CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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# Agenda Item 7

CX/MAS 17/38/7 March 2017

# JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

**Thirty-eighth Session** 

**Budapest, Hungary** 

# 8 - 12 May 2017

### PRACTICAL EXAMPLES ON THE SELECTION OF APPROPRIATE SAMPLING PLANS Replies to CL 2017/5-MAS

Comments of New Zealand, Switzerland, Peru, Colombia, Ecuador and Costa Rica

### **Comments of New Zealand**

# **GENERAL COMMENTS**

### **General Comments - publication:**

- 1. New Zealand agrees that there needs to be further consideration of providing theoretical approaches as guidelines, and the provision of practical examples in the form of information documents, prior to finalisation of this, or a later version of the Information Document on Practical Examples.
- 2. We believe that consideration of the proposal for a review of GL50, as well as any outcomes of this review, should take place prior to finalisation and publication of the Information Document on Practical Examples. As stated in our previous (November 2016) comments, it is not clear that the practical examples are needed as an *independent information document* available on the Codex website, until any review of GL50 is complete.
- 3. It is stated in the Information Document on Practical Examples that a revised version of GL50 will refer to the ISO standards, and therefore there might be no need to amend the information document in the future. We believe this approach is pre-empting the outcome of the review of GL50, and potentially limiting the scope of the GL 50 review to align with the Information Document (if published prior).

### General comments – introduction:

- 4. New Zealand does not agree that the Information Document on Practical Examples is, as stated in our previous (November 2016) comments, serving the intended purpose for which the practical examples were originally envisaged, that is, to illustrate the application of the Principles for the use of Sampling and Testing in International Food Trade as set out in CAC/GL 83-2013. In addition, the revised document does not take into account one of our previous (November 2016) comments; it does not provide information on what Consumer Risks and Producers Risks are deemed appropriate, and working out sampling schemes to do this.
- 5. New Zealand does not agree that the Information Document on Practical Examples is just an information document. The criteria for an Information Document are in REP14/GP and as follows:
  - (i) it has been developed and agreed upon by a Codex committee;
  - (ii) it contains information that is useful to national governments and/or Codex members and observers and Codex Committees; and
  - (iii) it is not appropriate to be adopted as a Codex standards, guidelines or codes of practice or as recommendations to be included in the Procedural Manual.

Our comment is that the Information Document on Practical Examples is more than an information document, since it is intended as an independent information document for use by Codex committees and by institutions specialising in sampling and compliance assessment. In this case it should be elaborated through the step procedure set out in the Procedural Manual.

6. We would like the use of the following descriptive terms to be considered, alongside our comments

- a. 'practical'. Does it mean for instance 'used in practice' or 'capable of being put into use' or 'practical as compared to theoretical examples elsewhere'? Perhaps a term like 'worked examples' or just 'examples' would be better?
- b. 'Appropriate sampling plans'. Sampling plans are selected for a particular purpose and for use in a particular set of circumstances. This is explained in detail in GL50; more explanation is needed here to clarify the context.
- c. 'Commodity committees may find alternative plans that are more appropriate'. It needs to be explained how commodity committees could find more appropriate plans than these ones, for which the choice is said to be usually unambiguous.
- d. 'Should not be regarded as prescriptive' and 'Each example is one option for the particular situation'. These statements indicate flexibility, but there seems to be a contradiction with the later statements that 'usually the determination of the appropriate sampling plan is unambiguous' and 'intended for ... compliance assessment.'
- e. 'They do not present fixed values but give reference to correspondent passages of the standards'. This statement needs to be expressed more clearly.

### **SPECIFIC COMMENTS**

### Specific comments: Example sampling plans

New Zealand submitted detailed comments on specific examples in response to CL 2016/4-MAS. We appreciate the changes that have been made in the new version of the Information Document on Practical Examples, and briefly note below the points that should still be considered.

7. Example FV-Q

New Zealand notes that the Information Document on Practical Examples has changed the sentence under the Isolated Lot Decision, so it reads 'is less than'.

We still question whether the ISO table references will result in the outcomes stated.

8. Examples MI-Q, FO-Q

Our suggestion concerning the MI-Q examples has been met to the extent that the reference to combining the process and measurement error standard deviations has been removed. However, the caveat that we suggested, 'If the measurement error is significant, and <u>purely of the repeatability type</u>, the methods suggested in ISO 3951-1:2013 Annex O may be considered' has not been incorporated. In addition, the requirement to refer to Annex O is no longer present; the methods being (purportedly) summarized by the instruction 'the sampling number n should be increased by n\*= n (1+gamma^2) where gamma = sigma\_mu /sigma (ISO 3951-1:2013, Annex O)'.

We have several objections to this:

- 1. n should be increased to, not by, the given quantity
- There is more than just this to it, e.g. in two of the three cases considered the estimate of sigma needs to be corrected, and the instruction that h and p\* should not be adjusted for the new sample size is omitted
- 3. The important restriction of the use of the methods that the measurements needs to be unbiased, (although this is not adequately discussed even in Annex O) is omitted.

If the methods in Annex O are to be used, it is essential that users consult the Annex, rather than rely on the short instruction currently given in the "conditions" column of MI-Q in the Information Document on Practical Examples.

We therefore continue to recommend our original wording, as given above.

We acknowledge that this leaves the question: what to do if the measurement error is not purely of the repeatability type. We are not aware that this has been successfully addressed mathematically. Probably, following a principle that a producer should not export product without reasonable evidence that his product is compliant, and that a consumer should not reject it without reasonable evidence that it is not, there should be a narrowing (producer) or widening (consumer) of the effective specification limits to allow for a reasonable amount of run bias in the respective measuring laboratories. But the Information Document on Practical Examples may not be a good place to put forward such 'ad hoc' solutions.

We also note that our suggestion that attribute sampling (control of the percent defective), even by variable, may be less appropriate in the case of fat or moisture control in milk products, and that control of the mean content may be more appropriate, has not resulted in any change to the document. In our previous (November 2016) comments we noted that in both these cases (MI-Q and FO-Q) control of the lot mean is more appropriate than control of the percentage defective. There is a difficulty in that for control of the lot mean when the process standard deviation is unknown, (the t-test,) some upper limit has to be placed on this standard deviation to get an estimate of consumers' risk. However, this objection does not apply when the process standard deviation is known, as is necessary for the sigma method of sampling by variables to be used.

9. Example M-FH

The statement regarding the decision criterion is ambiguous. It is not clear whether product is to be accepted if:

- a. at most one of the samples had concentration over 1000 CFU/g, or
- b. at most one sample had a non-zero concentration, and that one sample was under 1000 CFU/g.
- 10. Examples M-P, FV-P

The statement regarding how a lot complies with a MRL is not clear with regard to measurement error. The direction in which the allowance for measurement error is made should be stated.

11. Examples FO-R, F-R

The statement on lot compliance under the Decision is not clear, i.e. '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'.

The expression 'mean result ... does not indicate the presence of a residue' offers considerable scope for varying interpretation, and the direction of the required allowance for measurement uncertainty is not stated. We recommend amending this sentence to 'A lot is accepted when the mean result for analysis of the laboratory test portions does not exceed the MRLVD by more than the expanded measurement uncertainty'

12. Examples F-R, FO-R, MI-R, M-R

If these sampling plans for veterinary drugs in food commodities are to remain in the document, the only associated information should be reference to the CAC/GL 71-2009. There should be no interpretation of this guideline, as currently exists. If this wording is to remain, the actual wording that is in CAC/GL 71-2009 should be used.

13. Example F-C

New Zealand notes that this example no longer includes the references to CODEX STAN 193-1995 or the EU legislation.

However we are aware that Codex adopts a method of analysis or sampling only when there is a specified Codex limit. There is no Codex limit for dioxins, and dioxin-like PCBs, and accordingly we consider this document should follow normal practice and the example should be removed.

#### Switzerland

# GENERAL COMMENTS

Switzerland supports the work of the authors as well as the completion of this important document.

We believe that this Information Document efficiently achieves its assigned goal i.e. to help in choosing appropriate sampling plans and in hand with that will also increase significantly the usefulness of the GL 50.

Therefore, Switzerland is of the opinion that this new version should be uploaded on the Codex website dealing with other information documents: <u>http://www.fao.org/fao-who-codexalimentarius/infodoc/en/</u>

#### GENERAL COMMENTS

Peru has the following general comments on Codex Alimentarius CL 2017/5-MAS:

We recommend a review of the document because we believe that it does not relate to "practical examples of sampling plans", but instead to "guidelines for implementation of sampling plans".

Peru

### SPECIFIC COMMENTS

For the proper implementation of *Principles for the use of sampling and testing in international food trade* (CAC/GL 83-2013) we suggest:

#### 1. Page 5

States:

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 Re (Tables 1 and 2 e.g. for single sampling).

It should state:

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 not than the Rejection number Re (Tables 1 and 2 e.g. for single sampling).

#### 2. Page 6

Figure 1: Levels of inspection and the switching between those Figure 1: Levels of inspection and the switching between those

**Justification**: Replace as set out in ISO 2859-1:1999/Amd 1:2011: Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.

#### Colombia

### **GENERAL COMMENTS**

In response to comments by Canada, Norway and New Zealand, Colombia requests that EU sampling plans be included for the following reasons:

The proposal to include European Regulations is supported by the use of highly sensitive and complex analytical methodologies (e.g. GC/MS/MS and LC/MS/MS), which are implemented internationally and meet the validation criteria (selectivity/specificity, precision, detection limits, quantification and robustness) required by international health agencies from different countries.

It is therefore necessary to take into account these sampling models when not developing specific methods but rather performance criteria that satisfy the different analysis methods used for official control, especially for the determination of residues of veterinary drugs in meat, pesticides in fruit, cereals and vegetables, and mycotoxins in milk, as well as other national and international products of interest.

Finally, it is important to clarify that in the case of Directive 63 from 2002 "on establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin …", the Codex Alimentarius Commission has identified and agreed on sampling methods for the determination of pesticide residues for compliance with Maximum Residue Limits (MRL).

# SPECIFIC COMMENTS

EXAMPLE	CF	RITERIA		REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
Fruits and	Visible	defects	in	Isolated lots and continuous series of lots	General concept of lots:	We propose the inclusion of
vegetables -	fruits					criteria to assess the sample
Qualitative				Consumer and producer:		before and after harvest (this
				CAC/GL 50, Section 3.1, see specifically ISO 2859-	Producer:	involves the consumer and the
FV-Q				2:1985	Define sampling units: For	producer)
					example, plants, from which a	
				Procedure A: A plan is identified by the lot size,	certain number of fruits, bunches	The reference document does not
				limiting quality (LQ) and the inspection level (unless	etc. are taken.	specify this concept. It is assumed
				otherwise specified, level II shall be used). The	-	that it only refers to the harvested
				sampling size (n) is given in table A.	Consumer:	product.
					Define sampling units: For	
				Procedure B: A plan is identified by the lot size,	example, boxes, punnets etc.,	Variables and criteria need to be
				limiting quality (LQ) and the inspection level (unless	from which a certain number of	extended to include:
				otherwise specified, level II shall be used). The	fruits or plants are taken etc.	Appearance (e.g. ripeness,
				sampling size (n) is given in table B1 to	depending on the type of product.	physical defects)
				B10		We propose stating specific values
					Guidelines under CAC/GL 50-	obtained from tables (e.g. MIL-
				(see original document: not transcribed due to its	2004- General Guidelines on	STD-414 tables based on
				length)- circular letter annexed	Sampling	percentage of defects in
						accordance with the type of
						defined inspection), as well as
						establishing a sampling plan in
						accordance with the type of defect
						to be considered, making the
						sampling more rigorous.
						Some defects are more critical
						than others, therefore the more
						critical require a tighter
1						acceptance criterion.

EXAMPLE	CRITERIA	REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
EXAMPLE Pesticide residues in fruit and vegetables: FV-P	CRITERIAPesticide residues in apples for compliance with MRLSampling by attributes or variablesSampling dependent on pesticide residue plans for each country	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	PROPOSED ADDITION   REGULATION (EC) 396/2005- on maximum residue levels of pesticides in or on food of plant and animal origin   Sampling:   In accordance with the residue plans for each country   Decision:   Does not exceed 0.01 mg/kg in cases where no MRL has been established in Annexes II or III or in the case of active substances not included in Annex IV of Regulation 396/2005	Extend sampling criteria to include factors based on attributes or variables (CAC/GL 50-2004) and in accordance with the sampling plans cited in the European Regulation. The European regulation is included, which takes into account MRLs in accordance with the criterion of the example. The proposal to include European Regulations is supported by the use of highly sensitive analytical methodologies (e.g. GC/MS/MS and LC/MS/MS), which are implemented internationally and meet the validation criteria
		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. <b>Decision:</b> 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 supporting quality control data.		required by international health agencies from different countries.

Meat- residues Fat soluble pesticide residues Consumer and producer: carcass for compliance with MRL Consumer and producer: carcass for compliance with MRL Consumer and producer: carcass for compliance with MRL Consumer and producer: carcass for compliance sampling for The Determination Of Pesticide Residues For Compliance With MRLs Consumer and producer: carcass for compliance sampling. Inclusion is supported products of plant and animal origin Inclusion is supported products of plant and animal origin   M-P Sampling: The minimum number of primary samples to be taken from which a primary sample is taken in the lot build preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessibil parts of the lot. Each primary sample is considered to be a separate bulk sample. The minimum size of each laboratory sample is give in Thate 3, 2, 1. The analytical sample aprotons to be withdrawn. The size of the analytical portions to build be determined by the analytical portion should be determined by the analytical method and the efficiency of mixing. Decision: See FV-P EGULATION (EC) 396/2005 OF THE EUROPEAN PARLIAMENT: on maximum residue levels of pesticides included, given that it involves a specific ampling or analysis, as indicated by the supporting quality control data. We suggest that Regulation 396/2006 is included, given that it involves a specific ampling or support social control of part and animal origin. We as support social field of plant and animal origin. We as applicable: amplicable: include given that it involves a specific ampling shall be arreferenced in analysis, as indicated by the supporting quality control data. Ne supgest that anindicated of plant and anindicorigin.	EXAMPLE	CRITERIA	REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
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in or on food and feed of plant and animal origin.involves a specific sampling system established by each country based on its own residue plans in account the results are to ensure that the results are representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point ofinvolves a specific sampling sustem established by each country based on its own residue plans in account the results are to ensure that the results are representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point ofinvolves a specific sampling sustem established by each country based on its own residue plans in account the results are to ensure that the results are to ensure that the results of previous control programmes. Such sampling shall be carried out as close to the point of					0
animal origin.samplingSampling:sampling:Each Member State shall take a sufficient number and range of samples to ensure that the results are representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point ofsampling system established by each country based on its own residue plans in accordance with production statistics as well as market behaviour					, 0
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Each Member State shall take a sufficient number and range of samples to ensure that the results are representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point of residue plans in accordance with production statistics as with production statistics as well as market behaviour				Communities and	5
Each Member State shall take a sufficient number and range of samples to ensure that the results are representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point of accordance with production statistics as well as market behaviour				Sampling:	
sufficient number and range of samples production statistics as   to ensure that the results are   representative of the market, taking into account the results of previous control well as market behaviour   programmes. Such sampling shall be carried out as close to the point of account of				Food Mombor State shall take a	
to ensure that the results are representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point of					
representative of the market, taking into account the results of previous control programmes. Such sampling shall be carried out as close to the point of					
account the results of previous control programmes. Such sampling shall be carried out as close to the point of					wen as market benaviour
programmes. Such sampling shall be carried out as close to the point of					
carried out as close to the point of					
				supply as is reasonable, to allow for any	

			subsequent enforcement action to be	
			taken	
EXAMPLE	CRITERIA	REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
Cereal-	Pesticide residues in	Consumer and producer:	COMMISSION DIRECTIVE 2002/63/CE:	Inclusion is supported
Pesticide	rice grains	CAC/GL33-1999: Recommended Methods Of	Establishing methods of sampling for	given that sampling
Residues		Sampling For The Determination Of Pesticide	the official control of pesticide residues	procedures are those
		Residues For Compliance With MRLs	in and on products of plant and animal	recommended by the
C-P			<u>origin</u>	Codex Commission
		Sampling:		document CAC/GL 33 of
			Sampling	1999 as referenced in
		The minimum number of primary samples to be	Sampling procedures must be in	Directive 2002/63/CE.
		taken from a lot is determined from Table 1b. The	accordance with Commission Directive	
		primary samples must contribute sufficient material	2002/63/CE	
		to enable all laboratory samples to be withdrawn	Destates	
		from the bulk sample. The position from which a	Decision:	
		primary sample is taken in the lot should preferably	Where recults from the bulk comple	
		be chosen randomly but, where this is physically impractical, it should be from a random position in	Where results from the bulk sample exceed MRL, a decision that the lot is	
		the accessible parts of the lot.	non-compliant must take into account:	
			i) the results obtained from one or	
			several laboratory samples, as	
		Sampling devices required for grain are described	applicable; ii) the accuracy and	
		in ISO recommendations.	precision of analysis, as indicated by	
			the supporting quality control data.	
		The primary samples should be combined and	the supporting quality control data.	
		mixed well, if practicable, to form the bulk sample.		
		The minimum size of each laboratory sample (1 kg)	REGULATION (EC) 396/2005 OF THE	
		is given by Table 4, 2. The analytical sample should	EUROPEAN PARLIAMENT- on	
		be comminuted, if appropriate, and mixed well, to	maximum residue levels of pesticides	
		enable representative analytical portions to be	in or on food of plant and animal	We suggest that
		withdrawn. The size of the analytical portion should	origin.	Regulation 396/2005 is
		be determined by the analytical method and the efficiency of mixing.		included, given that it
			Sampling:	involves, a specific
		Desision		sampling system
			Each Member State shall take a	established by each
		See FV-P	sufficient number and range of samples	country based on its own
			to ensure that the results are	residue plans in
			representative of	accordance with market
				behaviour

EXAMPLE	CRITERIA	REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
			the market, taking into account the	
			results or previous control	
			programmes. Such sampling shall be	
			carried out as close to the point of	
			supply as is reasonable, to allow for any	
			subsequent enforcement action to be	
			taken.	

Contaminants(bulk) according to market presentation or type of presentation – homogeneity of the bulk lot (market milk)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: General Standard For Contaminants And Toxins In Food And Feed Sampling: See example C-C.401/2006international reg a normative which lays or methods of sar analysis for t contaminants And Toxins In Food And Feed Sampling: See example C-C.401/2006international reg a normative which lays or methods of sar analysis for t contaminants And Toxins In Food And Feed Sampling: See example C-C.401/2006international reg a normative which lays or methods of sar analysis for t contaminants And Toxins In Food And Feed See example C-C.Decision: See example C-C. For the given maximum limit mL=0.5 µg/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results x is lower than an upperIn addition, the the products, the lot shall be and insofar it does not affect the quality of the product, by either manual or mechanical means, immediately prior to	TION	JUSTIFICATION	PROPOSED ADDITION	REFERENCE DOCUMENT	CRITERIA	EXAMPLE
MI-Cmarket presentation or type of presentation – homogeneity of the bulk lot (market milk)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: General Standard For Contaminants And Toxins In Food And Feed Sampling: See example C-C.The aggregate sample shall be at least 1 kg or 1 litre except where it is not possible e.g. when the sample consists of one bottle.a normative methods of sar analysis for t contorl of c content in food.Decision: See example C-C. Decision: See example C-C. For the given maximum limit mL=0.5 μg/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results X is lower than an upper acceptance value Xu = mL + γ DThe number of incremental samples the ot to is accepted if the sample grand average of these results X is lower than an upper acceptance value Xu = mL + γ DIn this case, a homogeneous satisfying sampling. In this case, a homogeneous countries.a normative which lays of methods of sar analysis for t contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results X is lower than an upper acceptance value Xu = mL + γ DSampling. In this case, a homogeneous sufficient to take three incremental samples from a lot to form the aggregatea normative which lays of methodolgies the rotace, a homogeneous sufficient to take three incremental samples from a lot to form the aggregate	luding this	We suggest including	COMMISSION REGULATION (EC) No	Consumer and producer:	Aflatoxin M1 in milk	Milk (bulk) -
MI-Ctype of presentation – homogeneity of the bulk lot (market milk)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: General Standard For CODEX STAN 193-1995: General Standard For See example C-C.The aggregate sample shall be at least 1 tkg or 1 litre except where it is not possible e.g. when the sample consists of one bottle.which lays on methods of sar analysis for tThe aggregate sample shall be at least 1 (context innants And Toxins In Food And Feed Sampling: See example C-C.The number of incremental samples for inclusion of the usual form in which the products, the lot shall be thoroughly mixed insofar as possible of these results X is lower than an upper acceptance value Xu = mL + γ DThe aggregate sample shall be at least 1 kg or 1 litre except where it is not possible e.g. when the sample consists of one bottle.In addition, the for inclusion of Regulations is by the use commercialised. In the case of bulk international and insofar it does not affect the quality of these results X is lower than an upper acceptance value Xu = mL + γ DIn addition, the is sampling. In this case, a homogeneous distribution of aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate	julation as	international regulation	401/2006	CAC/GL 50 section 5, see specifically: ISO	(bulk) according to	Contaminants
homogeneity of the bulk lot (market milk)ISO 11648-1:2003: Statistical aspects of sampling from bulk materials — Part 1: General principles. CODEX STAN 193-1995: General Standard For Contaminants And Toxins In Food And Feed Sampling: See example C-C.The aggregate sample shall be at least 1 kg or 1 litre except where it is not possible e.g. when the sample consists of one bottle.methods of sar analysis for t control of contaminants and Toxins In Food And Feed Sampling: See example C-C.The aggregate sample shall be at least 1 kg or 1 litre except where it is not possible e.g. when the sample consists of one bottle.methods of sar analysis for t control of contaminants and Toxins In Food and Feed), the lot is accepted if the sample grand average of these results X is lower than an upper acceptance value Xu = mL + γ DThe aggregate sample shall be at least 1 kg or 1 litre except where it is not possible e.g. when the sample consists of one bottle.methods of sar analysis for t control of contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results X is lower than an upper acceptance value Xu = mL + γ DThe aggregate sample shall be at least 1 kg or 1 litre except where it is not contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results X is lower than an upper acceptance value Xu = mL + γ DThe aggregate sample shall be the product, by either manual or mechanical means, immediately prior to sampling. In this case, a homogeneous uitternational agencies from countries.	reference,	a normative refere		10725:2000: Acceptance sampling plans and	market presentation or	
bulk lot (market milk) sampling from bulk materials — Part 1: General principles. CODEX STAN 193-1995: General Standard For Contaminants And Toxins In Food And Feed Sampling: See example C-C. Decision: See example C-C. For the given maximum limit mL=0.5 μg/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results X is lower than an upper acceptance value Xu = mL + γ D	down the	which lays down	Sampling:	procedures for the inspection of bulk materials /	type of presentation -	MI-C
principles. CODEX STAN 193-1995: General Standard For Contaminants And Toxins In Food And Feed Sampling: See example C-C.kg or 1 litre except where it is not possible e.g. when the sample consists of one bottle.control of content in food.Decision: See example C-C. For the given maximum limit mL=0.5 µg/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results X is lower than an upper acceptance value Xu = mL + γ DThe number of incremental samples commercialised. In the case of bulk invici the graduated for commercialised. In this case, a homogeneous distribution of aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregatecontrol of control of content in food.	npling and	methods of sampling			homogeneity of the	
CODEX STAN 193-1995: General Standard For Contaminants And Toxins In Food And Feed Sampling: See example C-C.possible e.g. when the sample consists of one bottle.content in food.Decision: See example C-C. For the given maximum limit mL=0.5 $\mu$ g/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results $\overline{x}$ is lower than an upper acceptance value $\overline{x}u = mL + \gamma D$ The number of incremental samples of one bottle.In addition, the for inclusion of the usual form in which the products concerned are commercialised. In the case of bulk liquid products, the lot shall be thoroughly mixed insofar as possible adistribution of aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregatecontent in food.	ne official	analysis for the of		sampling from bulk materials — Part 1: General	bulk lot (market milk)	
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$	mycotoxin		kg or 1 litre except where it is not	principles.		
Sampling: See example C-C. Decision: See example C-C. For the given maximum limit mL=0.5 $\mu$ g/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results $\overline{x}$ is lower than an upper acceptance value $\overline{x}u = mL + \gamma D$ $u = mL + \gamma D$		content in food.	possible e.g. when the sample consists			
See example C-C. Decision: See example C-C. For the given maximum limit mL=0.5 $\mu$ g/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results $\overline{x}$ is lower than an upper acceptance value $\overline{x}u = mL + \gamma D$ The number of incremental samples in which the products concerned are commercialised. In the case of bulk liquid products, the lot 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 aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate			<u>of one bottle.</u>	Contaminants And Toxins In Food And Feed		
$\frac{determined is function of the usual form in which the products concerned are commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised. In the case of bulk is by the use commercialised international standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results \overline{x} is lower than an upper acceptance value \overline{x}u = mL + \gamma D is assumed distribution of aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate international samples from a lot to form the aggregate international samples from a lot to form the aggregate international samples from a lot to form the aggregate international samples from a lot to form the aggregate international samples from a lot to form the aggregate international samples from a lot to form the aggregate international samples from a lot to form the aggregate international samples from a lot to form the aggregate international samples from a lot to form the aggregate is the sample again the sample$		In addition, the prop				
Decision: See example C-C. For the given maximum limit mL=0.5 $\mu$ g/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results $\overline{x}$ is lower than an upper acceptance value $\overline{x}u = mL + \gamma D$ in which the products concerned are commercialised. In the case of bulk liquid products, the lot 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 aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate		for inclusion of Europ		See example C-C.		
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For the given maximum limit mL=0.5 $\mu$ g/kg (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results $\overline{x}$ is lower than an upper acceptance value $\overline{x}u = mL + \gamma D$ <b>liquid products, the lot shall be</b> 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 aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate	of highly	5				
$ \begin{array}{c} (CODEX STAN 193-1995: General Standard for Contaminants and Toxins in Food and Feed), the lot is accepted if the sample grand average of these results \overline{x} is lower than an upper acceptance value \overline{x}u = mL + \gamma D \end{array} \begin{array}{c} \begin{tabular}{ll} 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 satisfying criteria requiremental distribution of aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate contract of the adgregate distribution of a lot to form the adgregate distribution of adjust and the adjust$	analytical			•		
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the lot is accepted if the sample grand average of these results x̄ is lower than an upper acceptance value x̄u = mL + γ D within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate the lot is accepted if the sample grand average of the product, by either manual or mechanical means, immediately prior to sampling. In this case, a homogeneous distribution of aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate		, ·				
of these results $\overline{x}$ is lower than an upper acceptance value $\overline{x}u = mL + \gamma D$ $\overline{x}u = mL + \gamma D$ $\overline{x}$	at an	•				
acceptance value x̄u = mL + γ D sampling. In this case, a homogeneous distribution of aflatoxin M1 is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate criteria requiremental contents	level					
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within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregateagencies from countries.				acceptance value $\overline{x}u = mL + \gamma D$		
sufficient to take three incremental countries.	health					
samples from a lot to form the aggregate	different	5				
		countries.				
sample.						
			sample.			
The incremental samples, which might		l	The incremental samples, which might			
frequently be a bottle or a package, shall		l				
be of similar weight. The weight of an		l				

	incremental sample shall be at least 100	
	grams, resulting in an aggregate sample	
	of at least about 1 kg or 1 litre. Departure	
	from this method shall be recorded in	
	the record provided for under part A.3.8	
	of Annex I.	

#### Ecuador

### **GENERAL COMMENTS**

Ecuador thanks Germany for the opportunity to comment on the information document on practical examples of sampling plans.

Ecuador would like to state the following:

- The document attached to CL 2017/5-MAS is an informative document that refers to practical examples of sampling plans, which may or may not be accepted, and;
- The examples given in the document are based on or refer to documents such as: ISO, OIML, ICMSF that are internationally recognized.

Therefore, Ecuador believes that the document is very well structured and offers clear examples of sampling for different cases, and fulfils the main objective, which is to offer practical examples of sampling methodologies.

In view of what has been said, Ecuador does not submit comments on the document and supports the progression of the document to the next step.

#### **Costa Rica**

# **GENERAL COMMENTS**

Costa Rica appreciates the opportunity given to submit comments to the Committee. Nevertheless, our country has no further comments on the practical examples of sampling plans made in Appendix I because the examples given are based on standards from the International Organization for Standardization (ISO) that are in force and internationally accepted.