CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6 **CX/CF 13/7/6**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Seventh Session

Moscow, Russian Federation, 8 – 12 April 2013

PROPOSED DRAFT REVISION OF GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS

Codex Members and Observers wishing to submit comments on the recommendations put forward in paragraph 27 regarding the revision of the guideline levels for radionuclides in the Standard for Contaminants and Toxins in Food and Feed including the need to provide further guidance on the interpretation / implementation of such levels should do so in writing before **29 March 2013**. Comments should be directed:	
to: Mrs Tanja Åkesson Codex Contact Point Ministry of Economic Affairs P.O. Box 20401 2500 EK The Hague The Netherlands E-mail: info@codexalimentarius.nl	with a copy to: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy E-mail: codex@fao.org

Terms of Reference

1. The 6th session of the Committee on Contaminants in Foods (CCCF), held in Maastricht (the Netherlands) from 26 - 30 March 2012, agreed to establish an electronic Working Group (eWG) led by the Netherlands and co-chaired by Japan, working in English only and open to all members and observers, to develop a Codex document on the Review of the Codex Guideline Levels for Radionuclides in Food. The eWG should review the current Guideline Levels (GLs) for radionuclides in food; and develop in connection with the review, a clear guidance on the interpretation and application of the levels.[1] The Committee noted the importance of involving the International Atomic Energy Agency (IAEA) and other relevant organizations in this work. The 35th session of the Codex Alimentarius Commission (CAC) held in Rome (Italy) from 2 - 7 July 2012 approved this proposal as new work for the Committee.[2]

2. The eWG shall present an overview of the current GLs for radionuclides in food, and describe recent situations regarding trade of food with radionuclides. The eWG shall conclude whether the current GLs need to be changed, and provide the arguments why revision is needed. In this regard the eWG should consider the feasibility to convert the GLs to MLs as indicated in footnote 2 of the General Standard for Contaminants and Toxins in Food and Feed of the Codex Alimentarius (GSCTFF). If revision is considered needed, the eWG should propose levels for comments at Step 3 and consideration by the 7th CCCF in 2013.

3. If the eWG comes to a conclusion on the need of the revision of the GLs, the eWG should answer the question whether an issue of interpretation and implementation is linked to the current values, to determine whether development of a guidance document is necessary. If such a document is necessary, the eWG should advise the CCCF if it should be a single stand-alone document or be included in the GSCTFF.

4. To comply with the request of the 6th CCCF the chairs of the Netherlands and Japan have contacted the IAEA in this regard. The IAEA assured its cooperation regarding the scientific background of the paper.

[1] REP12/CF, paras. 48-51, 169-173.
[2] REP12/CAC, paras. 143-145, 249-262 and Appendix VI.

Guideline levels versus Maximum Levels

5. In footnote 2 of the GSCTFF it is mentioned that a Codex GL is the maximum level of a substance in a food or feed commodity which is recommended by the Codex Alimentarius Commission (CAC) to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction.

6. According to the definition in the Procedural Manual, an ML is the maximum concentration of a contaminant in a food or feed commodity, recommended by the CAC to be legally permitted in that commodity. In the preamble of the GSCTFF, there is an additional sentence which says that MLs shall only be set for those foods that contribute significant for the total exposure of the consumer.

7. According to the CAC the preferred format of a Codex standard in food or feed is a ML. Existing or proposed GLs shall be reviewed for conversion to a ML after a risk assessment is performed by JECFA, if appropriate.

General Standard for Contaminants and Toxins in Food and Feed

8. The GLs for radionuclides were first proposed by the Committee on Food Additives and Contaminants (CCFAC)[3] and adopted by the Codex Alimentarius Commission in 1989. Additions were later requested, especially by the IAEA, and revised GLs were adopted by the CAC in 2006[4]. These GLs are found in Schedule I – Maximum and Guideline Levels for Contaminants and Toxins in Foods of the General Standard for Contaminants and Toxins in Food and Feed.

9. The GLs presented in the GSCTFF are for radionuclides in “infant foods” and “foods other than infant foods”. According to the text of the GSCTFF these levels apply to radionuclides in foods for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency. The levels are based on an intervention exemption level of 1 mSv in a year, assuming that a maximum of 10% of the diet consists of contaminated food.

10. The activities of each radionuclide in the same group should be added together, but each group should be treated independently.

Product name	Radionuclides	Level in Bq/kg
Infant foods	^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am	1
Infant foods	^{90}Sr, ^{106}Ru, ^{129}I, ^{131}I, ^{235}U	100
Infant foods	^{35}S, ^{60}Co, ^{89}Sr, ^{103}Ru, ^{134}Cs,^{137}Cs, ^{144}Ce, ^{192}Ir	1000
Infant foods	^{3}H, ^{14}C, ^{99}Tc	1000
Foods other than infant foods	^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am	10
Foods other than infant foods	^{90}Sr, ^{106}Ru, ^{129}I, ^{131}I, ^{235}U	100
Foods other than infant foods	^{35}S, ^{60}Co, ^{89}Sr, ^{103}Ru, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{192}Ir	1000
Foods other than infant foods	^{3}H, ^{14}C, ^{99}Tc	10000

11. In the comments it is stated that the levels do not include all radionuclides. Included are those emitted from human activities and important for food for human consumption. Radionuclides from natural origin are excluded from consideration.

12. In Annex 1 to radionuclides in the GSCTFF, the scientific justification for the GLs is given. Annex 2 describes how the human internal exposure can be assessed when the GLs are applied: how the intake of radioactivity in foods (Bq) can be converted into the internal dose in humans (mSv).

[3] ALINORM 89/12A, para. 37 and ALINORM 89/40 para. 102.
[4] ALINORM 06/29/12, para. 198, Appendix XXXI and ALINORM 06/29/41, para. 65, Appendix IV.

Japanese limits and issues of the interpretation of these limits

13. Immediately after the accident at the Tokyo Electric Power Company's Fukushima Daiichi Nuclear Power Plant on 11 March 2011, the Japanese Government set provisional regulation values by adopting the "Index relating to limits on food and drink ingestion" which had been determined by the Japanese Government in preparation for nuclear emergencies on a basis of an intervention level of 5 mSv/year.

14. On 1 April 2012, the Japanese Government adopted 1 mSv/year consistent with the current Codex GLs as an intervention exemption level, and established new limits. The limit of total radioactivity attributable to Cs-134 and Cs-137 is 100 Bq/kg for general foods, 50 Bq/kg for milk and infant foods, or 10 Bq/kg for drinking water. In comparison: the Codex GL of these two radionuclides in the GSCTFF is 1000 Bq/kg. The difference is largely due to the difference in assumed ratio of contaminated foods: while Codex targeting imported foods uses 10%; and Japan targeting domestically produced foods uses 50%.The other important cause of difference is how radionuclides other than radioactive cesium are dealt with: Japan established limits for a total of cesium-134 and cesium-137 taking into consideration a factor of 1.2 to cover other radionuclides.

15. It should be noted that the Codex GLs on Radionuclides in foods are determined by using an "Import/Production Factor (IPF)". This is the ratio of the amount of foodstuffs imported from a radionuclide-contaminated area to the total amount produced and imported. Thus, it is possible for national governments to "*adopt different values for internal use within their own territories where the assumptions concerning food distribution that have been made to derive the Guideline Levels may not apply*". The new Japanese limits were established following this recommendation. While the Codex GLs are based on IPF of 10% according to international statistical data, the Japanese limits are based on the assumption that 50% of nationally distributed foods are contaminated. This higher percentage is used in Japan because Japan is the country where the nuclear power plant accident occurred and considers its food sufficiency. It seems that the IPFs used in developing Codex GLs and the Japanese limits are not well known in the world, probably because of the lack of sufficient risk communication.

16. In the 16th meeting of the Inter Agency Committee on Radiation Safety (IACRS, 12-13 May 2011, ILO headquarters, Geneva, Switzerland) the impact of the Fukushima Daiichi nuclear power plant incident was discussed. The European Commission proposed that the Codex Alimentarius should reconsider strontium and iodine. In the discussions, it has become clear that the Codex GLs had not been followed, in particular for iodine.

Consideration of a revision

17. To explore the need of a revision, and the details of the current GLs of radionuclides to be revised, the members of the eWG were asked to describe their opinions in response of a series of questions of the chairs. The questions were:

- Should the maximum levels of radionuclides be GLs or MLs, as defined in the GSCTFF? If a conversion of the GLs into MLs is considered needed, is a review by JECFA to be performed?

- The GSCTFF presents radionuclides, which are important for uptake into the food chain. Radionuclides of natural origin are excluded from consideration. Is this approach to be changed?

- The GLs of the radionuclides are defined per food category, and per group of radionuclides. Within a group the activities are to be added together. Groups should be treated independently. Do you support this approach or should it be altered? Should the food categories be changed?

- The GSCTFF presents different numerical values for the various groups of radionuclides. Do you support these values or are they to be revised?

18. The members of the eWG were asked to describe their opinions in response of these questions, and to include the arguments supporting their opinions. Besides the eWG was asked to decide whether the annexes of the GLs of radionuclides in the GSCTFF need revision, or an additional guidance document is considered necessary.

Conclusions

19. The eWG is of the opinion, that there is no need for changing the GLs to MLs. GLs are more flexible, and have the same status as MLs under the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (the WTO/SPS Agreement). There is no new scientific information that supports the need of a new risk assessment.

20. There is support for the current approach regarding the question whether the radionuclides of natural origin should be excluded from the GLs. Radionuclides of natural origin are ubiquitous and present in all foodstuffs to varying degrees. A suggestion of a member to introduce additional values for food corresponding to non-accidental situations, such as releases of radioactive effluents, was not supported, as it was noticed that such releases are under regulatory control.

21. With regard to the question, referring to the present approach of different GLs for different foods, and grouping of radionuclides, the eWG was of the opinion that the present structure of the GLs, consisting of groups of radionuclides to be assessed independently, for infant foods or foods other than infant foods, should maintain.

22. One member suggested reconsidering the previous situation of the GLs in 1989 with a single food category, as that was protective of both infants and adults. Other members of the eWG did not support this proposal, stating that society expects infants and young children to receive better protection. Another member proposed to add the category of dairy foods. There was also no support for this suggestion. Both members withdrew the proposals.

23. An observer proposed to discuss GLs for potable water in view of serious concerns raised over the safety of potable water after the Fukushima Daiichi nuclear accident. The observer noted that internationally traded potable water may fall within the scope of the Codex Alimentarius, and that the WHO could consider the elaboration of guidance levels to be applied in international trade under emergency situations in the context of the WHO Guidelines for Drinking Water Quality. This proposal was challenged by some members of the eWG, replying that drinking water does not represent a real problem for international trade. Besides, most drinking water originates from groundwater that will not suffer from direct contamination from fallout, and the presence of different sources of drinking water makes is possible to refrain from contaminated water.

24. Being of the opinion that there is no information that justifies changing a current GL value, all members of the eWG supported the values.

25. Various suggestions were made for improving the annexes, like adding better clarifications of arguments of choices such as the intervention exemption level of 1 mSv/year and the age-dependent ingestion dose coefficient, and the elaboration of the definition of "minor foods".

26. In this regard most members of the eWG stated that the current Fact Sheet of the Codex Secretariat[5] of 2 May 2011 regarding the Codex Guidelines levels for radionuclides in Food Contaminated Following a Nuclear or Radiological Emergency is very useful for the Codex members to understand the GLs of radionuclides correctly. They propose that the fact sheet rather than the GSCTFF may be modified, to provide assistance to countries for interpreting the use of the Codex GLs.

Recommendations

27. On request of the 6th CCCF of 2012, the eWG on the Revision of the GLs of Radionuclides in the GSCTFF has assessed the need of a revision of these GLs in the GSCTFF. On the basis of the positions of the members the following recommendations are made.

- As it was concluded not to change the current GLs of radionuclides in foods into MLs, and not to change the present approach using GLs for groups of radionuclides to be assessed independently, and not to change the current values, it is recommended to the 7th CCCF to consider to discontinue the work on the revision of GLs for radionuclides in the GSCTFF;

- It is recommended that the 7th CCCF discusses the concept of GLs for potable (drinking) water in emergency situations;

- It is recommended to the 7th CCCF to continue the work on the guidance to facilitate the interpretation and implementation of the Codex GLs on radionuclides. In reply to the question of the 6th CCCF whether this should be done as an independent guide or as an annex to the GSCTFF, the working group recommends not to change the annexes in the GSCTFF, but to revise the current Fact Sheet of the Codex Guidelines levels for radionuclides in Food Contaminated Following a Nuclear or Radiological Emergency of the Codex Secretariat of 2011, taken into account the comments made by the eWG. The revised document should then be used to develop a guidance.

[5] http://www.fao.org/food/food-safety-quality/a-z-index/japan0/en/ (Available in English only).

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