

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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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 THE PRACTICAL EXAMPLES OF SAMPLING PLANS**

DEADLINE: **15 March 2017**

COMMENTS: **To:** Codex Contact Point of Hungary
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Copy to: **The Codex Secretariat**
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Background

1. At the 37th session of CCMAS, the Committee agreed that Germany would prepare a revised text taking into account comments submitted to CL 2016/4-MAS.
2. Norway, New Zealand and Canada submitted comments, as follows, which have been taken into account:
 - The Practical Examples need to make clear that each example is one option for the particular situation. Commodity committees may find alternative plans that are more appropriate.
 - Changing the outdated example F-FH (fish/fishery products-food hygiene) “*Salmonella* in fresh, frozen and cold-smoked fish” which includes a reference to ICMSF (1986) Chapter 17, to another updated and more relevant example on F-FH *Listeria monocytogenes* (in smoked fish – ready to eat products)
 - Region-specific legislation (EU regulation) should not be included as a reference for sampling guidance. (Examples FO-C, F-C, Mi-C and M-C)
 - Need for clarification or correction (Examples FV-Q, MI-Q, FO-Q, M-FH, M-P, FV-P, FO-R, F-R, Mi-R and M-R)
3. There have been reservations about the premature presentation of an Information document on practical examples of sampling plans before the revision of the Guidelines for Sampling (CAC/GL 50-2004) on sampling.
4. However, the Examples are based on internationally accepted ISO standards as it is the case for the existing GL 50. In Germany’s opinion, a revised version of GL 50 will refer to those standards as well and there might be no need to amend the Information document in future, as long as the basic standards do not change significantly. Even if there will be significant changes, it would be easier to update an Information document than to revise the corresponding Guideline.
5. The development of practical examples as information document might relieve the revised GL 50 of presenting examples and thereby give the opportunity to make the text easier to read.
6. The concept of providing theoretical approaches as guidelines and to supplement these guidelines by practical examples in the form of information documents might need further consideration.

Request for comments

7. Comments are requested on the Information Document on Practical Examples presented in Appendix I.

Appendix I**INFORMATION DOCUMENT ON PRACTICAL EXAMPLES OF SAMPLING PLANS**

This Information Document provides help in choosing appropriate sampling plans. These sampling plans are examples and should not be regarded as prescriptive. Each example is one option for the particular situation. Commodity committees may find alternative plans that are more appropriate.

Therefore, they do not present fixed values but give reference to correspondent passages of the standards.

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.

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.

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 versus measure / 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.

Table 1: Code of 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 2: Example sampling plans

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	<p>Consumer: CAC/GL 50 section 3.1, see specifically ISO 2859-2:1985</p> <p><u>Sampling:</u> 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.</p> <p><u>Decision:</u> For given limiting quality (LQ) and number of samples n, a lot is compliant if the number of items with visible defects is less than the Rejection number Re (Tables A, D4).</p> <p>Producer: ISO 2859-2:1985: <u>Sampling:</u> see “Consumer”</p>	<p>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</p> <p><u>Sampling:</u> 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</p>

			<p><u>Decision:</u> 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 A_c (Table A).</p>	<p>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.</p> <p>Reduced inspection may be invoked when the inspection results of a predetermined number of consecutive lots</p> <p>Indicate that the process average is better than the AQL. The sample size is taken from Table 1 and Table 2-C.</p> <p><u>Switching rules:</u></p> <p>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).</p> <p>When tightened inspection is being carried out, normal inspection shall be re-instated when five consecutive lots have been considered acceptable on original inspection.</p> <p>The outline of the switching rules is shown in Figure 1.</p> <p><u>Decision:</u> 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 is less than not the Rejection number R_e (Tables 1 and 2 e.g. for single sampling).</p> <p>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</p> <p><u>Sampling:</u> see “Consumer”</p>
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			<p>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).</p>
			<p>NMKL procedure no 12. (Annex - Section 4):</p> <p>Figure 1: Levels of inspection and the switching between those.</p> <pre> graph TD Start[Start here] --> NI[Normal Inspection] NI --> TI[Tighten Inspection] NI --> RI[Reduced Inspection] TI --> NI RI --> NI NI --> NI_5[No rejections in 5 consecutive lots] NI_5 --> TI NI --> NI_2[2 rejections in 5 consecutive lots] NI_2 --> TI NI --> NI_10[No rejection in 10 lots] NI_10 --> RI NI --> NI_1[1 rejection] NI_1 --> RI </pre>
MI-Q	Fat content in Milk products	<p>Variables Plan</p> <p>Prerequisites:</p> <ol style="list-style-type: none"> 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 	<p>Consumer and Producer:</p> <p>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</p> <p>Sampling:</p> <p>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.</p> <p>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</p>

		<p>3. quality characteristic must be measurable on a continuous scale</p> <p>4. the measurement error is negligible, i.e. with a standard deviation σ_{μ} no more than 1/10 of the sample standard deviation s or process standard deviation σ.</p> <p>In the case that the measurement error is significant, the sampling number n should be increased by</p> $n^* = n(1 + \gamma^2)$ <p>where $\gamma = \sigma_{\mu} / \sigma$ ISO 3951-1:2013, Annex O)</p> <p>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</p>	<p>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.</p> <p>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 2859-2:2010 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).</p> <p>Summary table 1 directs users to the paragraphs and tables concerning any situation with which they may be confronted.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>c) Take a random sample of size n, measure the characteristic x in each item and then calculate \bar{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 \bar{x} is outside the specification limit(s).</p> <p>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) the procedure for obtaining and implementing a plan is as follows.</p> <p>a) From Table A.1 the sample-size code letter is obtained.</p> <p>b) 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.</p>
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			<p>c) Take a random sample of this size, measure the characteristic under inspection for all items of the sample and calculate the mean value.</p> <p>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).</p> <p><u>Decision:</u></p> <p>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).</p> <p>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.</p> <p>The lot is acceptable if $Q_U \geq k$ or $Q_L \geq k$ respectively.</p> <p>For the “σ” method, s must be replaced by σ</p>
FO-Q	water content in butter	Variables Plan Prerequisites: see example MI-Q	<p>Consumer and Producer: see MI-Q</p> <p><u>Sampling:</u> see example MI-Q</p> <p><u>Decision:</u> 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</p>
F-Q	Net weight in prepackaged fish	Special Plan	<p>Consumer and Producer: OIML R 87 (Edition 2004)^{b)}: Quantity of product in prepackages</p> <p><u>Sampling:</u> see Table 1: Sampling plans for prepackages</p> <p><u>Decision:</u> 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:</p>

			<p>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:</p> <p>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.</p> <p>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.</p> <p>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).</p> <p>3. No package contains an actual quantity less than the nominal quantity minus twice the tolerable deficiency.</p>
M-Q	Nonmeat Protein in Meat products	Variables Plan Prerequisites: see example MI-Q	<p>Consumer and Producer: see MI-Q</p> <p><u>Sampling:</u> see example MI-Q</p> <p><u>Decision:</u> 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</p>
MW-Q	Sodium content of prepackaged Mineral Water	Variables Plan Prerequisites: see example MI-Q	<p>Consumer and Producer: see MI-Q</p> <p><u>Sampling:</u> see example MI-Q</p> <p><u>Decision:</u> 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</p>
C-Q	Moisture in rice grains	Variables Plan on Bulk Material	<p>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</p>

		Sampling uncertainty implemented	<p>sampling from bulk materials — Part 1: General principles / ISO 24333:2009 Cereals and cereal products -- Sampling</p> <p><u>Sampling:</u> see example C-C</p> <p><u>Decision:</u> 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 $\bar{x}_U = m_L + \gamma D$</p>
FV-FH	<i>E. coli</i> in Frozen vegetables and fruits	Three-class attributes Plan	<p>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</p> <p><u>Sampling:</u> See Table 28: Sampling plans and recommended microbiological limits for vegetables, fruits, nuts, and yeast</p> <p><u>Decision:</u> The lot is accepted if not more than 2 items of 5 samples show the presence of <i>E. coli</i> with a concentration between 100 and 1000 CFU/g. The lot is rejected in the opposite case.</p>
M-FH	<i>Staphylococcus aureus</i> in fresh or frozen poultry meat	Three-class attributes Plan	<p>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</p> <p><u>Sampling:</u> see Table 22: Sampling plans and recommended microbiological limits for poultry and poultry products</p> <p><u>Decision:</u> The lot is accepted if not more than 1 item of 5 samples shows the presence of <i>Staphylococcus aureus</i> with a concentration between 1000 and 10.000 CFU/g. The lot is rejected in the opposite case.</p>
F-FH	<i>Listeria monocytogenes</i> in smoked fish – ready-to-eat	Two-class attributes Plan	<p>Consumer and Producer: CAC/GL 50-2004 section 3.2 and NMKL Procedure No 12, Annex – section 3 (tables 3 and 4), see specifically CODEX STAN 311-2013 <i>Standard for smoked fish, smoke-flavoured fish and smoke-dried fish</i>, section 6.4.</p> <p><u>Sampling:</u> See CAC/GL 61-2007 Guidelines on the application of general principles of food hygiene to the control of listeria monocytogenes in foods - Annex II Table 1 and 2</p> <p><u>Decision:</u> See CAC/GL 61-2007 Guidelines on the application of general principles of food hygiene to the control of listeria monocytogenes in foods - Annex III</p>

MI-FH	<i>Staph. aureus</i> in Cheese, 'hard' and 'semi-soft' types	Two-class attributes Plan	<p>Consumer and Producer: CAC/GL 50 section 3.2, see specifically: ICMSF (1986)^{a)}: Chapter 15 Sampling plans for milk and milk products</p> <p><u>Sampling:</u> see Table 24: Sampling plans and recommended microbiological limits for dried milk and cheese</p> <p><u>Decision:</u> The lot is accepted if no item out of 5 samples show the presence of <i>Staph. aureus</i> in 1g, where the concentration is higher than 10.000 CFU/g. The lot is rejected in the opposite case.</p>
MW-FH	Microorganisms in Natural Mineral Water	Two-class attributes Plan	<p>Consumer and Producer: CAC/RCP 33-1985: <i>Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters</i></p> <p>(see also ICMSF (1986)^{a)}: Chapter 25: Sampling plans for natural mineral waters, other bottled waters, process waters, and ice.)</p> <p><u>Sampling and Decision:</u> Annex I: Microbiological Criteria, Table: Microbiological Criteria, Point of application: at source, during production and end product. 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.</p>
FV-P	Pesticides Residues in Apples for Compliance with MRL	Variables Plan sampling uncertainty not applicable	<p>Consumer and Producer: CAC/GL33-1999: <i>Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS</i></p> <p><u>Sampling:</u> 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.</p> <p>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</p>

			<p>analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing.</p> <p><u>Decision:</u></p> <p>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.</p>
FO-P	Pesticides Residues in vegetable oils	Variables Plan sampling uncertainty not applicable	<p>Consumer and Producer:</p> <p>CAC/GL33-1999: <i>Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS</i></p> <p><u>Sampling:</u></p> <p>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.</p> <p>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.</p> <p><u>Decision:</u></p> <p>see FV-P</p>
MI-P	Pesticides Residues in Cheeses, including processed cheeses units 0.3 kg or greater	Variables Plan sampling uncertainty not applicable	<p>Consumer and Producer:</p> <p>CAC/GL33-1999: <i>Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS</i></p> <p><u>Sampling:</u></p> <p>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.</p>

			<p>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.</p> <p><u>Decision:</u> see FV-P</p>
M-P	Fat soluble Pesticides Residues in cattle carcass for Compliance with MRL	Variables Plan Sampling uncertainty not applicable	<p>Consumer and Producer: CAC/GL33-1999: <i>Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS</i></p> <p><u>Sampling:</u> 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.</p> <p>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.</p> <p><u>Decision:</u> see FV-P</p>
C-P	Pesticides Residues in rice grains		<p>Consumer and Producer: CAC/GL33-1999: <i>Recommended Methods Of Sampling For The Determination Of Pesticide Residues For Compliance With MRLS</i></p> <p><u>Sampling:</u> 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.</p> <p>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</p>

			<p>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.</p> <p><u>Decision:</u> see FV-P</p>
FV-C1	Aflatoxin in ready-to-eat Treenuts	<p>Variables Plan on Bulk Material</p> <p>Sampling, sample preparation, and analytical variances used to compute operating characteristic curves</p>	<p>Consumer and Producer: CODEX STAN 193-1995: General Standard For Contaminants And Toxins In Food And Feed</p> <p><u>Sampling:</u> 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 subplot should not exceed 25 tonnes. The minimum lot weight should be 500 kg. Representative sampling should be carried out from the same lot.</p> <p>In the case of <i>static lots</i> 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.</p> <p>In the case of <i>dynamic lots</i>, 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.</p> <p>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.</p> <p><u>Decision:</u> 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.</p>
FV-C2	Total Aflatoxins in Peanuts intended for	<p>Variables Plan on Bulk Material</p> <p>Sampling, sample preparation, and analytical variances used</p>	<p>Consumer and Producer: CODEX STAN 193-1995: <i>General Standard For Contaminants And Toxins In Food And Feed</i></p>

	further Processing	to compute operating characteristic curves	<p><u>Sampling:</u> 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).</p> <p>For the sampling procedure see example FV-C1.</p> <p>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.</p> <p><u>Decision:</u> If the aflatoxin test result is less than or equal to 15 µg/kg total aflatoxin in the test sample, the lot is accepted.</p>
FO-C	Erucic acid in vegetable Oil (bulk)		<p>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</p> <p><u>Sampling:</u> see example C-C</p> <p><u>Decision:</u> see example C-C</p> <p>for a given maximum limit m_L, the lot is accepted if the sample grand average of these results \bar{x} is lower than an upper acceptance value $\bar{x}_U = m_L + \gamma D$.</p>
F-C	Dioxins and dioxin like PCB's in Fish (individual packages or units)	Variables Plan Sampling uncertainty implemented	<p>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</p> <p><u>Sampling:</u> Since the Dioxin content usually is not process controlled, 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.</p>

			<p>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.</p> <p>b) For a single specification limit U (the ML for Dioxins and dioxin like PCB's), enter Table B.1, B.2 or B.3 as appropriate with this code letter and the (usually low) AQL, and obtain the sample size n and the acceptability constant k.</p> <p>c) Take a random sample of size n, measure the characteristic x in each item and then calculate \bar{x}, the sample mean and s, the sample standard deviation (see Annex J).</p> <p><u>Decision:</u> calculate the quality statistic $Q_U = (U - \bar{x})/s$ The lot is acceptable if $Q_U \geq k$</p>
MI-C	Aflatoxin M1 in Milk (bulk)		<p>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 CODEX STAN 193-1995: <i>General Standard For Contaminants And Toxins In Food And Feed</i></p> <p><u>Sampling:</u> see example C-C</p> <p><u>Decision:</u> see example C-C</p> <p>for the given maximum limit $m_L = 0.5 \mu\text{g/kg}$ (CODEX STAN 193-1995: <i>General Standard for Contaminants and Toxins in Food and Feed</i>), the lot is accepted if the sample grand average of these results \bar{x} is lower than an upper acceptance value $\bar{x}_U = m_L + \gamma D$.</p>
M-C	benzo(a)pyrene in meat	Variables Plan Sampling uncertainty implemented	<p>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</p> <p><u>Sampling:</u> see Mi-Q</p> <p>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</p>

		<p>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.</p> <p>3. 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),</p> <p>The procedure for obtaining and implementing a plan is as follows.</p> <p>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.</p> <p>b) 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.</p> <p>c) Take a random sample of size n, measure the characteristic x in each item and then calculate \bar{x}, the sample mean and s, the sample standard deviation (see Annex J). Where a contract or standard defines an upper specification limit U, the lot can be judged unacceptable without even calculating s if \bar{x} exceeds the specification limit.</p> <p>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) the procedure for obtaining and implementing a plan is as follows.</p> <p>4.</p> <p>5. a) From Table A.1 the sample-size code letter is obtained.</p> <p>6.</p> <p>7. b) 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.</p> <p>8.</p> <p>c) Take a random sample of this size, measure the characteristic under inspection for all items of the sample and calculate the mean value.</p> <p>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).</p> <p><u>Decision:</u></p> <p>calculate the quality statistic</p> $Q_U = (U - \bar{x}) / s$ <p>The lot is acceptable if</p> $Q_U \geq k$ <p>For the “σ” method, s must be replaced by σ</p>
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MW-C	Arsenic in Natural Mineral Water	Variables Plan on Bulk Material Sampling uncertainty implemented	<p>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 CODEX STAN 193-1995: <i>General Standard For Contaminants And Toxins In Food And Feed</i></p> <p><u>Sampling:</u> see example C-C</p> <p><u>Decision:</u> see example C-C</p> <p>for the given maximum limit $m_L=0.01$ mg/kg (CODEX STAN 193-1995: <i>General Standard for Contaminants and Toxins in Food and Feed</i>), the lot is accepted if the sample grand average of these results \bar{x} is lower than an upper acceptance value $\bar{x}_U = m_L + \gamma D$.</p>
C-C	Cadmium content in wheat	Variables Plan on Bulk Material Sampling uncertainty implemented	<p>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</p> <p><u>Sampling:</u> sampling from a commodity is classified into two different procedural types:</p> <ul style="list-style-type: none"> • sampling of bulk materials for the accurate estimation of an average value of the <u>quality characteristic assessed</u> in the lot by suppliers • inspection procedure for bulk materials for making a <u>decision concerning lot acceptance</u> by consumers. <p>ISO 11648 is an International Standard for the first type of procedure, ISO 10725 for the second type, which is based on the assumption that the value of the individual standard deviation of the specified quality characteristic is known and stable.</p> <p>The sample size can be estimated using Tables 3 - 22 of the standard ISO 10725:2000 with fixed producer's risk α and consumer's risk α and fixed cost ratio level from the relative standard deviations $d_I = \sigma_I/D$ and $d_T = \sigma_T/D$ (ISO 10725:2000, 6.3.4) with the sampling increment standard deviation σ_I and test sample standard deviation σ_T. The number $2n_I$ increment samples should be taken from the lot and each two of them should be pooled to</p>

			<p>two composite samples. From each of the two composite samples $2n_T$ test samples should be prepared (e.g. homogenized).</p> <p>For imprecise standard deviations, one measurement per test sample should be performed (ISO 10725:2000, 6.3.2.2).</p> <p>As an alternative, the number and size of the increment samples and of the test samples are given in ISO 24333 Table 1 or Table 2 for flowing or static bulk material respectively. That standard also gives information on suitable sampling devices.</p> <p><u>Decision:</u></p> <p>As emphasized above, prerequisite is the determination of the estimation standard deviation σ_E (ISO 10725:2000, 6.2.7 / ISO 11648-1:2003) by monitoring of the cadmium content and to assess that it is stable. It is permitted to use the values of standard deviations specified by an agreement between the supplier and the purchaser (e.g. 'autocontrol') (ISO 10725:2000, 6.2.1).</p> <p>Taking into account the discrimination interval $D = (K_\alpha + K_\beta) \sigma_E$ (formula C6 in C.4.2) and assuming that the measurement standard deviation is negligible compared to σ_E (which should be proven), the following four quantities might be fixed by agreement: the acceptance quality limit for the lot mean m_A (corresponding to AQL, producers' risk), the probability α of wrongly rejecting a conforming lot, the non-acceptance quality limit for the lot mean m_R (corresponding to LQ, consumers' risk), and the probability α of wrongly accepting a nonconforming lot.</p> <p>For a given acceptance quality limit m_A, the lot is accepted if the sample grand average of these results \bar{x} is lower than an upper acceptance value $\bar{x}_U = m_A + \gamma D$ with the constant for obtaining the acceptance value $\gamma = K_\alpha / (K_\alpha + K_\beta)$.</p>
FO-R	Residues of Veterinary Drugs in Fat	Variables Plan sampling uncertainty not applicable	<p>Consumer and Producer:</p> <p>CAC/GL71-2009: <i>Guidelines For The Design And Implementation Of National Regulatory Food Safety Assurance Programme Associated With The Use Of Veterinary Drugs In Food Producing Animals</i></p> <p><u>Sampling:</u> See example F-R, The minimum quantity required for laboratory samples is 500 g (Table A II Group 031).</p> <p><u>Decision:</u> see example F-R</p>
F-R	Residues of Veterinary Drugs in Packaged Fish	Variables Plan Sampling uncertainty not applicable	<p>Consumer and Producer:</p> <p>CAC/GL71-2009: <i>Guidelines For The Design And Implementation Of National Regulatory Food Safety Assurance Programme Associated With The Use Of Veterinary Drugs In Food Producing Animals</i></p>

		<p><u>Sampling:</u></p> <p>For non-suspect lots a statistically-based, unbiased sampling program is recommended (sampling is conducted at random throughout the lot under inspection, although often systematic sampling is employed). In stratified random sampling the consignment is divided into non-overlapping groups or strata e.g. geographical origin, time. A sample is taken from each stratum. In systematic sampling units are selected from the population at a regular interval (e.g., once an hour, every other lot, etc.). Where non-compliant results are detected it is possible to derive a crude estimate of the likely prevalence in the general product population (e.g. 'autocontrol'). The number of primary samples required to give a required statistical assurance can be read from Appendix A, Table 4.</p> <p>For exact or alternative probabilities to detect a non-compliant residue, or for a different incidence of non-compliance, the number of samples n to be taken may be calculated from:</p> $n = \ln(1-p) / \ln(1-i)$ <p>Where p is the probability to detect a non-compliant residue (e.g. 0.95), it is the supposed incidence of non-compliant residues (e.g. 0.10) in the lot.</p> <p>In biased or estimated worst case sampling, investigators use their judgment and experience regarding the population, lot, or sampling frame to decide which primary samples to select. Such directed or targeted sampling protocols on a sub-population (biased sampling) are designed to place a greater intensity of inspection/audit on suppliers or product considered to possibly have a greater potential than the general population of being non-compliant. If compliant results from biased sampling confirm non-biased program results, they provide increased assurance that the system is working effectively.</p> <p>The canned or packaged product should not be opened for sampling unless the unit size is at least twice the amount required for the final laboratory sample. The final laboratory sample should contain a representative portion of juices surrounding the product. The minimum quantity required for laboratory samples is 500 g of edible tissue (Table C VII Class B – Type 08, A).</p> <p><u>Decision:</u></p> <p>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.</p>
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Mi-R	Residues of Veterinary Drugs in Raw Milk	Variables Plan on Bulk Material Sampling uncertainty not applicable	Consumer and Producer: CAC/GL71-2009: <i>Guidelines For The Design And Implementation Of National Regulatory Food Safety Assurance Programme Associated With The Use Of Veterinary Drugs In Food Producing Animals</i> <u>Sampling:</u> See example F-R, The minimum quantity required for laboratory samples is 500 mL (Table B I Group 033). <u>Decision:</u> 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: <i>Guidelines For The Design And Implementation Of National Regulatory Food Safety Assurance Programme Associated With The Use Of Veterinary Drugs In Food Producing Animals</i> <u>Sampling:</u> See example F-R, The minimum quantity required for laboratory samples is 500 g (Table A I Group 030). <u>Decision:</u> See example F-R

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)