codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 **CX/MAS 01/3-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Twenty-third Session
Budapest, Hungary, 26 February – 2 March 2001

PROPOSED DRAFT GENERAL GUIDELINES ON SAMPLING
GOVERNMENT COMMENTS AT STEP 3

IRELAND

Editorial suggestions

Since this is a general guidance document intended for the commodity committees, Ireland considers that its quality would be enhanced by the following additions:

2.1.1 General
A sentence should be added which states, that the commodity committees should take cognisance of existing international sampling standards relating to their specific areas before developing a standard their area.

2.2 Commonly used terms and notions

"2.2. Consignment", comes before "2.2.1 lot", in the sampling hierarchy and they should be interchanged.

The inclusion of a flow diagram in this section would also add to its clarity – one taken from the literature is appended (not available in the electronic version - Annex 1 of the printed version).

5.2 Standardised sampling procedures for the inspection of individual lots.
There is a missing step, i.e. "preparation of the test sample for measurement" and this should be inserted between "Drawing of the test… and Measurement of specified"..

BRAZIL

Comments on CX / MAS 01/3 and CX / MAS 01/3 CORRIGENDUM

SECTION 1.
1.3 page 4
Delete this item including the table 1 or rewrite this table in a correct and clearest way.

1.4 page 6
Add all reference documents, include those described in section 6.
Add **ISO 11648 – 1**

2.1.2 page 8
Add to the sentence in the page 8 in the first paragraph last item:

- The procedures to be adopted for collecting, handling and recording the sample(s). **These procedures should be indicated by the appropriated CODEX COMMODITIES COMMITEE**.

2.4.1.2.1 page 16

in 14th line, **the constant K must be defined and it is important to explain how to obtain it.**

2.4.1.2.2.1 Page 16

Add title for TABLE 3.

TABLE 3. Acceptance/ rejections rules of the lots for single sampling plan by variable, known standard deviation

In the example after the table 3, below AQL = 2,5 %, add
sigma = known standard deviation = 3,5 mg

page 17

After the mean calculation, page 17, **delete the calculation for sigma**. This example do not need this calculation.

All figures: 2, 3 and 4 must have the title, write below the corresponding figure**, as the follow example for Figure2.**

FIGURE 2. Operating Characteristic Curve for single sampling plan by variable, known standard deviation, n=5, K=1,39.

2.4.1.2.3 Page 18

Add title for TABLE 4.

TABLE 4. Acceptance/ rejection rules of the lots for single sampling plan by variable, unknown standard deviation.

2.4.1.2.4 page 19

Add title for figure 3 and table 5

2.4.1.3 page 20

Add title for Figure 4.

Correct 1st paragraph "(20,7%)" **for** "(21,4%)"**;** "(36)"**for** "(36,5)"
Correct the table title "(30%)"**for** "(36,5%)"

2.4.2 page 23

Correct 2nd paragraph **"PPM"** for **"mg/kg"**

SECTION 3

3.1.1 page 25

After "The application of procedure A may be illustrated as follows", Delete:
Summary of sampling plan
(Table D1 in ISO 2859/2 – 1985 (E)

3.1.2 page 26

After "The application of procedure B may be illustrated as follows", Delete:
Summary of sampling plan
(Table B1 – B10 in ISO 2859/2 – 1985 (E)

3.2 page 26

Delete this reference and include to item 1.4, page 6 (original document)

3.2.1 page 26

After the equation to calculate C delete **summary of a two – class attributes plan** and write:
"The application of a two-class attributes plan may be summarized as follows:"

3.2.2 page 28
After the equation to calculate *P*a delete **summary of three-class attributes sampling plans** and write as follow
"The application of a two-class attributes plan may be summarized as follows:"
Before the EXAMPLE (page 28), complete the last sentence as follows
"Immediately reject the lot if the concentration of micro-organisms in any item > M **and/or number of marginally defective item > c.**

3.2.3 page 29
Bold "Two and three-class attributes plans are ideally suited for regulatory, port-of-entry, and other consumer-oriented situations where little information is variable concerning the microbiological history of the lot. The plans are independent of lot size if is large in comparison to sample size."

Transfer "Table 10 of the ICMSF publication classifies 15 different "cases" of sampling plans taking these factors into consideration, the stringency of the plans increasing with the type and degree of hazard. Case 1 requires the most lenient plan whereas Case 15 represents the most stringent requirement. In table 10, a sampling plan is recommended for each of the 15 "cases" for after examples

SECTION 4.

4.1 page 30 - Titles for table 7 and figure 5.

4.1 page 31 - Write a title for Table 7 and rewrite it as shown below, keeping the same figures:

"Table 7. Probability to accept lots in normal inspection plans with AQL = 2,5%.

Defective rates in the lots	**Probability to accept these lots**			
	n = 2 c = 0 **P_{95} = 2,53%** **P_{50} = 29,3%** **P_{10} = 68,4%**	**n = 8 c = 1** **P_{95} = 2,64%** **P_{50} = 20%** **P_{10} = 40,6%**	**n = 13 c = 2** **P_{95} = 6,63%** **P_{50} = 20%** **P_{10} = 36%**	**n = 20 c = 3** **P_{95} = 7,13%** **P_{50}= 18,1%** **P_{10} = 30,4%**
0%	**100%**	**100%**	**100%**	**100%**
				...
100%	**0%**	**0%**	**0%**	**0%**

Table 7 delete in all cells the indexes of **P_{95} , P_{50}** e **P_{10}**
Put 99% in the 3rd row and 6th cell
Delete all the footnotes 18, 19, 20, 21 e 22

4.1 page 32
Change in the 3rd paragraph the word **"lower"** by **"smaller"**

4.2.1 page 32
After **"General"** put **"The principle of such sampling plans is presented in Section 2.4.1.1"**

4.2.1 page 33
Bold all first paragraph and the 4th paragraph **"Unless otherwise specified inspection level II should be used ".**
Delete in 5th paragraph **"Summary of sampling plans by attributes".**
Put in 5th paragraph of 4th line of the flowchart/diagram **"n"** and **"c"** in parentheses

4.2.1page 33
delete in the 3th paragraph **"essentially the same conditions at essentially the same time"** and put **"statistical and controlled conditions"**
delete the 20th line **"Summary of sampling plans by attributes"**

4.2.2 page 33

In the first paragraph delete **"a"** before **"for covering frequent"**

first paragraph to bold:

"This document recommends the following simple sampling plans, **for covering frequent inspection situations."**

4.2.2. page 34

After the formulae to calculate C rewrite the text as follow:

"Table 8 (ISO 2859-1, Table I) indicates the corresponding between the letter code of the sample size and the lot size. Table 9 (ISO 2859-1, Table IIA) indicates the sample size in the case of a normal inspection."

Delete the Table 8, of the original document, and

Replace the table 8 for the Table I from ISO 2859-1. "Table 8. Sample size code letters"

Include new table: Table 9

Table II-A from ISO 2859-1 "Single sampling plans for normal inspection"

4.2.2.1 page 34

Delete the whole item including Table 9 and Figure 6 (page 35)

4.2.2.2 page 35

Delete Table 9 and Figure 6, of the original document and,

4.2.2.2 page 35

Delete this item and write a sentence as follow

"Examples of sampling plans covering frequent inspection situations using AQL = 2,5%, Table 10 and Figure 7 (original number). Table 10 have been obtained from the equation cited in item 4.2.2 whose charts are presented in Figure 7.

"Examples of sampling plans covering frequent inspection situations using AQL = 2,5%, Table 10 and Figure 7 (original number). Table 10 figures have been obtained from the equation cited in item 4.2.2 whose charts are presented in Figure 7.

4.2.2.2 page 36

NOTE: With the modifications suggested in this document, the Figure 7 from the original document will be Figure 6.

page 37

Write a title for Table 10 and rewrite it as shown below, keeping the same figures:

"Table 10. Probability to accept lots in normal inspection plans with AQL = 2,5%, using different letter codes."

Defective rates in the lots	**Probability to accept these lots**			
	Letter – code C n = 5 c = 0	**Letter – code F n = 20 c = 1**	**Letter – code G n = 32 c = 2**	**Letter – code H n = 50 c = 3**
0%	**100%**	**100%**	**100%**	**100%**
				...
100%	**0%**	**0%**	**0%**	**0%**

Write a title for Figure 6 (Figure 7, departing from the original document)

"Figure 6. Operating characteristic curve for single sampling plan normal inspection by attribute, AQL = 2,5 % and different letter codes.

4.2.2.3 page 37.
Delete the whole item including Table 11(page 37) and Figure 8 (page 38).

Include new table: (Table 11 according this document)
Table XC1 from ISO 2859-1 "Tabulated values for operating characteristic curves for single sampling plans"

Include new Figure: (Figure 7 according this document)
Chart C from ISO2859-1 "Operating Characteristic Curves for Single Sampling Plans"

4.3.1 page 39

The first 4 lines in the second paragraph must be bolded:
"**It is only applicable where**... till **closely approximating normality**."

4.3.1 page 40

Delete first sentence **"Summary of variable sampling plans"**
The letters and numbers used as a code must be always write down in a parentheses.

rewrite the 7th line as follow:
"Select sample size (n) , acceptability constant (k) and collect sample"

4.3.1.2 page 40
b) replace consult table 3 for **"see Table 3"**

4.3.2.1 page 40
Delete the letter **"a"** of 1st paragraph in 1st line

Rewrite the 3th paragraph as follow
"Table 12 (number according to this document) (ISO 3951 – Table IA) indicates the correspondence between the letter code of the sample size and the lot size. Table 13 (number according to this document) (ISO 3951 – Table IB) indicates the sample size in the case of a normal inspection."

Delete Table 12

Include new two tables**: (Table 12 and table 13 according this document)**
Table IA from ISO 3951 "Sample size code letters and inspection levels" and
Table IB from ISO 3951 "Sample size code letters and sample sizes for normal inspection"

4.3.2.2 page 41
Delete all the item 4.3.2.2, and table 13.

Page 42
Delete FOLL. Table 13
Write a new paragraph, after the new two tables, continuing item 4.3.2.1

"Examples of sampling planes by variables – s method, covering frequent inspection situations, Table 14 and Figure8 (numbers according to this document). Table 14 and Figure 8 illustrate the probability of acceptance and operating characteristic curves for single sampling plans - s method, using different letter code for normal inspection, respectively"

4.3.2.3 page 44

Delete the whole item and **rewrite the Table 14 using only integer numbers for defective rates in the lots (first column).**

Replace NQA in the table for AQL, and N for n.

Write a title for this table14

Page 45

Delete FOLL.Table14

Page 46

Write a title for Figure 11 (original document) or Figure 8 (according to this document), as shown below:

"Figure 8. Operating Characteristic Curve for single sampling plans variable, s- method, normal inspection with AQL= 2,5% and different letter codes."

4th paragraph: Include new table(Table 15 according to this document)

Write a new paragraph continuing item 4.3.2.1

"Table 15 (ISO 3951 – Table V-C-1) and Figure 9 (ISO 3951 – chart V-C) illustrate the probability of acceptance and Operating Characteristic Curves for single sampling plans normal inspection for the same letter code (c) and different AQLs."

Include new table **: (Table 15 according this document)**

Table V-C-1 from ISO 3951 " Tabulated values for operating characteristic curves for single sampling plans"

Include new Figure**: (Figure 9 according to this document)**

Chart V-C from ISO 3951 "Operating Characteristic Curves for single sampling plans"

4.3.3.1 page 47

What means the * in the equation?

Rewrite the 3rd paragraph, after the equation as follow

"The correspondence between the letter code of the sample size and the lot size is indicated in Table 12. The Table 13 (ISO 3951) indicates the sample size in the case of a normal inspection. These Tables are already presented in the item 4.3.2.1."

page 47

Delete Table 15 and Table 16 (original document)

4.3.3.2 page 48

Delete whole item, including the table 17.

Page 49

Delete Table 17 FOLL**.**

Page 50

Delete Figures 13 and 14.

4.3.3.3 page 51

Delete the whole item and write a new paragraph as follow

"Examples of sampling plans by variable, sigma method, covering frequent inspection situations using AQL = 2,5%, Table 18 and Figure 9 (original document) Table 16 and Figure 9 (numbers according to this document). Table 16 have been obtained from the equation cited in item 4.3.3.1 whose charts are presented in Figure 9.

NOTE: With the modifications suggested in this document, the Table 18 and Figure 9 from the original document will be Table 16 and Figure 9.

Write a title for Table 16 and rewrite it keeping the same figures as follow:

"Table 16. Probability to accept lots in normal inspection plans with AQL = 2,5%, using different letter codes."

Defective rates in the lots	**Probability to accept these lots**				
	Letter code D n= 3 K=1,17	**Letter code E n=4 K=1,28**	**Letter code F n=5 K=1,39**	**Letter code G n=7 K=1,45**	**Letter code H n=9 K=1,49**
0%	**100%**	**100%**	**100%**	**100%**	**100%**
…					**…**
	0%	**0%**	**0%**	**0%**	**0%**

Page 52

Delete Table 18 FOLL.

Page 53

Add title in Figure 9 and do the typo corrections:
Delete "e" from the word method sigma
Replace QL for LQ

Delete Figure 16 (original document)

4.3.4 page 54

After the item title
Delete the three first lines from **When** … till **authority.**

Consider the sentence For example till s instead of sigma, because it is not an example, and it should be add an item describing the rules and proceedings for switching from s method to the sigma method and vice-versa.

SECTION 5

Rewrite the section 5 considering all the contents of the ISO/DIS 10725

CZECH REPUBLIC

General comment

Document prepared for the 23rd Session of Codex Committee should have been circulated for comments in complete version (i.e. with all changes and amendments that are laying down in corrigendum). Moreover some changes and amendments are not clear enough and final wording is confused (see comments below). It would be better to prepare new consolidated document before 23rd Session.

A. Comments to the main document (CX/MAS 01/3)

1. page 2 - 3, Table of Contents
   a) some chapters under the Section 1 are missing (1.3, 1.4)
   b) two items under the chapter 2.1 are missing (2.1.1, 2.1.2)
   c) titles of all items under the chapter 2.2 don´t correspond to the names of items in text on pages 8 – 12,
   d) some items under the chapter 2.2 are missing (2.2.12 – 2.2.15)
   e) title of the chapter 2.3 doesn´t correspond to the title of the chapter on page 12
   f) titles of some items under the chapter 2.3 don´t correspond to the titles of items in text on pages 12 - 14
   g) title of the chapter 2.4 doesn´t correspond to the title of the chapter on page 14
   h) titles of items under the chapter 2.4 don´t correspond to the titles of items in text

i) title of the section 3 doesn´t correspond to the title of the section on page 25
j) numbering of items under the chapter 3.1 is not correct (should be 3.1.1 and 3.1.2)
k) titles of the chapters 4.1, 4.2 and 4.3 don´t correspond to the title of the chapter on page 30, 32 and 39
l) titles of items under the chapters 4.2 and 4.3 don´t correspond to the titles of items in text
m) titles of sections, chapters and items under 5, 6 and 7 don´t correspond to the titles in text

2. page 8, 2.2.1 Lot, Note – it is not clear, if it should be changed according to the corrigendum or if it should remain
3. page 19, Figure 3 – title in the box is not in English
4. pages 36, 38, 43, 46, 50, Figures 7, 8, 9, 11, 13, 14 – some of lines / curves are not visible in printed document

B. Comments to the Corrigendum (CX/MAS 01/3-CORRIGENDUM)

1. The Corrigendum should have contained new Table of Content.
2. page 2, Figure – it is not clear, why two lines are around the mean value
3. page 4 – it is not clear, where is the end of Foreword
4. page 4, item 1.1 – it is not clear, where should be the "3rd §" inserted into
5. page 4, "Insert a new section 1.3 …." – it is not clear, if should be whole "old text" replaced by new wording or if should be "new text" insert as new chapter and "old" chapter should be renumbered
6. page 4, Table 1 – changes in "old" Table 1 are not clear enough
7. page 4, 2.2.1 Lot – it is not clear, if "new" Note should be add to the "old" or if "old" note should be replaced
8. page 4, Remarks 1 and 2 (under the line) – remarks should have had another numbers, otherwise numbering of remarks in consolidated document is in duplicate (it also regards to the all other remarks in Corrigendum)
9. page 7, 2.4.1.2.3 – Table 4, Conclusion – it is not clear, why it is referred to the Table 3 in the Conclusion (correct reference should be probably to the Table 4)

DENMARK

With reference to the document CX/MAS 01/3 - Proposed Draft General Guidelines on Sampling we hereby submit the Danish comments to the proposal.

First of all we want to express our appreciation to the extensive work, which have been done by the drafters of the present document. We really find that the applicability of the General guidelines have been improved.

However, an examination of the proposed draft shows, that the intentions to make the draft easier, simpler and more user-friendly have, unfortunately, not been fulfilled. This goal would probably also have been very difficult to reach, as it is extremely difficult on one hand to describe sampling in a general and user-friendly way, and on the other hand to give a thorough and statistical correct description of sampling.

The draft stresses the importance to make decisions, when a sampling plan is drawn up, and before the samples are taken. However, this important aspect is often neglected. Section 2.1.2 gives a good overview of points to consider. It should also include a description on what characteristic is to be controlled at which limits, and how the characteristic is going to be determined or analysed.

The section with vocabulary and main notions of sampling is very useful when drawing up a sampling plan. Problems arise often from different understanding of terms. Therefore it is also important to indicate, where the meaning of sampling terms differ from the ISO 7002 standard.

The draft will be an important instrument for Codex Committees in their work with new standards. It gives a good statistical background for understanding sampling problems, so they can be avoided in new Codex Standards. The draft does not give any assistance in solving the practical aspects and problems as "How to sample a container?" or "What equipment is recommended for sampling?" The draft cannot be used as the Handbook in Sampling, which there still is a need for.

HUNGARY

The proposed Draft General Guidelines on Sampling is not very easily understandable and difficult to discuss. For this reason it is not enough to prepare a Corrigendum. The accepted changes and corrections should be included in the document CX/MAS 01/3.

Our detailed comments are the following:

1. The table of contents and the titles of sections or chapters in the text should be the same (e.g. 2.3. Sample Technique or Sampling Procedures etc.). Several indicated chapters in the document are not existing.
2. The erroneous quotations of sections should be corrected e.g. on page 7.
3. The indicated formula for σ on page 17 is erroneous. Namely, the value of σ can not be calculated on the basis of a small amount of samples. It must be either given or calculated in advance on the basis of a large amount of collected data during a long stable production.
4. The criterion for „lot is refused" is erroneous in the case of inspection of a range of values on page 20 and 22. Namely, the criterion for refusing in these can not be contracted. The decision must be based on the place of the mean value of x compared with U and L, respectively. The comparison of U–L with 2 Kσ or 2 Ks is not suitable for decision. Therefore we suggest to change these categories as follows:

   Page 20 Lot is refused if mean (x) < L+Kσ or mean (x) > U- Kσ

   Page 22 Lot is refused if mean (x) < L+Ks or mean (x) > U- Ks
5. Section 2.4.1.2.4.
   <u>There is no reason to compare the efficiency of the σ- and s-methods. When σ is unknown we must estimate it as s on the basis of the samples. In this manner the section 2.4.1.2.3. in the Corrigendum is not understandable.</u>

NEW ZEALAND

1.0 General comments

New Zealand supports the drafting of guidelines on sampling. Their development is an integral part of harmonising food inspection systems internationally. Limits are specified in many areas of the Codex Alimentarius, and guidance on how to demonstrate compliance with those limits is vital. Given their importance, New Zealand wishes to ensure that such a key document is both robust and easy to understand. We believe that if it fails either of these criteria, it will not be used, and therefore, it will not contribute to harmonisation.

While it is improved from previous versions, New Zealand does not believe that the current draft of the Guidelines meets these criteria, and suggests that it be revised significantly before it is progressed further in the Codex system, in light of the following comments.

1.1 Purpose and scope

New Zealand suggests that the drafting group clarify the purpose and scope of the document. We find it not comprehensive enough in many areas to serve as a single reference document on sampling. The current version of the document consists of a mixture of procedures, statistical theory, and policy (for example, on inspection standards to be applied in certain situations, which is a decision more appropriate for commodity committees).

New Zealand recommends that the Guidelines follow the approach of ISO Standard 8550, "Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots". This ISO standard discusses the issues more fully and refers readers to the appropriate standards for further information, rather than attempting to provide a single, comprehensive guideline to sampling. We also suggest that the excellent discussion on the principles behind statistical sampling in ISO Standard 2859, "Sampling procedures for inspection by attributes" be incorporated or referenced.

1.2 Intended audience

New Zealand suggests that the drafting group clarify the target audience of the document and review the text with those readers in mind. We find it very technically detailed in many areas, indicating a technical audience. However, we note that Codex standards are normally intended for use by governments in setting their official requirements. With that end in mind, New Zealand recommends that the document spell out principles and general guidelines, refer to specific technical documents that already exist (e.g. ISO standards), and not contain too much technical detail.

1.3 Consistency

As noted above, New Zealand suggests that the level of detail provided in the document be made more consistent. There are some very complex sections, but material on other seemingly crucial issues such as normality testing are dealt with by reference to other documents. New Zealand believes that relevant areas such as establishing consistency of variation for use of the "sigma method" and homogeneity testing, which are not dealt with in the current draft, be incorporated. We also recommend setting out examples in a consistent format.

1.4 Readability

New Zealand notes that the current draft of the document is improved from previous versions, but believes that it still too complex for the average reader to understand. Perhaps due to translation, some explanatory text is not entirely clear. New Zealand recommends that further work be done on examples to improve their illustrative value.

1.5 Definitions of terms

In many cases, definitions of terms are not very clear. New Zealand suggests that the definitions in existing documents be adopted. In particular, ISO Standard 3534, "Statistics – Vocabulary and Symbols" contains excellent definitions for most of the terms in the current document. These are highlighted in the specific comments below.

1.6 Specified limits

Given the stated purpose of the document (providing guidance for inspection of product on reception), New Zealand suggests that Limiting Quality levels (LQs) be specified, rather than Acceptable Quality Levels (AQL). This would better assist in ensuring that there is a small chance of receiving poor quality product.

1.6 Graphs and tables

The graphs of Operating Characteristic curves are incorrect in some cases. It appears that these curves have been drawn from a small set of discrete points, but since the curves are continuous, we recommend that the curves be redrawn using more points to make them smoother, and that the discrete points not be shown.

While real examples are essential to the document, New Zealand believes that it is unnecessary to publish vast tables and graphs of Operating Characteristics, as these can be looked up in the existing literature. Further, it we believe that it is premature to publish detailed material until the relevant Codex commodity committees have decided on the inspection standards to be applied. This matter should be addressed with some urgency, as potential users must be able to see the impact of the sampling in their particular area in order to provide meaningful comment.

1.7 Version control

The International Dairy Federation (IDF) released a revised draft of this document for comment in October 2000, since the last version produced by Codex. However, the current version (CX/MAS 01/3) does not reflect the comments and suggestions made to IDF, although some are captured in the corrigendum (CX/MAS 01/3-Corrigendum). New Zealand believes that it is important that the versions be synchronised. The addition of a lengthy corrigendum with significant alterations to the document initially provided made review and comment difficult.

New Zealand's comments on specific areas for improvement of the current draft Guidelines follow.

2.0 Specific comments on the Corrigendum (CX/MAS 01/3-Corrigendum)

Page 1, Foreword

New Zealand suggests that this foreword would be an ideal place to explain some of the concepts behind statistical sampling, especially since the majority of users of the Guidelines will not be statisticians or will have limited, if any, statistical training. We recommend, in particular, the introduction to ISO Standard 2859, "Sampling procedures for inspection by attributes" as a possible source of discussion material on sampling. A key concept here is that of variability. Variability allows us to 'extrapolate' from the test results to make assessments of lots as a whole.

Page 2, Specification limit and interpretation of results

New Zealand suggests that this section be revised in light of the following considerations.

- No sampling plan can give 100% assurance of complete compliance, even if 100% inspection is applied.
- It seems unlikely that country B would use the limit as the maximum or minimum for the average without seeing the potential for a lot to pass with a large number of individual results violating the limit and questioning whether they had applied the correct interpretation.
- It seems more likely that different countries would apply different sampling plans, in the absence of any guidance, and draw possibly different conclusions. Even if they applied the same sampling plan, sampling and measurement error could cause them to draw different conclusions.

Pages 2-3, Relationship between value…

New Zealand suggests that the key point to be made in this section is that the Codex limits are limits for the product in the lot, not limits for test results. The problem is taking the limited information provided by a sample taken from the lot and making a judgement as to whether the lot complies with a Codex limit.

Page 3, Methods of analysis

New Zealand does not agree with the performance-based approach as an acceptance criterion for alternative methods, as:

- it may preclude the use of a method, particularly a cost effective method, having a bias or greater variability when all that is required is a greater offset from the limit to ensure the required degree of compliance is achieved (this is consistent with the general principles underlying sampling by variables);
- this shows that measurement error cannot be ignored;
- a considerable amount of data is required to show differences between repeatabilities or reproducibilities (being standard deviations) using either the chi-squared or F-tests, when these differences exist. It seems unlikely that this amount of data will be collected with the result that the statistical tests for conformance will not fail; and
- regardless of the outcome of the statistical tests, measurement error will still be present for both methods, and will affect compliance decisions made.

Pages 3–4, Methods of sampling

New Zealand suggests that "sampling" should be defined before the bulk of this section, as there is possibly some confusion with physical sampling.

We also suggest that the examples do not necessarily show high confidence of a high degree of compliance. Country A has a 5% chance of rejecting a lot with 0.1% non-conforming, and Country B has a 5% chance of rejecting a lot with 10% conforming. In order to achieve the aim of this discussion, New Zealand believes that a high chance of rejection at a low level of non-conformance would be required, which, as indicated above, comes from consideration of the Limiting Quality.

New Zealand recommends that the section incorporate consideration of the fact that every random sample

will produce a different outcome, as measured by sampling error. This would entail revision of the last paragraph, which suggests that, given all other things are equal, the approach to randomisation is the only cause of differing decisions.

New Zealand believes that the criterion for acceptance and the number of samples are both critical aspects of sampling plans. We therefore suggest emphasising that these come from specifications of the risks (AQL and LQ).

New Zealand suggests that the last (bolded) statement in this section (that defining a numeric limit is not enough) is confusing, and recommends that further discussion of this point be added.

Page 4, New section 1.3, Users of sampling plans…

In line 2, "either" should be replaced with "or".

New Zealand suggests clarification of the term "professionals". It may mean "producers" or "contracting parties" (both suppliers and producers). The latter would seem more consistent with the term "self-inspection".

New Zealand suggests that in the last sentence, "appropriateness" would be better than "relevance". We understand that the purpose of these guidelines is to define the sampling plans to be used, to remove the potential for different inspection procedures for the same lots, as discussed in the foreword. New Zealand suggests that consideration be given in this section of whether it is appropriate for a producer to apply the same sampling plan as the receiver of the product. The producer must allow for 'adverse' effects of sampling and measurement error, so that the receiver will have a high chance of finding the lot acceptable. This is particularly the case when sampling plans are not determined by specification of the AQL and the LQ, as they should be, but from the AQL and number of samples for example.

Comments on the remainder of the corrigendum, which outlines changes to the guidelines themselves, are included in the following comments on the Guidelines.

3.0 Specific comments on the Guidelines (CX/MAS 01/3)

Page 4, Section 1.1, second bullet point

At the end of the paragraph, after "not normal", New Zealand suggests that "or able to be normalised" be added. For example, in many cases, data can be transformed into normality.

Pages 4-6, Section 1.3

New Zealand believes that Table 1 is critical, for it provides users with a guide to information elsewhere in the document. It is therefore essential that the table is as simple and as clear as possible. We recommend that it be revised in the following areas.

- Clarity and ease of use would be improved if the table were split first between bulk product and individual items, then further split between attribute and variables situations. A further split between isolated and continuing lots may also be desirable. We believe that there is no intrinsic reason for considering microbiological testing separately from other forms (these plans are a particular form of attribute sampling).
- New Zealand suggests that the first column in the upper part of the table is not needed, as the standard provides little guidance for non-homogeneous situations. The scope of the table and the document as a whole is essentially the sampling of homogeneous commodities (consistent with the definition of a lot).
- We believe that it is not certain that microbiological parameters can be considered homogeneous in general.
- New Zealand suggests that the "excluded" cases would be better described as "not applicable", for it is not possible to have sampling plans for those situations.
- We suggest that the examples be more clearly differentiated.
- New Zealand suggests that the table would be more useful if it contained less information, as its bulk makes it unwieldy.

- We recommend that important information currently included in footnotes be moved to the body of the document. (See the following comments on footnotes 3 and 5.)
- New Zealand suggests that references to the ISO relevant standards be provided (as in the section for double sequential and multiple sampling plans).

New Zealand suggests that the following crucial terms that appear in the table be defined:

- "individualizable" – clarification on whether this means that discrete samples can be taken;
- "homogeneous" (see comments on section 2.2.8);
- "punctual sampling"; and
- "empirical sampling" – given in the footnote for the definition of the punctual sampling.

New Zealand notes that the Corrigendum redefines "punctual sampling" as "pragmatic sampling", but suggests further explanation of the term. "Pragmatic sampling" might refer to what is commonly called "convenience sampling". However, convenience sampling is not random sampling, and its use may produce a misleading impression of the quality of a lot. Furthermore, the Operating Characteristics and other statistical properties of sampling plans presented in this document will not apply if convenience sampling is used.

Page 5, Footnote 3

New Zealand suggests that the footnote text be clarified. We note that it is not possible to determine the average content for each increment, as an average can only be calculated across all the increments. It may be intended to state that each increment exceeds the average content to which compliance is sought.

Page 5, Footnote 5

New Zealand notes that the recommendation to exclude any lots containing contaminants violates other Codex standards, for example those which allow maximum residue limits (MRLs). We suggest that the text be clarified to note that this is a policy matter, to be decided by the appropriate Codex commodity committees.

Page 7, Section 2.1.1

New Zealand suggests that it is better to refer to the Operating Characteristic, which is the relationship between the rate of non-conforming items (or level of non-conformance in general, including bulk materials) in lots, and the probability of acceptance of these lots upon inspection. The Operating Characteristic Curve is a graphical depiction of the Operating Characteristic.

Page 7, Section 2.1.2, first bullet point, first sub-bullet point

New Zealand notes that no sampling plan can ever ensure that every item in a lot is acceptable, and suggests revision accordingly.

Page 8, Section 2.2.1

Although the definition of "lot" is the same as ISO Standard 3534, homogeneity is presumed. New Zealand suggests that this could be unsatisfactory, particularly for microbiology, where the presumption may be incorrect and cause a sampling plan to produce a grossly misleading impression of the quality of a "lot".

The definition of "consignment" in the first bullet point on page 8, and in the **Note** in section 2.2.1, appear to contradict one another. New Zealand recommends that the definition of "consignment" in ISO Standard 3534 be used:

> **A quantity of some commodity delivered at one time. The consignment may consist of one or more lots or parts of lots.**

New Zealand suggests that some consideration be given to how consignments should be sampled. Although

each lot may be quite consistent it may be unreasonable to expect the consignment formed from several lots to be homogeneous throughout, and therefore not treatable as a lot. Stratification seems useful here.

Corrigendum, page 4, Section 2.2.1

New Zealand suggests that a definition of a "continuous series of lots" is not necessary, as this is covered by the definition of "consignment". It seems likely that a customer will receive lots from the same process, but these lots may not necessarily be continuous.

Pages 8-9, Section 2.2.2

New Zealand recommends that the definition of "sample" as per ISO Standard 3534 be used:

One or more items taken from a population and intended to provide information on the populations and possibly serve as a basis for a decision on the population or on the process which had produced it.

In the last line on page 8, New Zealand recommends that the word "an" (before "information") be omitted.

In the first line on page 9, New Zealand recommends that "possibly" be omitted.

New Zealand notes that the representative sample is not a statistical concept and is not defined in ISO Standard 3534. The representative sample is generally employed in non-statistical sampling with an assumption, implicit or otherwise, that its characteristics are the same as the product from which the sample is drawn. This therefore ignores inevitable product variation (sampling error). It is not possible to know that a sample is representative unless one tests the whole from which the sample is taken.

New Zealand notes that the second part of this definition is actually the definition of a "simple random sample", which is also defined in ISO Standard 3534.

Page 9, Section 2.2.3

New Zealand recommends that the definition of "sampling" as per ISO Standard 3534 be used:

The procedure used to draw or constitute a sample.

Page 9, Section 2.2.4

New Zealand recommends that the definition of "sampling error" as per ISO Standard 3534 be used:

Part of the total estimation error of a parameter due to the random nature of the sample.

New Zealand recommends that the definition of "total estimation error", as per ISO Standard 3534, be included:

In the estimation of a parameter, the difference between the calculated value of the estimator and the true value of this parameter.
Note – Total estimation error may be due to:

- *sampling error*
- *measurement error*
- *rounding-off of values or subdividing into classes*
- *a bias of the estimator*
- *other errors*

We suggest that this definition, describing a technical concept, is not required for the expected audience. However, the reader needs to appreciate that different samples will produce different outcomes because of variability.

Page 9, Section 2.2.5 (Renumbered 2.2.6 in corrigendum)

New Zealand recommends that the definition of "item" as per ISO Standard 3534 be used:

a. *An actual or conventional object on which a set of observations may be made, or*
b. *A defined quantity of material, on which a set of observations may be made, or*
c. *An observed value, either qualitative (attributes) or quantitative (measures)*

Note – The English terms "individual" and "unit" are sometimes synonyms for "items".

New Zealand recommends that the definition of "increment" as per ISO Standard 3534 be used:

A quantity of material taken at one time from a larger body of material.

Page 9, Section 2.2.6

New Zealand recommends that the definition of "sampling plan" as per ISO Standard 3534 be used:

A plan according to which one or more samples are taken in order to obtain information and possibly reach a decision.

Page 9, Section 2.2.7

New Zealand suggests that the table in section 2.2.7 be re-ordered, as it appears to have the least important characteristic first.

Pages 9-10, Section 2.2.8

New Zealand notes that whether a characteristic appears homogenous or non-homogenous largely depends on the sample size taken. If it is small enough, all characteristics can be made to appear non-homogenous, whereas if large enough, all characteristics will be uniformly distributed. We suggest that the issue is not whether the analyte is uniformly distributed, but whether it is possible to take a sample size appropriate to the distribution of the analyte throughout the lot.

New Zealand suggests that there is confusion with the "uniform distribution" in statistics under which there would be an equal chance that the characteristic lies anywhere within a defined range. What is meant is that the characteristic follows the same distribution regardless of the position within the lot. In particular, this implies that the mean level and the standard deviation are constant throughout the lot.

We note that the extra notes in the Corrigendum provide a more complicated definition, and recommend that the definition of "process under control", as per ISO Standard 3534, be used:

A process whose mean and variability remain stable.

New Zealand suggests that clarification be provided in footnote 7, at the bottom of page 10, as to how such a test would be performed. Testing for homogeneity is a non-trivial matter. We believe that such a test would require only a single sample (of several items) to ascertain homogeneity, not two (separate) samples, as the current text suggests.

Pages 10-11, Section 2.2.10

New Zealand recommends that the definition of "acceptable quality level" as per ISO Standard 3534 be used here:

A quality level which in a sampling plan corresponds to a specified but relatively high probability of acceptance. It is the maximum per cent defective (or the maximum number of defects per hundred units) that, for purposes of sampling inspection, can be considered

satisfactory as a process average.

We suggest that the second half of the third sentence in the second paragraph be reworded:

> "...but the higher the rate of defective items exceeds the AQL, the greater the probability of rejecting a lot",

but believe that this only true when the sample size is fixed, as covered in the next sentence.

In the last sentence of the second paragraph, New Zealand believes that safety should be a consideration, as well as economic viability.

In the third paragraph, New Zealand suggests omitting "meanwhile" from the opening of the paragraph. In line 3, we suggest replacing "shall" with "may". In the fourth paragraph, "risk" in the first sentence should be "risks".

New Zealand notes that in general, the less the AQL, the less the LQ, but not necessarily. Given that a sampling plan is completely determined by specifying two of n, the number of samples, c or k, the acceptance number or acceptability constant, the AQL and LQ, to control the quality received by the consumer the LQ should be specified as well as the AQL. This problem is highlighted by Examples 1 and 2, on pages 14 and 15. Although the 5 sample plan in example 1 has AQL of 2.5%, it has a greater chance of accepting lots of extreme poor quality (rates of non-conformance exceeding 35% approximately) than the sampling plan in Example 2, which uses 13 samples and has an AQL of 6.5%.

New Zealand notes that this raises the more general issue, discussed above, of whether it is appropriate to reference sampling plans by AQL if they are intended to provide assurance to the customer, although this document does recommend assessment of the risk by examining the Operating Characteristic.

In paragraph 5, New Zealand recommends that the definition of Limiting Quality (LQ), as per ISO Standard 3534, be added. In the third sentence, it is not clear what "at control" means, and we suggest that the phrase be omitted. We also recommend incorporating a risk management approach here: if a lot is unsatisfactory because of defects that have no safety implications, then acceptance criteria should be generous, but if the issue is safety related, a tighter approach may be appropriate.

In the last paragraph in this section, New Zealand finds the phrase "for minimising the variations" unclear, and suggests that "to minimise variations between them" may be intended. Since the assessment for each characteristic is made independently, New Zealand believes that it is not necessary to use the same samples, but using the same samples for several characteristics will usually minimise the cost.

Page 11, Section 2.2.12

As above, New Zealand suggests that a risk management approach be evident in this section, particularly in the fourth paragraph. Where a defect is visual or quality related, inspection should be biased toward the producer, but where a defect is safety related, consumers' interests should be paramount.

Page 11, Section 2.2.13

New Zealand suggests definition of the term "units", which is introduced. It is not clear whether it means "items" as previously defined.

Page 11, Section 2.2.14, second paragraph

New Zealand notes that the sample size is usually increased with lot size to reduce the chance of making an incorrect decision, either acceptance of a lot of poor quality or rejection of a lot of good quality, when the cost of misclassifying a lot is greater. This is a separate issue to misleading assessments due to lots not being homogeneous.

Page 12, Section 2.2.15

As above, New Zealand recommends that the Operating Characteristic be defined as describing the probability of acceptance of a lot as a function of its actual quality. The Operating Characteristic curve is merely a graphical representation of it.

Page 12, Section 2.3.3

New Zealand's earlier comments on representative sampling apply here. We also suggest clarification of the second sentence of the second paragraph ("shall be mandatory chosen"), as its meaning is unclear.

New Zealand suggests clarification of the example in the fourth paragraph, stating that it is not possible to have individual samples from a tank of milk, as it appears to contradict the second column of Table 1 (page 5) which states that in this situation samples are individualisable. The numbering of items or increments (Step 1), either really or virtually, does not seem possible for a continuum such as a powder or liquid.

In the fifth paragraph, New Zealand believes that the key word is may, as in "may be a solution", and that it be emphasised accordingly. In addition, the layers are normally referred to as strata. Finally in that paragraph, we recommend defining "punctual sampling".

New Zealand suggests re-wording the opening sentence of the sixth paragraph to, "When it is not possible to sample at random…". Later in that sentence, we suggest that "and" be replaced with "or", as in: "...badly tidied or when...". We suggest improvement of this example, as in general a sampler would not know of such behaviour. Also, if this behaviour did occur, one would expect the supplier to rectify the problem causing the behaviour.

New Zealand suggests that in footnote 9 on page 12, "informations" be amended to "information".

Page 13, Section 2.3.4.1

At end of paragraph, New Zealand suggests that "not representative of the lot" replace "not representative of the composite sample".

Page 13, Section 2.3.4.2

New Zealand notes that care is needed when using composite samples, as the level of a characteristic in a composite sample will be an average of the levels in the primary samples. As a result, variation among the primary samples, essential for making a correct assessment of the quality of the lot when using an inspection by variables sampling plan, will be suppressed. Consequently, the variability of a lot may be seriously underestimated with composite samples.

Page 13, Section 2.3.5

New Zealand notes that the sample container must be sterile when used for micro samples, and in many situations, preservatives must be used to prevent deterioration of the sample.

Page 13, Section 2.3.6

New Zealand suggests that beyond noting deviations from the recommended procedure, guidance be provided on how one might allow for them. For example, what would happen if the sample were not taken at random, but from a restricted portion of a lot? In this case, the samples are not representative of the lot as a whole, and the conclusions drawn would not be valid.

Page 14, Section 2.3.7

New Zealand suggests that measurement error is very important, as all results are influenced by measurement error, by random variation and possibly bias of the test procedure. We query whether it is intended that test results are used "as is", effectively assuming that no measurement error is present. In many cases, it is not possible to minimise measurement error, which may be of the same magnitude as sampling error. Therefore, it we suggest providing guidance on how make suitable allowances for measurement error, or inclusion of a more detailed discussion of the effects of measurement error.

New Zealand suggests inclusion of clear guidance on whether measurement error should be taken into account when inspecting lots on reception, or whether the assessments made using results as is. In the former case, since measurement error will increase variability, at least, the tolerances for acceptance of a lot would be expected to be wider than if measurement error is not allowed for. New Zealand notes that in several places, the document recommends checks to ensure the distribution follows normality, but suggests that disregarding measurement error may cause a greater error than departures from normality.

Page 14, Section 2.4.1

New Zealand suggests that the title be "non-conform*ing* items".

Page 14, Section 2.4.1.1, second paragraph

New Zealand recommends that the text align with standard terminology in ISO Standard 2859:

> "A sampling plan *for inspection by* attributes..."

also later in the line:

> "...which *operates by classifying* each increment of the sample..."

and later in the paragraph:

> "...or quantitative (for example *the* sodium content of dietary food, *classified as conforming or non-conforming in relation to a limit*)".

Page 15, Figure 1

New Zealand suggests that the horizontal line in the graph corresponding to a 10% probability of acceptance be omitted, and that similar horizontal lines on other graphs be omitted.

Page 15, Example 2

New Zealand suggests inclusion of the Operating Characteristic curve in this example, as per other examples.

Page 15, Footnote 10

New Zealand agrees that it is a good idea to use the same data in the two examples, but recommends that this important information be clearly stated in the text, rather than as a footnote.

Page 16, Table (and similar table on page 18)

New Zealand believes that these tables are not really necessary and could be omitted.

Page 17, Figure 2

New Zealand notes that the graph does not decrease smoothly at 22% non-conformance, and suggests that it be revised accordingly.

Page 18, Section 2.4.1.2.3

New Zealand suggests that in the first sentence on page 18, the Student distribution has "n-1" degrees of freedom, rather than "n".

Page 19, Section 2.4.1.2.4

The sentence beginning, "The following Table 5" suggests that to be more efficient, a sampling plan should reject more. New Zealand suggests that this be revised to convey that a sampling plan is more efficient if, for the same number of samples taken, it provides greater discrimination between good and poor quality product, i.e. the Operating Characteristic Curve decreases more steeply.

Page 20, Figure 4

New Zealand suggests that this graph be revised to decrease smoothly in the 20%-25% range.

Page 21, Section 2.4.1.4

New Zealand suggests that this chart be related to Table 1.

In question 2, New Zealand suggests substituting "as or transformable to" for "according to".

Page 21, Footnote 12

New Zealand believes that the requirement that the transformation be published in the international scientific literature is excessive, and suggests that this is a matter for the supplier of the commodity to provide such evidence to the purchaser. For example, justification for the use of logarithmic and square root transformations is not found in the literature. These are common assumptions and derived assuming the underlying distributions are lognormal and Poisson respectively, or at least that the variance is proportional to the square of the mean in the former case and to the mean in the second. However, they are theoretical models. Further, the appropriate transformation may vary from case to case, so published material may not provide generic evidence that a certain transformation is appropriate. The requirement also implies that evidence of normality must be provided where this assumption is made.

For footnote 12, we suggest:

> "A transformation to convert the distribution of a variable to normality cannot be used unless there is agreed documentary evidence to justify it",

although we consider this point to be sufficiently important to include in the body of the table.

Page 22, Section 2.4.1.5

As above, New Zealand suggests that approximate normality may suffice, as the probabilities of acceptance may not be unduly affected, or indeed not affected as much as by ignoring measurement error.

Page 22, Section 2.4.1.6 and footnote 13

New Zealand suggests that inspection by attributes sampling plans require more samples, i.e. greater cost, to provide assurance as to the quality of a lot.

Page 23, Section 2.4.3.1

New Zealand recommends that the example in this section be revised. Although the application of the formula appears correct, we suggest that it is not practical to take a sample of 2165 apples from a lot of size

3454, as this is a sampling rate of over 60%. It would be quite expensive to test each of the apples individually as implied by the plan. This type of contamination could also be tested using a sampling by variables approach.

As above, New Zealand recommends that important information be moved from the footnotes (14 and 15 in this case) to the body of the text. We suggest that clarification be provided here on whether this is a policy decision on the standard to be applied or a mathematical requirement for the approximation to be considered correct. Some clarification should be given for the reasons behind these footnotes. If this is a policy matter, New Zealand believes that it is more appropriate for the Codex commodity committees to make this type of decision.

In terms of the phrasing of footnote 14, New Zealand suggests that “essential” be replaced by “usual”, and "inferior" be replaced by the more common English usage "less than". We also suggest that footnote 15 be amended to “P is usually taken as less than or equal to 0.2%”.

Page 25, Section 3.1

There appears to be little difference between the two procedures A and B, thus New Zealand suggests that this section is rather confusing. In particular, the paragraph immediately preceding the table could be clarified.

Page 26, Section 3.2

New Zealand suggests that this section be revised to improve its consistency with the rest of the document, as here sampling plans are selected by setting M, n and c and not through considerations of risk (probabilities of acceptance of lots containing certain rates of non-conformance etc.)

New Zealand notes that these sampling plans may not be suitable for microbiological parameters, as:

- the sampling plans assume homogeneity of the parameter, which may be doubtful for micro and difficult to verify;
- there will be a chance of accepting a lot having some non-conformance of levels above M, but no upper limit on what these levels may be; and
- attributes sampling plans with 5 samples must necessarily be quite poor in their ability to discriminate between good and poor quality lots.

Page 26, Section 3.2.1

New Zealand suggests deleting the description “Two Class” from the title of these plans, as we find it unusual and possibly confusing for readers.

In the formula, we recommend using standard nomenclature for binomial coefficients, where currently, “n” and “i” are reversed from standard usage.

Page 27, Section 3.2.1, Example

New Zealand suggests that this example be revised, since salmonella has serious food safety implications and there is no assurance that the vegetables will be cooked, for example. This sampling plan has a 35% chance of accepting lots with a 10% rate of non-conformance.

Page 27, Section 3.2.2

Our comments on section 3.2.1 apply. We suggest revising these plans, as they currently are not set according to a risk managed approach, assume homogeneity which may not be valid, and have a positive chance of accepting lots containing a proportion above M, but no control on how high this level might be.

To clarify the first paragraph, third bullet point, New Zealand suggests that “there” be changed to “where”,

or a new sentence started. Toward the end of that sentence, we suggest that the text read "the *maximum* number acceptable".

In the second paragraph, starting "The value m…", New Zealand notes that the choice of the parameter m will depend on what is being tested, it will be zero for some characteristics and non-zero for others. We recommend omitting the last sentence.

In the third paragraph, New Zealand suggests removing the underlining from the last point, as all appear equally important.

Page 27, Footnote 17

New Zealand suggests including a definition of the term "punctual sampling". While we note that stratification may be a solution, we suggest that it is risky to attempt to segregate good quality product from that of poor quality in the way suggested.

Page 28, Section 3.2.2

As above, New Zealand suggests that the proposed selection of the number of samples is not a risk managed approach. We note that this is the first time the cost of testing has been mentioned, it is quite unlike the proposed sampling scheme for lead (Pb) in apples in Section 2.4.3.1.

In the formula, as above, New Zealand recommends that the standard nomenclature for binomial coefficients be used, as "n" and "i" are reversed from standard usage.

New Zealand suggests revision of the example on page 28, as immediately two results exceed M.

Page 29, Section 3.2.3

New Zealand suggests that Table 10 of the ICMSF publication be included here. This would improve consistency with the rest of the document, which has attempted to provide all the information required for a user to select a sampling plan. We also suggest review of the sampling plan provided to improve its objectivity.

Page 31, Section 4.1 (and following sections), graphs and tables

- In the cells heading the columns, New Zealand suggests revision of the titles to "Probability of Acceptance of..." rather than "Probability to accept...".
- We suggest that it is not necessary to provide all these points on the Operating Characteristic when the graphs are also provided.
- To streamline the tables, New Zealand suggests providing only the AQL, Indifference Quality level (IQL) and the LQ; and avoiding the use of footnotes. P95, P50 and P10, being the AQL, IQL and LQ respectively, could be defined beforehand, as they apply globally to all these tables (if these tables are retained).
- We recommend the use of full-stops (periods) rather than commas for decimals in the English version of the document.
- As footnote 22 relates to only one cell of Table 7, New Zealand suggests that it would be simpler to provide this single value (99.5%).
- We suggest that these tables be streamlined to show only the AQL, IQL and LQ values for each sampling plan, as these are the points on the Operating Characteristic of most interest to users.
- As a trade off against reducing the size of the tables, New Zealand suggests that the graphs be enlarged at least to the page margins so that users could read other points accurately.

Page 32, Figure 5, third paragraph

New Zealand suggests rewording the sentence to: "The graph shows that, for a constant AQL, the higher the

sample size, the smaller the risk to the consumer of accepting lots with high levels of defects".

Page 32, Footnote 23

New Zealand recommends moving this important point to the body of the text. We suggest that these concepts be discussed in the introduction to Section 4 or earlier in the document.

Page 33, Note (i)

New Zealand suggests amending the phrase "discontinuation of inspection" to "complete rejection of all product from that supplier". We believe that this would better describe the process involved, as the current phrasing implies that lots may be accepted without inspection.

Page 33, Section 4.2.1

The third paragraph on page 33 repeats the definition of a lot provided earlier in the document: that it is homogeneous. Therefore, New Zealand suggests that this text be omitted or revised to note that a lot has the listed characteristics *by definition*. However, as above, we suggest that it is not satisfactory to presume homogeneity in a lot of product.

Page 33, Section 4.2.2

New Zealand suggests rewording the last sentence to: "For each AQL, a graph *shows* the OC curves of the corresponding recommended plans." As above, we recommend that the formula use standard nomenclature for binomial coefficients.

Page 39, Discontinuation of inspection

At the end of the first sentence, New Zealand suggests adding "and all product from that source must be rejected." We suggest that next sentence begin, "Importation and inspection…".

Page 39, Section 4.3.1

New Zealand notes that this section is expressed in a more practical way than previously in the document, as the distribution is normal or approximately normal, and transformations are used.

We suggest that condition (3) may be unnecessary, for it is already covered by either of the conditions (1) or (2). We suggest that these formulae could be clarified, for they suggest that decisions are made on individual results rather than using the sample mean, plus an offset.

In the last paragraph, New Zealand notes that there will be no consistent value of the sample standard deviation, s, for there will be lot to lot variation as well as sampling error, even if the underlying true standard deviation, sigma, is stable. We recommend that a method for controlling variability as well as the mean be provided. When there is stability, as indicated by a control chart, the estimate of sigma is the average standard deviation across the lots considered.

Page 40, Section 4.3.1.1

New Zealand does not find the reference back to the former table useful here, and suggests that it be omitted. We also suggest that it is not necessary to provide formulae for standard deviations, as these formulae are known well enough that they are not required in this document.

Page 40, Section 4.3.1.2

New Zealand suggests adding a check for conformity of the standard deviation to sigma.

Page 47-56, Tables

New Zealand recommends that the tables on pages 47 to 56 (inclusive) be renumbered. We also note that the table labelled "Table 15" contains the abbreviation "NQA", and suggests that this may instead be "AQL".

Page 47, Footnote 28

New Zealand recommends clarification of how was it decided that Plan I (between H and J) is of poor interest. We suggest that this may be a matter for the commodity committees to decide. We note that this creates a difference between this document and the corresponding ISO document to which users may refer.

Page 54, Section 4.3.4

New Zealand suggests that much of the general information here has already been covered elsewhere, and therefore, this section could be reduced. We suggest the following amendments to the text:

First paragraph:

- In the first sentence, replace "or the interruption of inspection" with "rejection of all product".
- In the third sentence, specify what constitutes sufficient proof.
- In the last sentence, amend to "using the value of sigma instead of s".
- In the last sentence, note that switching to the sigma method entails changing the whole sampling plan (the values of n and k will also change).
- In the last sentence, specify to what "inspection tables" this sentence refers. We imagine that, as outlined earlier in the document, this is a case of monitoring the variability with a control chart or similar tool.

Second paragraph:

- Replace the last word, "enough", with "justified".

Fourth paragraph:

- Amend condition (a) for consistency with the corresponding rule for sampling by attributes.
- Review condition (b), as it may lead to the use of the sigma method, which would automatically bring about a reduction of testing, assuming that the same inspection standard is applied.

Fifth paragraph:

- Review condition (a), as we believe that the reversion to normal inspection on the rejection of a single lot may be too harsh, particularly if there is a long history of compliance and the single lot just fails.

Page 54, Section 5.1

New Zealand suggests amending the section title to "General" rather than "Generals".

New Zealand believes that the opening paragraph raises difficulties that are not addressed. Since these guidelines are intended to deal with inspection of lots in all circumstances, we suggest that either the second sentence be omitted or a reference to a relevant standard be given.

We note that this material appears to be a very brief excerpt of ISO Standard 10725, "General requirements for the competence of testing and calibration laboratories", but suggest that more information is necessary here for this section to stand alone.

Page 55, Section 5.1

New Zealand recommends revising the fourth bullet point to state, "when the quality characteristic is stable, and the standard deviation known".

In the fifth bullet point, we suggest that these standards may not be suitable for these materials, as measurement error is not allowed for.

Page 55, Section 5.2, Selection of a sampling plan

New Zealand recommends moving this general summary, with minor modifications, to the beginning of the document.

We note that the use of composite samples will reduce the apparent variability relative to its true value, and may thereby provide a misleading impression of lot variability and the quality overall. Refer also to Section 2.3.4.2.

New Zealand suggests that definitions for the terms PRQ, CRQ, and "discrimination distance", which are introduced here, be provided. The abbreviations appear to be values of the process mean where we believe that they should be rates of non-conformance, with which these means are associated. We recommend providing information as to how the discrimination distance is determined taking account of the population standard deviations of the three components.

Finally, New Zealand suggests that clarification be provided as to where the 0.562 multiplier of D comes from in the acceptance formulae. We would expect the formula to depend upon nc, the number of results, and ni, the number of increments per sample, in some way.

UNITED STATES

GENERAL COMMENTS

The proposed Codex Draft General Guidelines on Sampling appears to provide a range of sampling plans that has the potential to assist the sampling efforts of most, if not all, of the commodity committees. However, the document appears to reflect shortcomings with regard to the narrative presentation of information for the Codex commodity committees.

SPECIFIC COMMENTS

CX/MAS 01/3

Section 2.2.14, Lot Size and Sample Size

This section should imply that when the sampling density (f) is low (e.g., $f < 10\%$) the effect of lot size has little effect on the sampling error of the estimate. Given that $f < 10\%$ and that the lots are homogeneous with respect to the component of interest, a statement such as "It is the absolute sample size that is more important . . ." can be correctly made.

Section 2.3.3 Representative Sampling

The document mentions several types of sampling procedures, random, stratified, etc. However, there are no procedures presented to demonstrate how theses sampling procedures may be conducted for different commodities and conditions of sampling. A section outlining how one should collect a sample appears important and should be included in the document.

Section 2.4.1.3 Compared Effectiveness of an Inspection of Defective Rate by Attributes and of an Inspection of Defective Rate by Variables.

This presentation shows that the sample size for variable plans is usually smaller than that for attributes, provided that the assumptions for the variable plans are met.
A narrative lead-in to 2.4.1.4 appears needed relative to Figure 4.

Other considerations

One piece of information that is critical to encouraging the use of and adherence to the proposed plans in the document is the issue of cost, which was not mentioned. The proposed plans should also include plans that provide the user an opportunity to more economically sample by offering plans with higher risks and lower sample sizes so that trade-off can be made, where conditions permit.

The Codex Alimentarius Commission has already adopted sampling plans for "noncritical attributes" – packaged products available in large quantities such as canned foods, based upon theoretical considerations. They are probably only used when large lots are loaded or unloaded, when all parts of the consignment are accessible as in a manufacturing plant or in a primary warehouse.

As a consequence, it is probably necessary to develop and use tiered double, multiple or sequential sampling plans as are used in sampling peanuts for aflatoxins. Such plans for critical analytes have proved generally successful because they usually release a majority of conforming consignments with a small expenditure of resources and permit concentration of resources on marginal lots. The fear of huge financial losses should a lot be discovered as noncompliant encourages compliance. What are needed in this document are discussions of the consequences of tradeoffs of the higher sampling risks that are associated smaller samples. This should be done for fixed probabilities (e.g., 90%, 95%, 99%) to indicate what fraction of lots of various sizes will be incorrectly released when the parameter and/or statistic of interest is at stated amounts or ratios relative to the legal limit.

CX/MAS 01/3 CORRIGENDUM

Section Forward, Sub-heading, Specification Limit and Interpretation of Results

The examples used to demonstrate differing interpretations of specifications appear unrealistic with regard to the objective of the document. The analysis of all items in a lot should not be regarded in the same light as the analysis of, say, a randomly selected sample from the lot.

A possible alternative would be to demonstrate sampling with respect to one country having a specification for the percent of nonconforming items, while another country has a specification pertaining to the sample mean. Also, a similar presentation could be made whereby the two countries have differing AQLs or RQLs as specifications.

Section Forward, Second Indentation, Methods of Sampling

This section appears to present the same information as on Page 1 except that it merely demonstrates that two countries may require differing AQLs, hence they will require differing sampling levels.

It would appear that a topic on "Methods of Sampling" would outline the types of potential sampling plans that may be used. These may possibly refer to attributes, variables, single, double, multiple and etc. It could also mean that differing techniques such as random and stratified and etc are presented.

New Section 1.3, Users of Sampling Plans Recommended by the Guidelines.

It is not clear whether the current 1.3 will become 1.4 or be replaced by the new section.

How does the new 1.3 differ from 1.2 "Document Target Audience?"

Section 2.2.8 (2.2.9), the definition for homogeneous has a superscript 4 that refers to a footnote. It is not clear how the footnote applies. That is, does it mean that one may assume that a lot is homogeneous based on the statistical analyses of the test sample results?

Sections 2.3.7, (2.4), Estimation Errors, sampling plans are associated with two types of error:
It appears that additional consideration should be given to the name for the section that is proposed to be called "Estimation Errors." The title appears to imply that the sampling objective is to estimate some population parameter and that 2.3.7 or 2.4 are errors that must be given consideration.

The objective of the document is to provide acceptance-sampling plans. These plans are associated with a hypothesis-testing objective. Typically, such plans are designed to test the null hypothesis H_0: $\theta = \theta_0$ against the alternative H_1: $\theta = \theta_1 > \theta_0$. Here θ_0 and θ_1 refer to AQL and RQL lot qualities that are expected to be accepted by the sampling plan $100(1 - \alpha)\%$ of the time and $100(\beta_1)\%$ of the time, respectively.

Though sampling plans can roughly accomplish both the estimation and hypothesis testing objectives. However, if the objective is the estimation of a given lot parameter, it is likely that the sample design would be approached differently. In addition, one generally thinks of the producer and consumer risks or errors as being the errors of an acceptance-sampling plan. The errors that are referred to in the document are important but beyond the scope of the present proposal.