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**Agenda Item 15**

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**9<sup>th</sup> Session**

**New Delhi, India, 16 – 20 March 2015**

**DISCUSSION PAPER ON RADIONUCLIDES**

**(Prepared by the Electronic Working Group led by The Netherlands and co-chaired by Japan)**

**INTRODUCTION**

1. The Guideline Levels (GLs) for radionuclides in the General Standard for Contaminants and Toxins in Food and Feed (GSTCFF)<sup>1</sup> apply to radionuclides in foods destined for human consumption and traded internationally, contaminated following a nuclear or other radiological accident, or malevolent actions. When radionuclide levels in food do not exceed the GLs, the food should be considered safe for human consumption. The levels apply for trade in both emergency exposure situations and existing exposure situations, which are a result of a nuclear emergency.
2. Drinking water and bottled packaged drinking waters are not subject to Codex Guideline Levels for radionuclides, but are subject to radionuclide concentrations contained in the “Guidelines for Drinking Water Quality” published by the World Health Organization. These guidelines are not specific for nuclear emergencies.
3. The GLs allow for adoption of different national values when the various assumptions used to derive the GLs do not apply. These assumptions relate to the contribution of imported food to the total diet, contribution of minor foods, and different population groups.
4. The 32<sup>nd</sup> Meeting of the Radiation Safety Standards Committee (RASSC) in 2012 noted that there are several international standards for radionuclides in food and drinking water. Some are intended to be applied in emergency situations, others in existing exposure situations<sup>2</sup>, and some relate to food in international trade following a nuclear emergency.
5. The RASSC concluded that there seems to be some uncertainty around the duration of the applicability of the GLs. Consequently, it was recommended that CCCF consider if additional guidance is needed on this issue. In addition, it was concluded that there is no specific guidance on methods of analysis and sampling for food contaminated due to nuclear or radiological emergencies. It was thus recommended that CCCF consider if the identification of methods of analysis and the development of sampling plans could assist in the application of the GLs. Finally, the RASCC concluded that importing countries tend to apply levels to imports that are used by the affected country, rather than the GLs. As people’s protection is already assured by the GLs, it was recommended that countries adopt levels no lower than the Codex GLs for radionuclides for international trade of food and feed. However, this is not wholly satisfactory as it can give rise to a situation where a country directly affected by a nuclear or radiological emergency has implemented national levels that are lower than the GLs in order to protect their consumers (e.g. because more than 10% of their food could be contaminated). It would be difficult to justify exporting foods from an affected country if the radionuclide contamination was less than the GLs but greater than the national regulatory levels.

<sup>1</sup> CODEX STAN 193-1995

<sup>2</sup> <http://www-ns.iaea.org/tech-areas/radiation-safety/radiation-protection.asp?s=3&l=95>

6. The RASSC requested the International Atomic Energy Agency (IAEA) Secretariat in 2013 to establish an Inter-Agency Working Group (IAWG). The RASSC Secretariat established this Working Group, comprising experts from international organizations, including the Joint FAO-IAEA Division, FAO, IAEA, and WHO, as well as invited consultant experts and the International Commission on Radiological Protection (ICRP) as an observer. This Working Group has met three times. A discussion paper produced in the early meetings was considered by the RASSC and feedback on the GLs was provided to the Committee on Contaminants in Foods (CCCF). At its third meeting in May 2014 the IAWG further developed a draft of a new IAEA Technical Document (TECDOC). This document will detail the various national and international standards related to radionuclide contamination of food and drinking water, the basis on which they have been derived and the circumstances in which they are intended to be used, with particular focus on an existing (post-accident) exposure situation. The TECDOC will include a framework to help countries develop activity concentration levels for use at the national level in an existing (post-accident) exposure situation. A Technical Meeting with the purpose of providing guidance and input on the development of the TECDOC was held at the IAEA's Headquarters in September 2014.
7. At the 8<sup>th</sup> Session of Committee on Contaminants in March 2014, the Representative of the IAEA noted the outcome of the IAWG led by IAEA on the review of standards related to food and drinking water contaminated with radionuclides. The Representative indicated that, with regards to work relevant to CCCF, the IAWG concluded that there are no major gaps in the international standards for radiological safety in relation to food and water. However, there are still technical issues to be resolved such as (i) the stage of food production to which the Codex guideline levels apply, (ii) the period of time these GLs should apply in food trade following a nuclear or radiological emergency, (iii) the identification of internationally validated methods of analysis for radionuclides in foods, and (iv) the development of sampling plans to enhance the implementation of the Codex GLs.
8. In regard to the outcome of the IAWG, the CCCF recalled the decision taken at its 7<sup>th</sup> Session in 2013 to discontinue work on the development of guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF, and that after completion of the work carried out by the IAWG, the CCCF could decide to start new work on radionuclides as necessary.
9. In view of this, the Committee agreed to establish an electronic Working Group (EWG) led by the Netherlands and co-chaired by Japan to follow-up on the conclusions and recommendations of the IAWG to determine the need and feasibility to pursue work on the matters raised in points (i) to (iv) as described above. The Committee also agreed to request the EWG to look into the opportunity to develop guidance to facilitate the interpretation and implementation of the GLs for radionuclides in food in the GSCTFF for consideration at its next session. If further work is identified, proposals for analytical methods, sampling plans, etc. should be presented for consideration by the Committee.
10. The chairs from The Netherlands and Japan contacted experts of the IAEA to call for more clarification of the results of the IAWG, and for technical support regarding the issues to be addressed in the discussion paper. The chairs then developed with the technical support of IAEA and the members of the EWG the discussion paper for consideration by the 9<sup>th</sup> Session of the Committee in March 2015.
11. To follow the request of the 8<sup>th</sup> Session of the Committee, the chairs of the EWG asked the members of the EWG to give their opinions on the questions of the IAWG and the need for changes in the GSCTFF. The members of the EWG are presented in Appendix II.
12. Codex members and observers are invited to consider the conclusions and recommendations of the EWG as presented in paragraphs 36-41 with a view to advising the Committee on how to proceed further with additional work on radionuclides in the GSCTFF. When considering the conclusions and recommendations, Codex members and observers are invited to keep in mind the points raised at the 8<sup>th</sup> Session of CCCF (see paragraphs 7 and 9) and to take into consideration the discussion that took place in the EWG (see paragraphs 13-35) in relation to the interpretation and implementation of guideline levels for radionuclides in foods in the GSCTFF. International validated analytical methods for possible inclusion in the GSCTFF are presented in Appendix I.

**(i) Stage of food production to which the Codex guideline levels apply**

13. In May 2011, the Codex Secretariat issued a Fact Sheet on a Codex Guidelines Levels for Radionuclides in Foods contaminated Following a Nuclear or Radiological Emergency, prepared on a basis of the past discussion in the former Committee on Food Additives and Contaminants (CCFAC). It states in paragraph 4 that "the stage" means "ready to eat". On the other hand, the GSCTFF states that, in general, MLs are set on primary products.

14. A member of the EWG noted that GLs for foods “ready to eat” do not provide guidance on how to control foods destined for further processing.
15. Most members were of the opinion that the stage of “ready to eat” is in line with the GSCTFF, where for the radionuclides under “scope” it is stated that the GLs apply to food after reconstitution or as prepared for consumption, e.g. for tea the GL apply to the infusion. A few members however stated that GLs are mainly aimed at international food trade. The stage should facilitate border control, and should therefore be “before distribution”.
16. Certain primary products, such as agricultural produce, may be considered to be “ready to eat” where they can be consumed as such without processing. In these cases, preparation processes (e.g. deboning) may be included in the sample preparation procedure to reflect actual intake of radionuclides from such foods. With regard to such preparation processes, most members of the EWG were of the opinion that there is no need for the inclusion of these. Others members however stated that basic food preparation should be taken in consideration to make the GLs consistent across the different food groups. It was proposed to include this in the GSCTFF. Another member proposed this aspect to be discussed in the Committee on Methods of Analysis and Sampling (CCMAS).
17. The members that were of the opinion that the GLs should apply to food “before distribution” noted that processing is included in these cases and that the degree of contamination will not increase during processing.

**(ii) Period of time these GLs should apply in food trade following a nuclear or radiological emergency**

18. The Fact Sheet on Codex Guidelines Levels for Radionuclides in Foods contaminated Following a Nuclear or Radiological Emergency states in paragraph 4 that “the period” means “permanent basis”. The period of time for which radiological contamination remains is however not permanent. For most agricultural products the actual period will be rather limited (e.g. 5 years) depending on the level of environmental contamination and the countermeasures applied. For products originating from semi-natural ecosystems such as wild mushrooms, wild berries, and game, the period might be much longer. Therefore, a permanent basis can be considered to be a pragmatic solution, but is conservative of nature.
19. The members of the EWG supported this definition, but most of them with critical remarks. Some members think that it is not possible to define one fixed timeframe as it depends on the different variables, as described in the GSCTFF. One member noted that the GLs apply to foods “which have been contaminated following a radiological emergency”. The levels should thus cease to apply when the underlying assumptions (e.g. fraction of contaminated food, and minor crops) are no longer valid. Besides, the different half-lives of the radionuclides will affect the timeframe. It was proposed to take the different half-lives of the radionuclides into consideration, and guidance to this be described in the GSCTFF. Consequently, some members recommend to re-examine this idea, whereas others think it is not possible to establish an emergency period. A member was of the opinion that as long as a certain percentage of foods (percentage to be agreed upon) exhibit artificial radioactivity concentrations above the emergency phase GLs, monitoring and controls should remain in place regardless of the length of time since the radiological incident. It recommended that this period of time be determined on a case-by-case basis. In this regard, Another member proposed that GLs should only be applicable during the first year. After that, the GLs should be adapted to changed conditions. Some guidelines regarding this approach is considered needed by the members of the EWG if the timeframe is to be defined on a case-by-case basis.

**(iii) Identification of internationally validated methods of analysis for radionuclides in foods**

20. Different analytical methodologies are necessary for different types of radionuclide (i.e. alpha-, beta- and gamma-emitters). The time required to complete analysis varies for the different methods. Immediately after an accident, rapid analytical methods are considered necessary. Rapid methods exist for analyzing some radionuclides without the need of using complex and tedious preparation.

21. It was noted that methods for measuring gamma-ray are the most appropriate and most important from the view of protecting the health of consumers. After a while, the measurement of radionuclides which do not emit gamma-ray may be necessary, even if it takes a longer time to analyse them. As there are Codex GLs for radionuclides, which do not emit gamma-ray, analytical methods for all of these radionuclides may be necessary. In reaction to this, it was stated that detailed analysis for all important radionuclides shall be performed. This would allow, not only to know their activity concentrations but also to establish their ratios to Cs-137. In these cases only a limited number of samples is needed.
22. With regard to existing methods of analysis, it was questioned whether a list should be provided, with all available methods or internationally validated methods only. Some members of the EWG supported the need of a list of the internationally validated methods, whereas others were of the opinion that all available methods should be listed. Those asking for validated methods concluded that this would reduce trade disputes. A third group of members did not support a list; they were of the opinion that there should only be a list of performance criteria for analytical methods added to the GSCTFF. A member noted, that any method meeting recognised performance criteria would be acceptable.
23. If a list of methods of analysis is to be provided in the GSCTFF, the EWG is of the opinion that it should address all radionuclides for which GLs are recommended. Listing methods for detection of gamma-ray emitting radionuclides in emergency situations is not considered essential but is considered valuable.
24. Different members of the EWG provided a series of internationally validated methods. These can be found in Appendix I to this report. They recommended that the list of internationally validated methods should be added to the GSCTFF.
25. Other members were of the opinion that laboratories should be free to use the most appropriate analytical method(s), so there is no need to include specific methods in the GSCTFF.

#### **(iv) Development of sampling plans to enhance the implementation of the Codex GLs.**

26. The Codex Alimentarius Commission adopted the General Guidelines on Sampling (CAC/GL 50-2004). These Guidelines are aimed at commodity committees and can be used, if applicable, by governments. The sampling plans described in the Guidelines may be implemented either by governmental food control authorities or by professionals themselves (self-inspection performed by producers and/or traders).
27. The Guidelines do not include detailed sampling procedures. They are applicable for control at reception, and may not be applicable for control of end-products and for process control during production.
28. The Guidelines cover the control of homogeneous goods, i.e. control of the percentage of defective items by attributes or by variables, for goods in bulk or in individual items, and control of a mean content. They do not cover the control of non-homogeneous goods. They do not deal with double, multiple and sequential sampling plans, deemed too complex in the frame of the Guidelines.
29. The members of the EWG were asked whether the Guidelines are applicable to and sufficient for the radionuclide testing, or new sampling plans specific to radionuclides are considered necessary. All members were of the opinion that the Guidelines are applicable and sufficient for radionuclide testing while giving users enough flexibility in the application of the detail of the Guidelines. One member suggested to consult CCMAS in this matter.
30. A member suggested that sampling plans and methods of analysis should follow the recommendations of ISO.

#### **Additional guidance in the GSCTFF**

31. The 8th CCCF included a request for the EWG to look into the opportunity to develop guidance to facilitate the interpretation and implementation of the GLs for radionuclides in the GSCTFF.
32. Most members of the EWG were of the opinion that the answers to the questions as raised by the IAWG do not give rise to changes or additions to the current GSCTFF.
33. One member proposed to include a paragraph in the GSCTFF how the GLs apply in relation to the European MPLs.

34. Another member noted, that minor points could be addressed to improve clarity, e.g. intervention exemption levels, and age-dependent ingestion dose coefficient.
35. One member asked for an extended text of the human exposure procedure, based on the most recent information from ICRP and IAEA.

## CONCLUSIONS

36. In reply of the question of stage of food production to which the Codex guideline levels apply, most members of the EWG were of the opinion that these apply for food "ready to eat", as currently described in the GSCTFF. Some members propose to change this into "before distribution". Other would like to discuss to include clarification with regard to the processing of food.
37. With regard to the period the GLs should apply, most members of the EWG supported the position that it should be on a "permanent basis". This is conservative of nature but a pragmatic solution. Other members recommend to determine the period on a case-by-case basis. In these cases the GLs should be applicable for a restricted period of e.g. one year, and after that period the GLs should be reexamined taking into account relevant variables such as half-lives, percentage of contaminated foods, and other parameters.
38. Most of the members of the EWG supported the suggestion to include a list with internationally validated methods of analysis into the GSCTFF. Some would like to see all available methods. Others members are of the opinion that it is sufficient to establish a list of performance criteria. Some members are of the opinion that there is no need to include such list as laboratories are free to select the most appropriate analytical method.
39. With regard to sampling, the members of the EWG are of the opinion, that the current General Guidelines on Sampling of the Codex Alimentarius are applicable and sufficient for radionuclide testing.
40. Most members of the EWG did not ask for additional guidance to facilitate the interpretation and implementation of the GLs for radionuclides in the GSCTFF. Some members made suggestions but they did not prepare literal proposals or changes in the GSCTFF.

## RECOMMENDATIONS

41. The EWG recommends the Committee,
  - To discuss the various answers given by the members of the EWG in reply to the questions of the IAWG;
  - To discuss whether the answers give rise to changes of the GSCTFF or to clarification of the current text in the GSCTFF;
  - Depending on the outcome of these discussions to consider whether new work is needed with regard to changes of the GLs for radionuclides in food as described in the GSCTFF.

## Appendix I

## Internationally validated methods (method reference)

ASNI N42.14-1999	American National Standard for Calibration and Use of Germanium Spectrometers for the Measurements of Gamma-Ray Emission Rates of Radionuclides.
IAEA/AQ/27	Rapid Simultaneous Determination of <sup>89</sup> Sr and <sup>90</sup> Sr in Milk: A Procedure using Cerenkov and Scintillation Counting.
AS ISO/IEC 17025-2005	General requirements for the competence of testing and calibration laboratories.
ISO 11929	Determination of the characteristic limits (decision threshold, detection limit and limits of confidence interval) for measurements of ionizing radiation-fundamentals and application.
18589-4: 2007 and ISO 18589-5: 2009	extraction chromatography, ion chromatography and liquid scintillation spectrometry, Alpha spectrometry, Gamma Spectrometry
ASTM D7784 - 12	"Standard Practice for the Rapid Assessment of Gamma-ray Emitting Radionuclides in Environmental Media by Gamma Spectrometry"
ASTM D3648 - 04(2011)	"Standard Practices for the Measurement of Radioactivity"
ASTM C1268 - 94(2008)	"Standard Test Method for Quantitative Determination of Americium 241 in Plutonium by Gamma-Ray Spectrometry"
ASTM D7362 - 07	"Standard Guide for Rapid Screening of Vegetation for Radioactive Strontium Aerial Deposition"
ASTM E181 - 10	"Standard Test Methods for Detector Calibration and Analysis of Radionuclides"
ASTM D7362 – 07	"Standard Guide for Rapid Screening of Vegetation for Radioactive Strontium Aerial Deposition"
ISO 11929:2010	Determination of the characteristic limits(decision threshold, detection limit and limits of the confidence interval)for measurements of ionizing radiation-Fundamentals and application."

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