B. NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Plain text = Methods and provisions as proposed by CCNFSDU37
BOLD = As currently listed in CODEX STAN 234-1999
Strike Through/Underline = Proposed edits to methods proposed by CCNFSDU37 and/or to CODEX STAN 234-1999

STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CODEX STAN 72-1981) - METHODS OF ANALYSIS

Commodity	Provision	Method	Principle	Type
Infant Formula	Vitamin B12	AOAC 2011.10 | ISO 20634	HPLC	II
		AOAC 986.23 Total B12 as cyanocobalamin	**Turbidimetric**	**~~II~~ III**
Infant Formula	Myo-Inositol	AOAC 2011.18 | ISO 20637	LC-pulsed amperometry	II
Infant Formula	Chromium	AOAC 2011.19 | ISO 20649 | IDF 235	ICP-MS	~~II~~ III
	Chromium (Section B of CODEX STAN 72 only)	**EN 14082**	**Graphite furnace atomic absorption after dry ashing**	**II**
		EN 14083	**Graphite furnace AAS after pressure digestion**	**III**
		AOAC 2006.03	**ICP emission spectroscopy**	**III**
Infant Formula	Selenium	AOAC 2011.19 | ISO 20649 | IDF 235	ICP-MS	**~~II~~ III**
		AOAC 996.16 or AOAC 996. 17	**Continuous hydride generation Flame atomic absorption spectrometry (HGAAS)**	**III**
		EN 14627	**Hydride generation atomic absorption spectrometry (HGAAS)**	**II**
		AOAC 2006.03	**ICP emission spectroscopy**	**III**

Infant Formula	Molybdenum	AOAC 2011.19 **|** ISO 20649 | IDF 235	ICP-MS	**~~II~~ III**
	Molybdenum (Section B of CODEX STAN 72 only)	**EN 14083**	**Graphite furnace AAS after pressure digestion**	**~~III~~ II**
	Molybdenum (Section B of CODEX STAN 72 only)	**AOAC 2006.03**	**ICP emission spectroscopy**	**III**
Infant Formula	~~Vitamin A Palmitate (Retinyl Palmitate), Vitamin A Acetate (Retinyl Acetate)~~ Total Vitamin E (dl-α-Tocopherol and dl-α-Tocopherol Acetate)	AOAC 2012.10 **|** ISO 20633	HPLC	II
	Vitamin E	**AOAC 992.03** **Measures all rac-vitamin E (both natural + supplemental ester forms) aggregated and quantified as α-congeners**	**HPLC**	**III**
		EN 12822 **(Measures Vitamin E (both natural + supplemental ester forms) aggregated and quantified as individual tocopherol congeners (α, β, γ, δ).**	**HPLC**	**~~II~~ III**
Infant Formula	~~Total Fatty Acid Profile Fatty acids~~ Fatty acids (including trans fatty acids)	AOAC 2012.13 **|** ISO 16958 | IDF 231	Gas Chromatography	II
	Fatty acids (including trans fatty acid)	**AOAC 996.06**	**Gas chromatography**	**~~II~~ III**
		AOCS Ce ~~1h-05~~ 1i-07	**Gas chromatography**	**III**
	Total fat	**AOAC 989.05** **ISO 8381|IDF 123**	**Gravimetry (Röse-Gottlieb)**	**I**

Infant Formula	Iodine	AOAC 2012.15 **|** ISO 20647 | IDF 234	ICP-MS	II
		~~AOAC 992.24~~	**~~Ion-selective pontentiometry~~**	**Recommended to be revoked**

PERFORMANCE CRITERIA FOR ELEMENTAL METHODS (for Consideration)

Provision	**ML (minimum) (ug/kg)**	**ML (minimum) (ug/100kcal)**	**Applicable range (ug/kg)**	**LOD (ug/kg)**	**LOQ (ug/kg)**	**Precision RSDR (%)**	**Recovery (%)**
Selenium	6	1	10-500	4	10	<15	90-110
Chromium	9	1.5	20-1600	7	20	<15	90-110
Molybdenum	9	1.5	20-1000	7	20	<15	90-110

Numeric Criteria were developed based on Standard Method Performance Requirements (SMPR) were developed for methods of analysis: AOAC 2011.19 | ISO 20649 | IDF 235
Numeric Criteria are referenced to “ready-to-feed” formula.
None of the methods currently listed in CODEX STAN 234 meet the numeric criteria.

EXPRESSION OF RESULTS BY USING PROPOSED METHODS OF ANALYSIS (PROPOSAL FOR INCLUSION IN CODEX STAN 72)

Results obtained by using the proposed methods of analysis for nutrients in infant formula are calculated and expressed in amounts per 100g powder, or per 100g Ready to Feed (RTF) product. RTF samples can be from liquid origin. When RTF is reconstituted from powders, 25 grams of powdered infant formula is to be mixed with 200 grams of water.

In the CODEX Standard for Infant Formula (CODEX STAN 72-1981), the essential composition is expressed in amounts per 100 available kilocalories, and amounts per 100 available kilojoules.

By using the amount of kcal and kjoules per 100g powder, or RTF product, on the product label of the sample analyzed, the nutrient concentrations can be calculated and expressed in amounts per 100 kcalories or kjoules as follows:

$$\mathrm{w} = \frac{v}{y}\ x\ 100\ x\ f$$

w = nutrient concentration in mg/100 kcal or kjoules
v = nutrient concentration in mg/100g
y = amount of kcal or kjoules per 100g powder or RTF as indicated on sample package
f = dilution factor:
Example 1: In case of analysis of powders and of liquid Infant formula, f=1
Example 2: In case of reconstituted powders (25 g powder with 200 g of water), f=9.

APPENDIX III

AMENDMENTS TO THE PROCEDURAL

(For endorsement by CCGP and adoption by CAC)

(note: the amendments are in bold underlined font)

Revision of the *Principles for the Establishment of Codex Methods of Analysis*

Section II: Elaboration of Codex Standards and related text

Guidelines for the inclusion of specific provisions in Codex Standards and related Texts

Principles for the establishment of Codex Method of Analysis

Working Instructions for the Implementation of the Criteria Approach in Codex

Note **1**: These criteria are applicable to fully validated methods except for methods such as PCR and ELISA, which require other set of criteria**.**

Note 2: The approaches described for developing method performance criteria are intended for single-analyte provisions. The approaches described may not be suitable for provisions involving sum of components.

Revision of Format for Codex Commodity Standards

Section II: Elaboration of Codex Standards and related text

Format for Codex Commodity Standards

Methods of Analysis and Sampling

This section should contain the following wording:

"For checking the compliance with this standard, the methods of analysis and sampling contained in the Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) relevant to the provisions in this standard, shall be used."

The methods of analysis and sampling considered necessary should be selected in accordance with the guidance given in the section on Methods of Analysis and Sampling in the *Relations between Commodity Committees and General Subject Committees*. Preference should be given to set performance criteria according to the guidance established in the General Criteria for the Selection of Methods of Analysis using the Criteria Approach. If two or more methods have been proved to be equivalent by the Codex Committee on Methods of Analysis and Sampling, these could be regarded as alternatives.

APPENDIX IV

Process to Update Methods of Analysis in CODEX STAN 234-1999

(for internal use by CCMAS)

The revision purpose of the endorsement may be to include a new method, to withdraw a method, to amendment or change the type of the method.

The revision to include, withdraw or amend a method is necessary when:

- the provision or the maximum level are changed and the method does not meet the required performance;
- the method has any wrong or ambiguous/insufficient information;
- the method does not meet the performance criteria or it uses reagents with safety concerns for the analyst or for the environment;
- the organization responsible for the method revoked or updated methodology;
- the Committee responsible for the establishment of the provision proposes a revision;
- there is a new method that is fit for purpose;
- two methods that are included for the same provision shown to be non-equivalent;
- every 10 years.

The revision to change the type of the method may occur when:

- the Type II method does not meet the current required performance or under normal laboratory conditions it is not practical and applicable;
- Type IV methods that fill the requirements to be a Type II or III;
- Type III methods that fit better to the purpose than the Type II method with better applicability in routine use, due to, for example: equipment, speed, accessibility, affordability, accuracy, precision and recovery;
- Type I methods defined for a parameter that currently can be assessed by validated methods that use another principle of determination, for example, protein determination by Kjeldahl or Dumas;
- the method was misclassified

At any time a Codex member or a committee may request revision of methods of analysis based on the criteria for revision mentioned in this document. Any such request for revision should identify clearly the reason and the information that justifies the change. The proposals should be sent to the Codex Secretariat that will prepare a list with the methods proposed by the committees and members and also with the ones that have been endorsed over 10 years previously an every CCMAS session. The working document with this list of methods of analysis should be evaluated in the “endorsement session” of CCMAS.

As already agreed to by the Committee as one of the 4 steps, related standard developing organizations (SDOs) will check the references of their methods[1]. The Committee expressed gratitude to all SDOs that have continued to provide CCMAS with information regarding the status of various methods with respect to revision and update[2]. It is essential for an updated and consistent single list of methods of analysis that any such revisions and updates are brought to the attention of CCMAS.

The proposal to replace methods on the list as the outcome of this evaluation will be forwarded to the originally proposing committee for the ratification of the endorsement. If the relevant committee agrees with the proposal, the proposed method should return to CCMAS for endorsement and the CODEX STAN 234-1999 should be updated accordingly. The CCMAS should take the responsibility to revise general methods and those from inactive/dissolved committees.

The flowchart I shows the steps of the updating procedure.

[1]REP14/MAS. Para. 79
[2]REP14/MAS. Para. 80

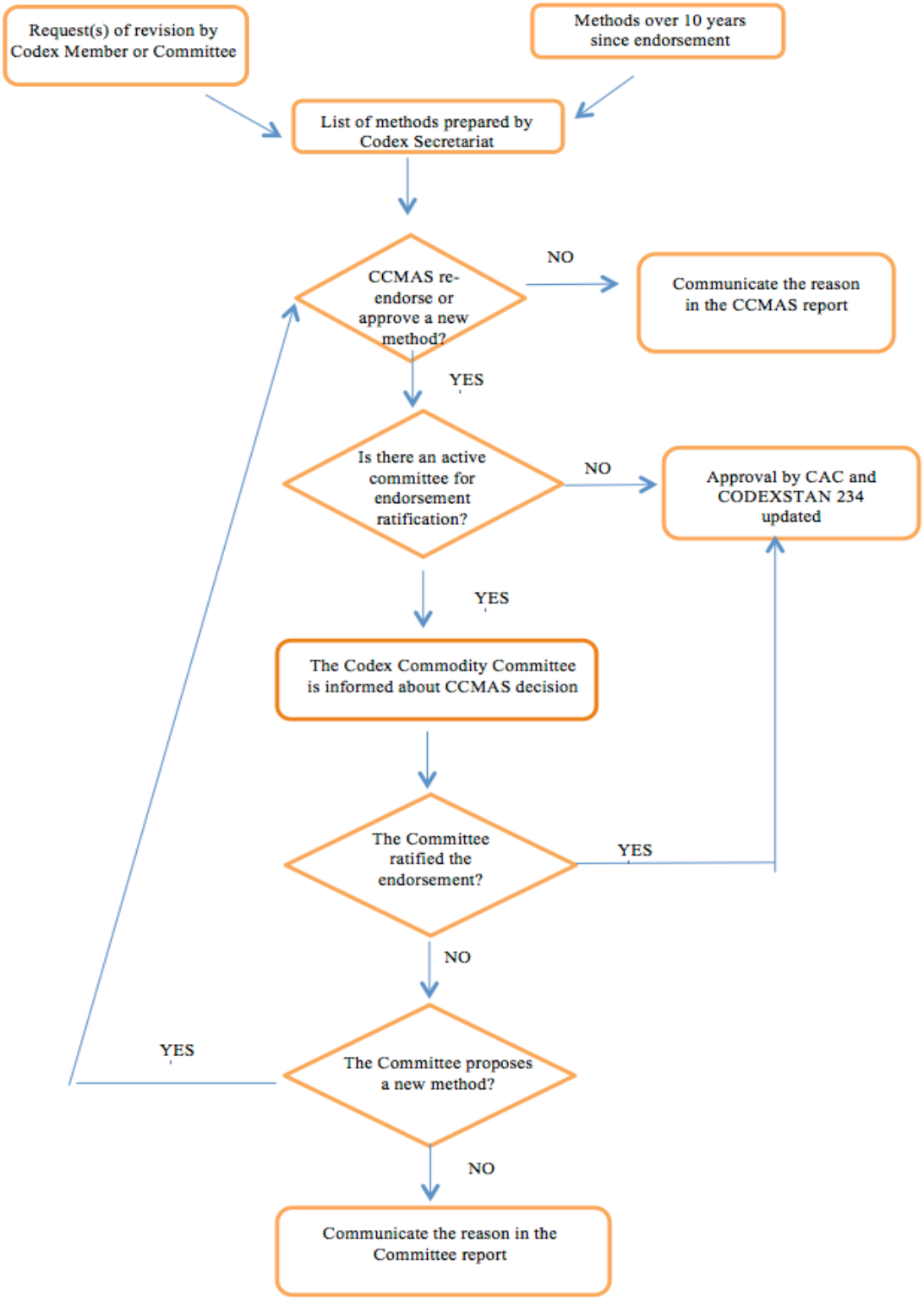


Fig 1. Steps of the Methods of Analysis Updating Procedure

APPENDIX V

Practical Examples on the Selection of Appropriate Sampling Plan

(For comments)

1. This Information Document provides help in choosing appropriate sampling plans. These sampling plans are examples and should not be regarded as prescriptive. Therefore, they do not present fixed values but give reference to correspondent passages of the standards.

2. The justification of the choice („why“) of the individual sampling plans and the corresponding decision criteria ensues from the standards to be used in the individual situations. Usually the determination of the appropriate sampling plan is unambiguous, a fact, which will help avoid future conflicts between importing and exporting countries.

3. The given examples are intended for institutions specializing in sampling and compliance assessment. These institutions are familiar with the quoted standards (ISO, OIML, ICMSF, etc.) and should be able to understand the text in spite of the highly condensed presentation.

4. Sampling and decision concepts include wrong acceptance and wrong rejection of a lot, which are interrelated.

Examples of Sampling Plans:

The following Table 1 presents the matrix combinations vs measurand / provision with the reference codes of the corresponding examples (Table 2). The third dimension of product form of marketing (packages/bulk material/foodstuff for consumption) is implemented into the particular examples.

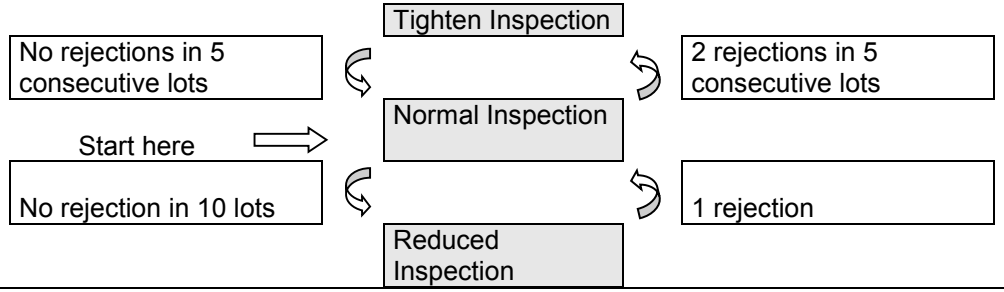
	Fruits/ vegetables	fats/oil	fish/fishery products	milk/milk products	meat/meat products	natural mineral waters	cereals
Qualitative/quantitative characteristics/sensory inspection	FV-Q	FO-Q	F-Q	MI-Q	M-Q	MW-Q	C-Q
food hygiene	FV-FH	n.r.	F-FH	MI-FH	M-FH	MW-FH	n.r.
pesticide residues	FV-P	FO-P	n.r.	MI-P	M-P	n.r.	C-P
contaminants	FV-C1/2	FO-C	F-C	MI-C	M-C	MW-C	C-C
residues of veterinary drugs	n.r.	FO-R	F-R	MI-R	M-R	n.r.	n.r.

n.r = not relevant

Table 1: Code of Examples

Example	Criteria	Type of Sampling Plan	Sampling and Decision Reference	
			Isolated Lots	**Continuous series of lots**
FV-Q	Visible defects in fruits	Attribute Plan Sampling uncertainty not applicable	**Consumer:** CAC/GL 50 section 3.1, see specifically ISO 2859-2:1985**:** Sampling: Procedure A: A plan is identified by the lot size, limiting quality (LQ) and the inspection level (unless otherwise specified, level II shall be used). The sampling size (n) is given in table A. Procedure B: A plan is identified by the lot size, limiting quality (LQ) and the inspection level (unless otherwise specified, level II shall be used). The sampling size (n) is given in table B1 to B10. Decision: For given limiting quality (LQ) and number of samples *n*, a lot is compliant if the number of items with visible defects does not exceed the Rejection number Re (Tables A, D4). **Producer:** ISO 2859-2:1985: Sampling: see “Consumer”	**Consumer:** CAC/GL 50 section 4.2 (Table 10) see specifically: NMKL Procedure No 12, Annex – Section 4 (Table 5) and Fig.1 (see below) and ISO 2859-1:1999: Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection Sampling: Normal inspection: use of a sampling plan with an acceptance criterion that has been devised to secure the producer a high probability of acceptance when the process average of the lot is better than the acceptance quality limit. Normal inspection is used when there is no reason to suspect that the process average differs from an acceptable level. The sample size is taken from Table 1 and Table 2-A. Tightened inspection: use of a sampling plan with an acceptance criterion that is tighter than that for the corresponding plan for normal inspection. Tightened inspection is invoked when the inspection results of a predetermined number of consecutive lots indicate that the process average might be poorer than the AQL. The sample size is taken from Table 1 and Table 2-B. Reduced inspection: use of a sampling plan with a sample size that is smaller than that for the corresponding plan for normal inspection and with an acceptance criterion that is comparable to that for the corresponding plan for normal inspection. The discriminatory ability under reduced inspection is less than under normal inspection.

			Decision: For given LQ corresponding to AQL of consumer sampling plan from ISO 2859-1 if applicable, Table D5) and number of samples *n*, a lot is compliant if the number of items with visible defects does not exceed the Acceptance number Ac (Table A).	Reduced inspection may be invoked when the inspection results of a predetermined number of consecutive lots indicate that the process average is better than the AQL. The sample size is taken from Table 1 and Table 2-C. Switching rules: when normal inspection is being carried out, tightened inspection shall be implemented as soon as two out of five (or fewer than five) consecutive lots have been non-acceptable on original inspection (that is, ignoring resubmitted lots or batches for this procedure). When tightened inspection is being carried out, normal inspection shall be re-instated when five consecutive lots have been considered acceptable on original inspection. The outline of the switching rules is shown in Figure 1. Decision: for given inspection level, Acceptable Quality Level (AQL) and number of samples *n*, a lot is compliant if the number of items with visible defects does not exceed the Rejection number Re (Tables 1 and 2 e.g. for single sampling). **Producer:** ISO 2859-1:1999: Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection Sampling: see “Consumer”

				Decision: for given inspection level and Acceptable Quality Level (AQL), a lot is compliant if the number of items with visible defects does not exceed the Acceptance number Ac (e.g. Tables 1 and 2 for single sampling).
			NMKL procedure no 12. (Annex - Section 4): **Figure 1: Levels of inspection and the switching between those.**  	
MI-Q	Fat content in Milkproducts	Variables Plan Prerequisites: 1. The lots have not been screened previously for nonconforming items. 2. Continuing series of lots of discrete products all supplied by one producer using one production process 3. quality characteristic must be measurable on a continuous scale 4. the measurement error is negligible, i.e. with a standard deviation no more than 10 % of the	**Consumer and Producer:** ISO 3951-1:2013: Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL Sampling: for the “s” method acceptance sampling plan the sample standard deviation is used, for the “σ” method acceptance sampling plan the presumed value of the process standard deviation is used. If there is sufficient evidence from the control charts (e.g. ´autocontrol´) that the variability is in statistical control, consideration should be given to switching to the “σ” method. If this appears advantageous, the consistent value of s (the sample standard deviation) shall be taken as σ. Normal inspection is used at the start of inspection (unless otherwise designated) and shall continue to be used during the course of inspection until tightened inspection becomes necessary or reduced inspection is allowed. Tightened inspection shall be instituted when two lots on original normal inspection are not accepted within any five or fewer successive lots. Reduced inspection may be instituted after ten successive lots have been accepted under normal inspection, provided that these lots would have been acceptable if the AQL had been one step tighter, production is in statistical control.	

		sample standard deviation s or process standard deviation σ In the case that the measurement error is significant, it should be combined with s or σ respectively, according to ISO 3951-1:2013 Annex O 5. production is stable (under statistical control) and the quality characteristic x is distributed according to a normal distribution or a close approximation to the normal distribution	In case that switching rules are not applicable, a particular consumer's risk quality (CRQ) associated with a consumer's risk should be fixed (e.g. Table K1 or K2). In case of very short series of lots, ISO 2859-2:1985 might be applied, where the fat content of the sample items with respect to the limit (taking into account the measurement uncertainty) might be classified as attribute (see example FV-Q). Summary table 1 directs users to the paragraphs and tables concerning any situation with which they may be confronted. Sample sizes are given in table A2 for the sample size letters given in Clause 23, Chart A (for agreed and fixed AQL at 95 % probability of acceptance and LQ at 10 % probability of acceptance). This should be verified by inspecting the OC curve from among Clause 24, Charts B to R relating to this code letter and AQL. For the "s" method (CAC/GL 50 section 4.3 (Table 14) and NMKL Procedure No 12, Annex – section 5 (Table 6) see specifically (ISO 3951-1:2013, Clause 15), the procedure for obtaining and implementing a plan is as follows. a) With the inspection level given (normally this will be II) and with the lot size, obtain the sample-size code letter using Table A.1. b) For a single specification limit, enter Table B.1, B.2 or B.3 as appropriate with this code letter and the AQL, and obtain the sample size n and the acceptability constant k. For combined control of double specification limits when the sample size is 5 or more, find the appropriate acceptance curve from among Charts s-D to s-R. c) Take a random sample of size n, measure the characteristic x in each item and then calculate x, the sample mean and s, the sample standard deviation (see Annex J). Where a contract or standard defines an upper specification limit U, a lower specification limit L, or both, the lot can be judged unacceptable without even calculating s if x is outside the specification limit(s). For the "σ" method (CAC GL 50 section 4.3 (table 17) and NMKL Procedure No 12, Annex – section 5 (table 7)), see specifically (ISO 3951-1:2013, Clause 16) from Table A.1 the sample-size code letter is obtained. Then, depending on the severity of inspection, enter Table C.1, C.2 or C.3 with the sample-size code letter and the specified AQL to obtain the sample size n and acceptability constant k. Take a random sample of this size, measure the characteristic under inspection for all items of the sample and calculate the mean value. The sample standard deviation s should also be calculated, but only for the purpose of checking the continued stability of the process standard deviation (see ISO 3951-1:2013, Clause 19).

			Decision: a lot is compliant if the average fat content of sample items does not fall below the minimum value fixed by AQL and LQ taking into account the corresponding standard deviation (s or σ) and acceptability constant K. The acceptability constant is given in tables B1 to B3 (s-method) and C1 to C3 (σ-method). If single upper or lower specification limits (U or L) are given, calculate the quality statistic $Q_U=(U-x)/s$ or $Q_L=(x-L)/s$ where x the sample mean and s, the sample standard deviation. The lot is acceptable if $Q_U \geq k$ or $Q_L \geq k$ respectively. For the "σ" method, s must be replaced by σ
FO-Q	water content in butter	Variables Plan Prerequisites: see example MI-Q	**Consumer and Producer:** see MI-Q Sampling: see example MI-Q Decision: A lot is compliant if the average water content of sample items does not exceed the maximum value fixed by AQL taking into account the corresponding standard deviation (s or σ) and acceptability constant K. See also example MI-Q
F-Q	Net weight in prepackaged fish	Special Plan	**Consumer and Producer:** OIML R 87 (Edition 2004)[b)]: Quantity of product in prepackages Sampling: see Table 1: Sampling plans for prepackages Decision: for fixed 'Risk Type' (according to fixed AQL given in OIML R 87) the lot is accepted if all of the following criteria are met: 1. The average actual quantity of product in a package is at least equal to the nominal quantity, which is evaluated in the following way:

			The total error of the quantity of product in a package is given by the sum of the differences between the individual product weights and the nominal weight. The average error is given by that total error divided by the sample size. The lot is accepted if the average error is a positive number. In case of a negative number, the lot is accepted if the standard deviation of the individual product weights times the sample correction factor of Table 1 is higher than the absolute value of the average error. 2. The number of packages containing an actual quantity less than the nominal quantity minus the tolerable deficiency (Table 2) is less or equal the Number of packages in a sample allowed to exceed the tolerable deficiencies (Table 1). 3. No package contains an actual quantity less than the nominal quantity minus twice the tolerable deficiency.
M-Q	Nonmeat Protein in Meat products	Variables Plan Prerequisites: see example MI-Q	**Consumer and Producer:** see MI-Q Sampling: see example MI-Q Decision: A lot is compliant if the average content of nonmeat protein of sample items does not exceed the maximum value fixed by AQL taking into account the corresponding standard deviation (s or σ) and acceptability constant K. See also example MI-Q
MW-Q	Sodium content of prepackaged Mineral Water	Variables Plan Prerequisites: see example MI-Q	**Consumer and Producer:** see MI-Q Sampling: see example MI-Q Decision: A lot is compliant if the average sodium content of sample items does not exceed the maximum value fixed by AQL taking into account the corresponding standard deviation (s or σ) and acceptability constant K. See also example MI-Q

C-Q	Moisture in rice grains	Variables Plan on Bulk Material Sampling uncertainty implemented	**Consumer and Producer:** CAC/GL 50 section 5, see specifically: ISO 10725:2000: Acceptance sampling plans and procedures for the inspection of bulk materials / ISO 11648-1:2003: Statistical aspects of sampling from bulk materials — Part 1: General principles / ISO 24333:2009 Cereals and cereal products -- Sampling Sampling: see example C-C Decision: for a given maximum limit, the lot is accepted if the sample grand average of these results $\bar{x}$ is lower than an upper acceptance value $\bar{x}_U = m_L + g\ D$ with the constant for obtaining the acceptance value $g = K_a / (Ka + Kb)$.
FV-FH	*E. coli* in Frozen vegetables and fruits	Three-class attributes Plan	CAC/GL 50 section 3.2 and NMKL procedure no 12 Annex sampling plans, Section 3, Table 3 and Table 4 see specifically: ICMSF (1986)[a)]: Chapter 18 Sampling plans for vegetables, fruits, and nuts Sampling: see Table 28: Sampling plans and recommended microbiological limits for vegetables, fruits, nuts, and yeast Decision: the lot is accepted if not more than 2 item of 5 samples shows the presence of *E. coli* with a maximal content of 1000 CFU/g. The lot is rejected in the opposite case.
M-FH	*Staphylococcus aureus* in fresh or frozen poultry meat	Three-class attributes Plan	**Consumer and Producer:** CAC/GL 50 section 3.2 and NMKL Procedure No 12, Annex – section 3 (tables 1 and 2), see specifically: ICMSF (1986)[a)]: Chapter 13 Sampling plans for poultry and poultry products Sampling: see Table 22: Sampling plans and recommended microbiological limits for poultry and poultry products Decision: the lot is accepted if not more than 1 item of 5 samples shows the presence of *Staphylococcus aureus* with a maximal content of 1000 CFU/g. The lot is rejected in the opposite case.
F-FH	*Salmonella* in fresh, frozen and cold-smoked fish	Two-class attributes Plan	**Consumer and Producer:** CAC/GL 50 section 3.2 and NMKL Procedure No 12, Annex – section 3 (tables 3 and 4), see specifically: ICMSF (1986)[a)]: Chapter 17 Sampling plans for fish and shellfish

			Sampling: see Table 27: Sampling plans and recommended microbiological limits for seafoods Decision: the lot is accepted if no item out of 5 samples show the presence of *Salmonella* in 1g. The lot is rejected in the opposite case.
MI-FH	*Staph. aureus* in Cheese, 'hard' and 'semi-soft' types	Two-class attributes Plan	**Consumer and Producer:** CAC/GL 50 section 3.2 see specifically: ICMSF (1986)[a)]: Chapter 15 Sampling plans for milk and milk products Sampling: see Table 24: Sampling plans and recommended microbiological limits for dried milk and cheese Decision: the lot is accepted if no item out of 5 samples show the presence of *Staph. aureus* in 1g, where the concentration is higher than 10.000 CFU/g. The lot is rejected in the opposite case.
MW-FH	Microorganisms in Natural Mineral Water	Two-class attributes Plan	**Consumer and Producer:** CAC/RCP 33-1985: *Code of hygienic practice for collecting, processing and marketing of natural mineral waters* (see also ICMSF (1986)[a)]: Chapter 25: Sampling plans for natural mineral waters, other bottled waters, process waters, and ice.) Sampling and Decision: Annex I: Microbiological Criteria, Table: Microbiological Criteria, Point of application: at source, during production and endproduct. Assuming a log normal distribution and an analytical standard deviation of 0.25 log cfu/ml, the sampling plans would provide 95% confidence that a lot of water containing a defined not acceptable geometric mean concentration of specific microorganisms would be detected and rejected based on any of five samples testing positive.
FV-P	Pesticides Residues in Apples for Compliance with MRL	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: *Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs*

			Sampling: the minimum number of primary samples to be taken from a lot is determined from Table 1b. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot. The primary samples should be combined and mixed well, if practicable, to form the bulk sample. The minimum size of each laboratory sample is given by Table 4, 1.2. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing. Decision: analytical results must be derived from one or more laboratory samples. The lot complies with a MRL (Pesticide Residues in Food and Feed, Codex Pesticides Residues in Food Online Database, FAO and WHO 2013) where the MRL is not exceeded by the analytical result(s). Where results for the bulk sample exceed the MRL, a decision that the lot is non-compliant must take into account: (i) the results obtained from one or more laboratory samples, as applicable; and (ii) the accuracy and precision of analysis, as indicated by the supporting quality control data.
FO-P	Pesticides Residues in vegetable oils	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: *Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs* Sampling: the minimum number of primary samples to be taken from a lot is determined from Table 1b. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot. The primary samples should be packaged units, or units taken with a sampling device. They should be combined and mixed well, if practicable, to form the bulk sample. The minimum size of each laboratory sample (0.5 l or 0.5 kg) is given by Table 4, 5.4. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing. Decision: see FV-P

MI-P	Pesticides Residues in Cheeses, including processed cheeses units 0.3 kg or greater	Variables Plan sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: *Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs* Sampling: the minimum number of primary samples to be taken from a lot is determined from Table 1b. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot. Whole unit(s) or unit(s) of the primary samples should be cut with a sampling device. Cheeses with a circular base should be sampled by making two cuts radiating from the centre. Cheeses with a rectangular base should be sampled by making two cuts parallel to the sides. The minimum size of each laboratory sample (0.5 kg) is given by Table 5, 3.3. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing. Decision: see FV-P
M-P	Fat soluble Pesticides Residues in cattle carcass for Compliance with MRL	Variables Plan Sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL33-1999: *Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs* Sampling: the minimum number of primary samples to be taken from a lot is determined from Table 1a, or Table 2 (in the case of a suspect lot). The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot. Each primary sample is considered to be a separate bulk sample. The Minimum size of each laboratory sample is given in Table 3, 2.1. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing. Decision: see FV-P

C-P	Pesticides Residues in rice grains		**Consumer and Producer:** CAC/GL33-1999: *Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs* Sampling: the minimum number of primary samples to be taken from a lot is determined from Table 1b. The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample. The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot. Sampling devices required for grain are described in ISO recommendations. The primary samples should be combined and mixed well, if practicable, to form the bulk sample. The minimum size of each laboratory sample (1 kg) is given by Table 4, 2. The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing. Decision: see FV-P
FV-C1	Aflatoxin in ready-to-eat Treenuts	Variables Plan on Bulk Material Sampling, sample preparation, and analytical variances used to compute operating characteristic curves	**Consumer and Producer:** CODEX STAN 193-1995: *General standard for contaminants and toxins in food and feed* Sampling: see ANNEX 2. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 25 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 25 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 25 tonnes. It is recommended that a lot or a sublot should not exceed 25 tonnes. The minimum lot weight should be 500 kg. Representative sampling should be carried out from the same lot. In the case of *static lots* of treenuts contained either in a large single container or in many small containers, it is not ensured that the contaminated treenut kernels are uniformly dispersed throughout the lot. Therefore, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. The minimum number of incremental samples, the minimum incremental sample size and the minimum aggregate sample size depend on the lot weight and are given by Table 1.

			In the case of *dynamic lots*, the samples are taken from a moving stream of treenuts. The size of the aggregate sample depends on the lot size, the flow rate of the moving stream and the parameters of the sampling device. Two laboratory samples each of 10kg are taken from the aggregate sample. The laboratory samples should be finely ground and mixed thoroughly. The test portions taken from the comminuted laboratory samples by a random process should be approximately 50 grams. Decision: if the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxin in the test samples from both laboratory samples, the lot is accepted.
FV-C2	Total Aflatoxins in Peanuts intended for further Processing	Variables Plan on Bulk Material Sampling, sample preparation, and analytical variances used to compute operating characteristic curves	**Consumer and Producer:** CODEX STAN 193-1995: *General standard for contaminants and toxins in food and feed* Sampling: see AFLATOXINS TOTAL, ANNEX 1: Each lot which is to be examined must be sampled separately. Large lots should be subdivided into sublots to be sampled separately. The weight or number of sublots depend on the lot size and is laid down in Table 1. The number of incremental samples to be taken depends also on the weight of the lot, with a minimum of 10 and a maximum of 100 (Table 2). For the sampling procedure see example FV-C1. The weight of the incremental samples should be approximately 200 grams or greater, depending on the total number of increments, to obtain an aggregate sample of 20 kg. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. A minimum test portion size of 100 g should be taken from the finely ground and mixed laboratory sample. Decision: if the aflatoxin test result is less than or equal to 15 µg/kg total aflatoxin in the test sample, the lot is accepted.
FO-C	Erucic acid in vegetable Oil (bulk or packages)		**Consumer and Producer:** CODEX STAN 193-1995: *General standard for contaminants and toxins in food and feed* COMMISSION REGULATION (EU) 2015/705 of 30 April 2015 laying down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs

			Sampling: Large lots shall be divided into sublots on condition that the sublot may be separated physically. The weight or number of sublots of products traded in bulk consignments shall be as given in Table 1. The weight or number of sublots of other products shall be as given in Table 2. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot indicated in Tables 1 and 2 may be exceeded by a maximum of 20 %. The aggregate sample shall be at least 1 kg or 1 litre except where this is not possible e.g. when the sample consists of one package or unit. The minimum number of incremental samples to be taken from the lot or sublot shall be as given in Table 3. In the case of bulk liquid products the lot or sublot shall be thoroughly mixed insofar as possible and insofar it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of contaminants is assumed within a given lot or sublot. It is therefore sufficient to take three incremental samples from a lot or sublot to form the aggregate sample. The incremental samples shall be of similar weight or volume. The weight or volume of an incremental sample shall be at least 100 grams or 100 millilitres, resulting in an aggregate sample of at least about 1 kg or 1 litre. If the lot or sublot consists of individual packages or units the number of packages or units which shall be taken to form the aggregate sample is given in Table 4. Decision: The lot or sublot is accepted if the analytical result of the laboratory sample does not exceed the respective maximum level laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used. The lot or sublot is rejected if the analytical result of the laboratory sample exceeds beyond reasonable doubt the respective maximum level laid down in Regulation (EC) No 1881/2006 taking into account the expanded measurement uncertainty and correction of the result for recovery if an extraction step has been applied in the analytical method used.
F-C	Dioxins and dioxin like PCB´s in Fish (individual packages or units)	Variables Plan Sampling uncertainty implemented	**Consumer and Producer:** CODEX STAN 193-1995: *General standard for contaminants and toxins in food and feed* COMMISSION REGULATION (EU) No 589/2014 of the European Community laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012, ANNEX II

			Sampling: As far as possible incremental samples shall be taken at various places distributed throughout the lot or sublot. The aggregate sample shall be made up by combining the incremental samples. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled or when the product has a very high commercial value. The minimum number of incremental samples to be taken from the lot or sublot shall be as given in Table 4. Specific provisions for the sampling of lots containing whole fishes of comparable size and weight are given in Paragraph 3. Large lots shall be divided into sublots on condition that the sublot can be separated physically. For weight and number, Table 2 shall apply. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 20 %. The aggregate sample uniting all incremental samples shall be at least 1 kg. Decision: The lot is accepted, if the result of a single analysis — performed by a screening method with a false-compliant rate below 5 % indicates that the level does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006, — performed by a confirmatory method does not exceed the respective maximum level of PCDD/Fs and the sum of PCDD/Fs and dioxin-like PCBs as laid down in Regulation (EC) No 1881/2006 taking into account the measure- ment uncertainty. For screening assays a cut-off value shall be established for the decision on the compliance with the respective maximum levels set for either PCDD/Fs, or for the sum of PCDD/Fs and dioxin-like PCBs. The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 1881/2006, if the upperbound analytical result obtained with a confirmatory method and confirmed by duplicate analysis, exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty. The mean of the two determinations, taking into account the measurement uncertainty is used for verification of compliance.
MI-C	Aflatoxin M1 in Milk (bulk or bottles)		**Consumer and Producer:** CODEX STAN 193-1995: *General standard for contaminants and toxins in food and feed* COMMISSION REGULATION (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs. F.1.: Method of sampling for milk, milk products, infant formulae and follow-on formulae, including infant milk and follow-on milk.

			Decision: for purposes of control, the maximum residue limit for veterinary drugs (MRLVD) is applied to the residue concentration found in each laboratory sample taken from a lot. Lot compliance with a MRLVD is achieved when the mean result for analysis of the laboratory test portions does not indicate the presence of a residue, which exceeds the MRLVD. Regulatory action is only taken on samples containing residues, which can be demonstrated to exceed the regulatory action limit with a defined statistical confidence.
Mi-R	Residues of Veterinary Drugs in Raw Milk	Variables Plan on Bulk Material Sampling uncertainty not applicable	**Consumer and Producer:** CAC/GL71-2009: *Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals* Sampling: see example F-R, The minimum quantity required for laboratory samples is 500 mL (Table B I Group 033). Decision: see example F-R
M-R	Residues of Veterinary Drugs in Meat/Meat products	Variables Plan sampling uncertainty not applicable	Consumer and Producer: CAC/GL71-2009: *Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals* Sampling: see example F-R, The minimum quantity required for laboratory samples is 500 g (Table A I Group 030). Decision: see example F-R

Table 2: Example sampling plans

[a)] Microorganisms in Foods 2. Sampling for microbiological analysis: Principles and specific applications. 1986. 2nd Ed. International Commission on Microbiological Specifications for Foods.

[b)] International Organization of Legal Metrology (OIML), Bureau International de Métrologie Légale 11, rue Turgot - 75009 Paris - France, Publication OIML R 87 Edition 2004 (E)