CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 7 **CX/MAS 17/38/7**
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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 purely of the repeatability type, 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
   2. 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: http://www.fao.org/fao-who-codexalimentarius/infodoc/en/

Peru

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”.

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	CRITERIA	REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
Fruits and vegetables - Qualitative **FV-Q**	Visible defects in fruits	**Isolated lots and continuous series of lots** **Consumer and producer:** CAC/GL 50, Section 3.1, see specifically ISO 2859-2:1985 …. 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…….. (see original document: not transcribed due to its length)- circular letter annexed	**General concept of lots:** **Producer:** **Define sampling units: For example, plants, from which a certain number of fruits, bunches etc. are taken.** **Consumer:** **Define sampling units: For example, boxes, punnets etc., from which a certain number of fruits or plants are taken etc. depending on the type of product.** **Guidelines under CAC/GL 50-2004- General Guidelines on Sampling…**	We propose the inclusion of criteria to assess the sample before and after harvest (this involves the consumer and the producer) The reference document does not specify this concept. It is assumed that it only refers to the harvested product. Variables and criteria need to be extended to include: Appearance (e.g. ripeness, physical defects) We propose stating specific values obtained from tables (e.g. MIL-STD-414 tables based on 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 acceptance criterion.

EXAMPLE	CRITERIA	REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
Pesticide residues in fruit and vegetables: **FV-P**	Pesticide residues in apples for compliance with MRL **<u>Sampling by attributes or variables</u>** **<u>Sampling dependent on pesticide residue plans for each country</u>**	**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:** 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.	**<u>REGULATION (EC) 396/2005- on maximum residue levels of pesticides in or on food of plant and animal origin</u>** **<u>Sampling:</u>** **<u>In accordance with the residue plans for each country</u>** **<u>Decision:</u>** **<u>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</u>**	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 required by international health agencies from different countries.

EXAMPLE	CRITERIA	REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
Meat-Pesticide residues **M-P**	Fat soluble pesticide residues in cattle carcass for compliance with MRL	**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	**COMMISSION DIRECTIVE 2002/63/CE: Establishing methods of sampling for the official control of pesticide residues in and on products of plant and animal origin** **Sampling** **Sampling procedures must be in accordance with Commission Directive 2002/63/CE** **Decision:** **Where results from the bulk sample exceed MRL, a decision that the lot is non-compliant must take into account: i) the results obtained from one or several laboratory samples, as applicable; ii) the accuracy and precision of analysis, as indicated by the supporting quality control data.** **REGULATION (EC) 396/2005 OF THE EUROPEAN PARLIAMENT: on maximum residue levels of pesticides in or on food and feed of plant and animal origin.** **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 of supply as is reasonable, to allow for any**	Inclusion is supported given that sampling procedures are those recommended by the Codex Commission document CAC/GL 33-1999 as referenced in Directive 2002/63/CE. We suggest that Regulation 396/2005 is included, given that it involves a specific sampling system established by each country based on its own residue plans in accordance with production statistics as well as market behaviour

			subsequent enforcement action to be taken	
EXAMPLE	**CRITERIA**	**REFERENCE DOCUMENT**	**PROPOSED ADDITION**	**JUSTIFICATION**
Cereal-Pesticide Residues **C-P**	Pesticide 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	**COMMISSION DIRECTIVE 2002/63/CE: Establishing methods of sampling for the official control of pesticide residues in and on products of plant and animal origin** **Sampling** **Sampling procedures must be in accordance with Commission Directive 2002/63/CE** **Decision:** **Where results from the bulk sample exceed MRL, a decision that the lot is non-compliant must take into account: i) the results obtained from one or several laboratory samples, as applicable; ii) the accuracy and precision of analysis, as indicated by the supporting quality control data.** **REGULATION (EC) 396/2005 OF THE EUROPEAN PARLIAMENT- on maximum residue levels of pesticides in or on food of plant and animal origin.** **Sampling:** **Each Member State shall take a sufficient number and range of samples to ensure that the results are representative of**	Inclusion is supported given that sampling procedures are those recommended by the Codex Commission document CAC/GL 33 of 1999 as referenced in Directive 2002/63/CE. We suggest that Regulation 396/2005 is included, given that it involves, a specific sampling system established by each country based on its own residue plans in 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.	

EXAMPLE	CRITERIA	REFERENCE DOCUMENT	PROPOSED ADDITION	JUSTIFICATION
Milk (bulk) - Contaminants **MI-C**	Aflatoxin M1 in milk (bulk) according to market presentation or type of presentation – homogeneity of the bulk lot (market milk)	**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: *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 $\bar{x}$ is lower than an upper acceptance value $\bar{x}u = mL + \gamma D$	**COMMISSION REGULATION (EC) No 401/2006** **Sampling:** **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.** **The number of incremental samples determined is function 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 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 sample.** **The incremental samples, which might frequently be a bottle or a package, shall be of similar weight. The weight of an**	We suggest including this international regulation as a normative reference, which lays down the methods of sampling and analysis for the official control of mycotoxin content in food. In addition, the proposal for inclusion of European Regulations is supported by the use of highly complex analytical methodologies (LC/MS, HPLC/FL), which are implemented at an international level satisfying validation criteria required by international health agencies from different countries.

			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.