ingredients of a compound ingredient present below 5%, has to be declared on the label and would like to proposed a more clear wording in this section of the Labelling Standard which will be submitted to the Codex Committee on Food Labelling:

"5.2.2 When an irradiated product is used as an ingredient in another food, this shall be declared in the list of ingredients, even if the irradiated product is an ingredient of a compound ingredient present in a compound foodstuff below 5%."

? Concerning the bracket at the end of the paragraph, we would like to make the Codex Secretariat aware about differing reference numbers in the English and French versions of the Codex Standard for the Labelling of Prepackaged Foods: English Rev. **1**-1999; French Rev. **2**-1999).

6.3 Foods in Bulk Containers

? Add after first sentence: *"In the case of products sold in bulk to the ultimate consumer the words 'irradiated' or 'treated with ionising radiation' should appear together with the name of the product on a display or notice above or beside the container in which the products are placed.*"

7 Methods of analysis and sampling

? The following text is proposed: "*When required, and where applicable, analytical methods for the detection of irradiated foods may be used to enforce labelling requirements or restrictions on irradiated foods. The analytical methods used should be those adopted by the Codex Commission.*"

Information on Standardised Methods for the Detection of Irradiated Foods

The European Community would like to inform that the European Committee for Standardisation (CEN) has recently standardised additional methods for the detection of irradiated foods. The European Community will ask CCMAS to endorse these methods as General Codex Methods. In response to the request of the Codex Commission "to give further consideration to validated methods that would be suitable for use in developing countries" (ALINORM 01/41, para 200), the European Community informs that 2 of the 3 additional methods are very easy and cheap to perform, although it is the view of the European Community that all CEN standards for the detection of irradiated foods are suitable for developed as well as developing countries.

CI (CONSUMERS INTERNATIONAL)

Consumers International would like to thank you for the opportunity to submit comments on the above named paper. We would like the following comments to be considered.

6.2 and 6.3 (of the old standard) should be combined into one paragraph.The wording might be: "The labelling of irradiated foods shall indicate the treatment, and the declaration of the fact of irradiation made clear on the relevant shipping document".

The heading of 6.2 should be: "Food intended for direct consumption".