CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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CL 2020/55-FH **OCTOBER 2020**

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy

SUBJECT: **REQUEST FOR COMMENTS ON (I) THE DECISION TREE FOR IDENTIFICATION OF CRITICAL CONTROL POINTS AND (II) METHODS OF ANALYSIS FOR IRRADIATED FOODS**

DEADLINE: **30 November 2020**

COMMENTS:

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Background

1. The 51st Session of the Committee on Food Hygiene (CCFH51) advanced the revised *General Principles of Food Hygiene* (CXC 1-1969) to CAC43 for adoption at Step 5/8. CCFH51 further agreed to return the diagram to the decision tree for identification of critical control points (CCP) to Step 2 for drafting by Brazil, Honduras, Jamaica and Thailand for comments at Step 3 and consideration by CCFH52.[1]

2. Brazil has prepared two options for the decision tree based (see Appendix I) on discussions and comments made at CCFH51 to help facilitate discussion and preparation of a proposal for CCFH52. In their opinion both decision trees address all the situations mentioned in paragraphs 160 to 163 of Appendix IV-REP20/FH (3.7 Determine Critical Control Points (Step 7/Principle 2) and helps in their understanding. It was also proposed moving the statement related to 'GHP that requires greater attention' as a footnote of Q1. The order in the option 2 is more like the order of questions in Diagram 2 Example of Decision Tree to Identify CCPs from the former CXC 1 - 1969. This proposal has the advantage to be currently used and understood worldwide. However, the order of questions in option 1 is more objective.

3. CCFH51 also considered a proposal from CCMAS to transfer the methods in the *General Methods for the Detection of Irradiated Foods* CXS 231-2001) to the *Standard for Methods of Analysis and Sampling* (CXS 234-1999) and noted the offer of Brazil to review the methods in CXS 231 to determine their fitness for purpose and their possible conversion to performance-based criteria for consideration by CCFH52.[2] Brazil has prepared a background paper and recommendations (Appendix II) to inform further discussion and proposals for CCFH52.

4. In view of the postponement of CCFH52 to 2021 due to the COVID19 pandemic, and taking advantage of the additional time at our disposal, comments are requested on the decision tree as well as the methods for detection of irradiated foods to facilitate the preparation of proposals for consideration by CCFH52.

[1] REP20/FH, para 88
[2] REP20/FH, para. 8

REQUEST FOR COMMENTS

5. Members are invited to provide comments as follows:

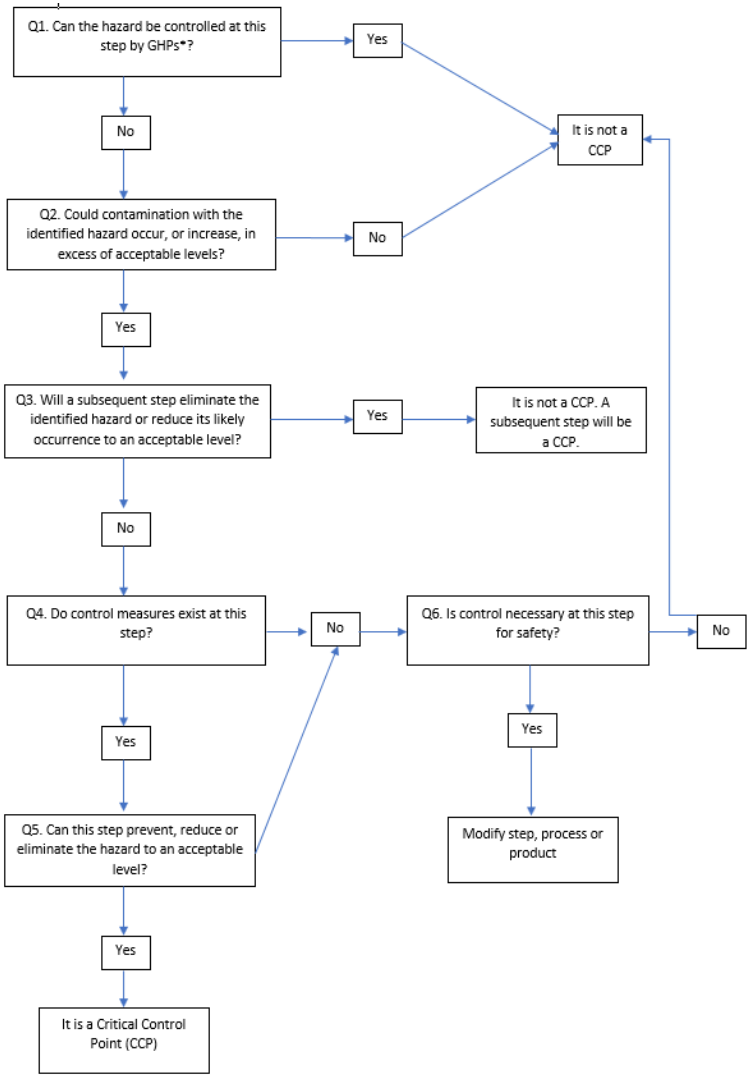
   a. Which of the two decision trees (see Appendix I to this CL) is more suitable to serve as a basis for development of a proposal for CCFH52 and provide information on changes that can be made to make the chosen decision tree more user-friendly taking into account the revised GPFH as presented in REP20/FH, Appendix IV; and

   b. On the (i) proposal to not establish performance criteria; and (ii) fitness for purpose of the methods for identification of irradiated foods as outlined in para. 23 of background document on methods for identification of irradiated foods attached as Appendix II to this CL.

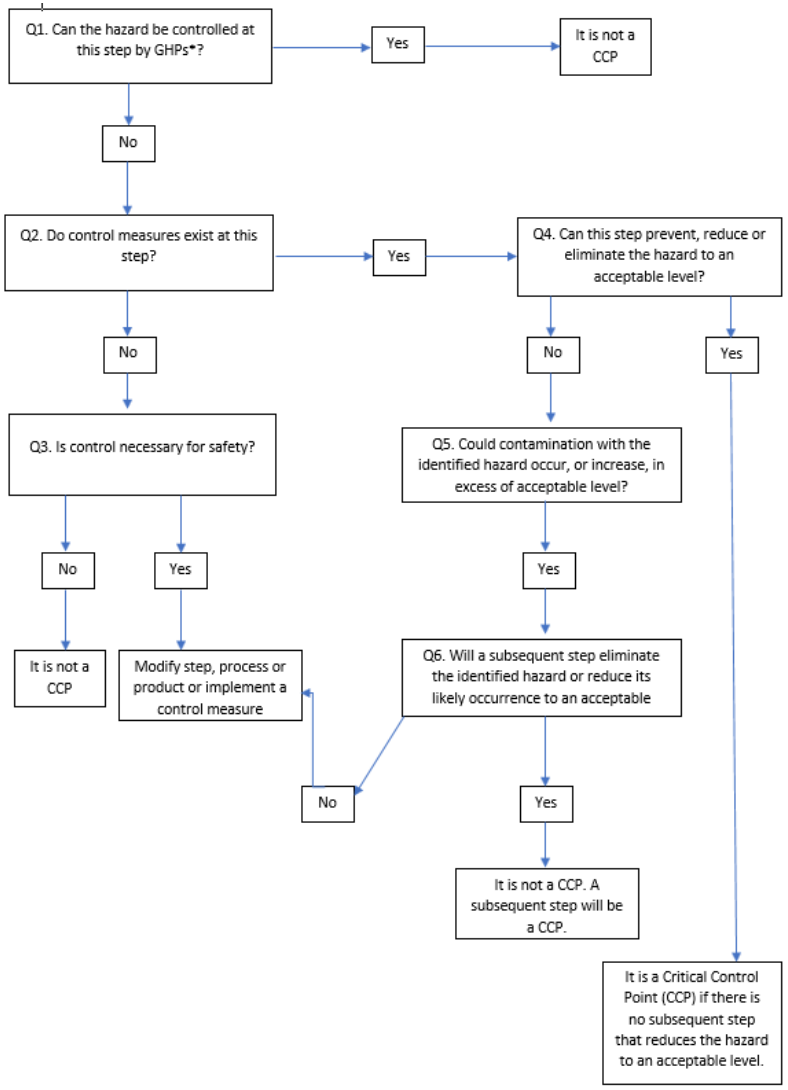
APPENDIX I

GENERAL PRINCIPLES OF FOOD HYGIENE: DECISION TREE

OPTION 1



OPTION 2



* GHP could be routine GHP or GHP that require greater attention to control the hazard (e.g. monitoring and recording).

APPENDIX II

GENERAL METHODS FOR THE DETECTION OF IRRADIATED FOODS (CXS 231–2001)
BACKGROUND

1. CCFH51 agreed in principle to transfer the methods from the *General Methods for the Detection of Irradiated Foods* (CXS231-2001) to the *Recommended Methods of Analysis and Sampling* (CXS234-1999) in order to follow the CAC decision to have all methods of analysis in a single document and noted the offer of Brazil to assist with this task[3] To perform this task it is necessary to evaluate if the methods listed in CXS 231 are fit for purpose and the possibility to convert them into performance-based criteria for consideration by CCFH52.

a) Purpose of the methods in CXS231-2001

2. Irradiation is a way to reduce hazards associated with infectious parasites and microbial contamination of foods and may be used as a method of control.

3. In the scope of the CCFH there are two different documents that establish requirements for food irradiation:

- *Code of Practice for Radiation Processing of Food* (CXC 19-1979); and
- *General Standard for Irradiated Foods* (CXS 106-1983).

4. The General Standard and the Code of Practice address the application of ionizing radiation to the treatment of foods and strongly emphasize the role of dosimetry for ensuring that irradiation will be properly performed.

5. The success of radiation processing of food depends on:

- measuring the absorbed dose delivered to the food product (through reliable dosimetry);
- determining the dose distribution patterns in the product package (through process qualification procedures); and
- controlling the routine radiation process (through process control procedures).

6. In the *Code of Practice for Radiation Processing of Food* (CXC 19-1979) measuring the dose and monitoring of the physical parameters of the process are essential for process control.

7. The measurement of absorbed dose involves the use of a dosimetry system which consists of not only well established physical or chemical dosimeters but also the instrument which measures the relevant radiation induced effect in the dosimeter (e.g. spectrophotometers, electron paramagnetic resonance (EPR) spectrometers) and their associated reference standards (such as wavelength and absorbance standards), and the procedure for using the system. The measuring instrument must be well characterized, so that it gives reproducible and accurate results. Any radiation induced effect (also called the dosimeter response) which is reproducible and can be quantified can, in principle, be used for dosimetry.

8. A dosimeter is a device that, when irradiated, exhibits a quantifiable change that can be related with the absorbed dose in a material using appropriate measurement instrument and procedures. Examples of routine dosimeters could be consulted in ISO/ASTM Guide 51261 (e.g: alanine, polymetylmethacrylate, cellulose triacetate, thermoluminescence, lithium fluoride film, radiochromic dye films, ceric cerous sulfate solution, ethanol chlorobenzene solution, MOSFET).

9. A convenient method of determining the absorbed dose experimentally in a certain medium is to use a routine dosimeter by inserting it into that medium.

10. The need for adequate record keeping, including records of quantitative dosimetry, is emphasized in the General Standard. Evidence for correct processing, including adherence to any legal or technological dose limits, depends on the maintenance of full and accurate records by the irradiation facility. The facility's records link all the information from several sources to the

[3] REP20/FH, para. 8

irradiated food products. Such records enable verification of the irradiation process and should be kept.

11. For dosimetry, the activities of principal concern are process validation and process control. The objective of such formalized procedures is to establish documentary evidence that the irradiation process has achieved the desired results. The key element of such activities is inevitably a well characterized reliable dosimetry system that is traceable to recognized national and international dosimetry standards. Only such dosimetry systems can help establish the required documentary evidence.

12. The *General Standard for Irradiated Foods* (CXS 106-1983) establishes analytical methods for the detection of irradiated foods that may be used as a reference to enforce authorization and labelling requirements.

13. Therefore, it is understood that the methods contained in CXS 231 are used just for labelling purposes in order to verify if a food was irradiated or not. The proposal of methods in CXS 231 are not dosimetry type.

14. This understanding was clarified in paragraph 100 of the Report of the Twenty-third Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS23), in 2001, when a delegation recalled that the Codex *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) required mandatory labelling of irradiated foods and it was therefore necessary to establish methods for control purposes.

15. In paragraph 101 some delegations and the Secretariat recalled that the Codex provision concerned was the requirement for the labelling of irradiated foods in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985), that it was under the terms of reference of the CCMAS to consider general methods and that this was not an endorsement of methods proposed by commodity committees.

16. At that session, CCMAS had an extensive debate on the typing of proposed methods. Some delegations indicated that these methods could be attributed to Type I as they provide only an estimate of positive or negative results while other delegations pointed out that methods could be differentiated between Type II and Type III. In the end the CCMAS decided to endorse the proposed methods and concluded that the method EN 1785:1996 for detection of irradiated foods containing fat on the basis of GC/MS analysis of 2-alkylcyclobutanones should be endorsed as Type III and the remaining methods were specified as Type II.[4]

<u>Methods evaluation and possible conversion of methods to performance-based criteria</u>

17. It was noted that the year of publication of the methods is incorrect/out of date. However, the new version of CXS 234 does not include the year of adoption of the method, so the year was removed.

18. Five methods are considered quantitative: EN13708, EN1784, EN1785, EN1786, EN1787, EN1788. The EN13784, EN13783 and EN13751 are screening methods.

19. The methods recommended in CXS 231 have different principles and are intended for different matrices. Although all methods listed are for radiation detection, the provision detected is different between the methods. So, the exact provision analyzed for each method and the commodities for which the method was validated were specified.

20. The conversion of specific methods of analysis to performance criteria depends on the information on the criteria listed below to enable the conversion into suitable generalized analytical characteristics:

• accuracy;

[4] A Type II method is the one designated Reference Method where Type I methods do not apply. It should be selected from Type III methods (as defined below). It should be recommended for use in cases of dispute and for calibration purposes.
A Type III Method is one which meets the criteria required by the Committee on Methods of Analysis and Sampling for methods that may be used for control, inspection or regulatory purposes.

• applicability (matrix, concentration range and preference given to 'general' methods);

• detection limit;

• determination limit;

• precision: repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within laboratory and between laboratories), but generated from collaborative trial data rather than measurement uncertainty considerations;

• recovery;

• selectivity;

• sensitivity;

• linearity.

21. The methods listed in the table below provide only an estimate of positive or negative results. At this point it was not possible assess the analytical performance of the method which has been determined in its validation.

22. Additionally, according to the Codex Procedure Manual *Working Instructions for the Implementation of the Criteria Approach in Codex*, the specified maximum level, minimum level, any other normative level or the concentration range of interest has to be stated. In case of the methods mentioned in CXS 231 and listed in table below there is no minimum and maximum level set to the provisions.

23. Codex members and observers are **invited** to provide comments on the (i) decision to not establish performance criteria , (ii) the fit for purpose of the methods in the table and the respective amendments: deletion of the year, and specification of the commodities and provisions.

Table. 1

Commodity	Provision	Method	Principle	Type
Food containing fat (Raw meat and chicken, cheese, fruits)	Detection of irradiated food - Detection of radiation-induced hydrocarbons	EN 1784	Gas chromatographic analysis of hydrocarbons	Type II
Food containing fat (Raw meat and chicken, liquid whole egg)	Detection of irradiated food - Detection of radiation-induced 2-alkylcyclobutanones	EN 1785	Gas chromatographic/ spectrophotometric analysis of 2/alkylcyclobutanones	Type III
Food containing bone	Detection of irradiated food - Radiation induced Electron Spin Resonance (ESR) signal attributed to hydroxyapatite (principal component of bones)	EN 1786	ESR spectroscopy	Type II
Food containing celulose (nuts and spices)	Detection of irradiated food - Radiation induced Electron Spin Resonance (ESR) signal attributed to crystalline cellulose	EN 1787	ESR spectroscopy	Type II
Food containing silicate minerals (herbs, spices, their mixtures and shrimps)	Detection of irradiated food - Thermoluminescence glow ratio used to indicate the irradiation treatment of the food	EN 1788	Thermoluminescence	Type II
Food containing silicate minerals (shellfish, herbs, spices, seasonings)	Detection of irradiated food - Measurement of photostimulated luminescence intensity	EN 13751	Photostimulated luminescence	Type III
Food containing cristaline sugar (dried fruits and raisins)	Detection of irradiated food - Radiation induced Electron Spin Resonance (ESR) signal attributed to crystalline sugar	EN 13708	ESR spectroscopy	Type II
Herb, spices ~~and raw minced meat~~ (herbs and spices)	Detection of irradiated food - Difference between total microorganism count and viable microorganism count	EN 13783 NMKL 231	Direct Epifluorescent Filter Technique/Aerobic Plate Count (DEFT/APC) (screening method)	Type III
Food containing DNA (food products, both of animal and plant origin such as various meats, seeds, dried fruits and spices.	Detection of irradiated food - Detection of DNA fragmentation presumptive to irradiation treatment.	EN 13784	DNA comet assay (screening method)	Type III