CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3 **MAS-CRD/07**

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS SAMPLING

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES

Comments of New Zealand

CX/MAS 21/41/3: Endorsement of Methods of Analysis and Sampling Plans for Provisions in Codex Standards

Background

Refer: CX/MAS 21/41/9 – The Revision of the General Guidelines on Sampling (CXG 50 – 2004).

- The revised Guidelines (CXG 50) are intended to provide information on the design of sampling plans for Codex Commodity Committees and governments to enable sampling plans to be designed so that product assessment, test methods, and limits, can be harmonized for each provision within Codex.
- They are of fundamental importance for facilitating and harmonizing world trade in foods by providing a range of statistically valid sampling plans applicable to most commodity types and situations. It is also necessary to consider fairness and cost in the design of sampling plans. While attribute plans may be 'simple' to design and use, variables plans may be more economical in terms of testing. The Guidelines provide information on both the design and evaluation of sampling plans and the sampling plan apps in the e-book provide for ease of use for those without access to statisticians.
- This innovative use of 'apps' uses current technology to provide a simpler way to understand, design and evaluate sampling plans for the international trade of food commodities to ensure those plans are fair and valid.

This CCMAS 41 agenda item contains a 'package' consisting of:

- Revised General Guidelines on Sampling (CXG 50-2004) (Appendix I)
- Information Document: Guide to the selection and design of sampling plans (Appendix II)
- Information Document: e-book (Codex Sampling) for General Guidelines on Sampling (CXG 50-2004) (Appendix III)

The revised Guidelines (CXG 50) will be considered at Step 4. There is more work to do to complete the E-book and this is intended to be done following CCMAS 41.

Basis for this CRD:

Refer: CX/MAS 21/41/3 – Endorsement of Methods of Analysis and Sampling Plans for Provisions in Codex Standards

This CRD is intended to show how to use the 'package' for the design of sampling plans for provisions in the Standard for Gochujang.

- An important point is that estimates were done on some of the information used in this design process, in order to produce the sampling plans. This information would normally be provided by the commodity committee.
- The same principles can be applied to design of sampling plans for provisions in the Standard for Chili Sauce, the Standard for Mango Chutney (CXS 160-1987), the General Standard for Dried Fruits, and the General Standard for Canned Mixed Fruits, as detailed in Appendix V of CX/MAS 21/41/3.

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Options for Sampling Plans for Gochujang

Regional Standard CXS294R-2009[1] lists the following provisions for Gochujang:

Provision	Provision
Capsaicin	Minimum 10 ppm (w/w)
Crude protein	Minimum 4% (w/w)
Moisture	Maximum 55% (w/w)

No sampling plans have been provided for these provisions although some sampling plans are proposed in CX/MAS 21/41/3[2] and CX/MAS 21/41/3 Add.1[3] submitted to CCMAS41. Based on the headings of these tables, the plans appear to relate to the assessment of the net weights of packs, the provision for which is outlined below.

Nominal Package Weight	
<1000g	15% Tolerance
1000-5000g	No less than 98.5% of packs should conform
>5000g	No less than 99% of packs should conform

Sampling plans for weights and sampling plans for compositional parameters are discussed separately.

Sampling Plans for Weights

New Zealand's understanding is that these plans are from a historical standard 'Codex Sampling Plans for Pre-packaged Foods (AQL 6.5)' CODEX STAN 233-1969. This original standard was for inspection by attributes sampling plans, based on an "AQL" (Acceptance Quality Limit, now referred to as the Producer's Risk Point (PRQ) of 6.5%). This standard was replaced by the current 'General Guidelines on Sampling (CAC/GL 50-2004)'.

Potential issues with these plans include:

- Plans based on a common AQL do not explicitly control consumer's risk[4]
- Consumer's risks will vary according to sample size that depends on lot size
- Classifying packs as conforming or non-conforming with respect to conformance of their weights with a nominal label weight might be inefficient as weight is a measured characteristic.

Net weights are usually assessed using either the Minimum Quantity System (MQS) (all packages must contain at least the minimum quantity stated on the label) or the Average Quantity System (AQS) (the average quantity of packs in a lot must exceed the label weight). Both systems are used although AQS is becoming increasingly more common. In all cases requirements for weights and measures are set by national legislation so there may be no need to include provisions in Codex standards. Refer to the e-book[5] Section 6.2 for more details on sampling plans the Average Quantity System.

Note however that weights are often not normally distributed due to rejection and feedback mechanisms used in packing systems, so that usually attributes plans are used to assess compliance of weights under the MQS system. The assumption of normality is not critical for "Rule 1" of AQS, that the average weight of packs must comply with the label weight, but attributes plans are used for Rules 2 and 3.

[1] REGIONAL STANDARD FOR GOCHUJANG (Asia1) CXS 294R-2009
[2] Endorsement of Methods of Analysis and Sampling Plans for Provisions in Codex Standards
[3] Endorsement of Methods of Analysis and Sampling Plans for Provisions in Codex Standards (WG)
[4] The risk of accepting poor quality product
[5] Information Document: Codex sampling e-book in CX/MAS 21/41/9

Sampling Plans for Compositional Parameters

The design of sampling plans below follows the questionnaire format described in Appendix II[6]..

1. Nature of the Provision

Does the provision apply to the overall distribution (most of the lot must comply) or to the average level?

The provision applies to the overall distribution; accepted lots should contain a suitably 'small' percentage of nonconforming product.

2. Type of data

Are the test results expressed as pass/fail outcomes (or equivalent) or are they measurements?

The results are measurements of composition, on a (w/w) weight per unit weight basis, so that variables plans would appear more suitable than attributes plans, at least initially.

4. Variables data

Is the characteristic normally distributed, a compositional characteristic or does it follow some other distribution?

This is unknown at this stage, but it might be reasonable to assume that these characteristics are normally distributed, as Gochujang is produced in a reasonably well-controlled batch process.

5. Variables plans, normally distributed characteristics

Is measurement error negligible or significant?

Although limited data has been provided on the repeatability of the HPLC capsaicin method, it is not possible to say whether the measurement error is significant and needs to be allowed for in the design of a sampling plan, as this decision also depends on knowledge of the process variation. If the "error-variance ratio", the ratio of the repeatability error and process variances (see CXG50 5.3.1), is less than 10% measurement error does not usually need to be taken into account in the design of sampling plans.

In addition, no precision data is provided in either of the AOAC 984.13 or 934.01 methods, meaning an assessment, whether measurement error is significant, cannot be carried out.

Provision	Method	Principle	Type
Capsaicin	AOAC 995.03	HPLC	II
Capsaicin	Described in the Standard (Annex I)	Gas chromatography	IV
Crude protein	AOAC 984.13 (Nitrogen conversion factor: 6.25)	Kjeldahl	I
Moisture	AOAC 934.01 (≤ 70°C, ≤ 50 mm Hg)	Gravimetry	I

[6] Information Document: Guide to the selection and design of sampling plans (Appendix II) in CX/MAS 21/41/9

In the light of this, three design scenarios are considered:

1. Measurement error is negligible
2. Repeatability error is significant but there is no bias, i.e. the non-repeatability error component of measurement error is negligible.
3. Significant general measurement error, with [randomly varying] bias, i.e. reproducibility error

Design Scenario 1 - Measurement error is negligible

Crude protein and Moisture

It is assumed that for now that the same sampling plan will used for protein and moisture. Strictly speaking these parameters are expressed as mass fractions so that because measurement error is assumed negligible, plans based on the beta distribution (CXG50 Section 4.3.1) would be applicable.

However alternatively, it might be possible to assume that the data is normally distributed, so that App1 could be used to design a suitable plan. To achieve this, it is necessary to specify allowable levels of consumer's and producer's risks.

Supposing that we are prepared to allow a 5% chance of rejecting lots containing 5% nonconforming product (the producer's risk quality) and a 10% chance of accepting lots containing 20% nonconforming product (the consumer's risk quality).

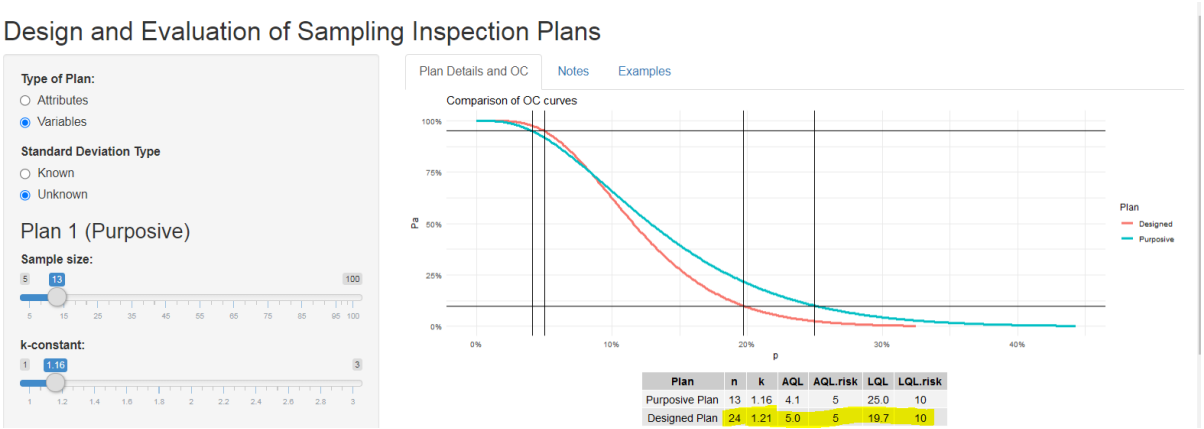
Consumer's Risk Quality level (CRQ)

What percentage nonconforming would you allow in lots that you would want to reject most of the time?	20%
How often would you want to accept such lots (default = 10%)?	10%

Producer's Risk Quality level (PRQ)

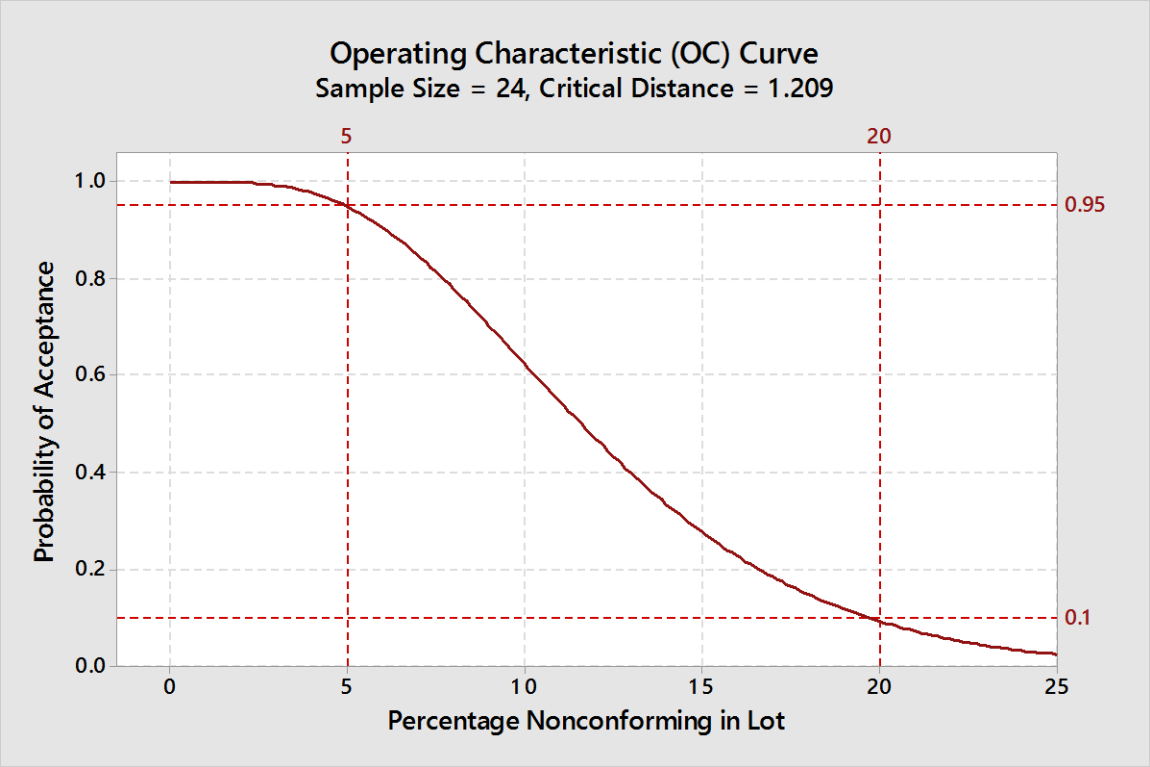
What percentage nonconforming would need to be present in lots that you would want to accept most of the time?	5%
How often would you want to reject such lots (default = 5%)?	5%

Using App1 we find the resulting variables plan is (n=24, k=1.209) i.e. 24 samples would be taken at random from a lot and tested individually.



The mean and standard deviation of these 24 results would be calculated and a lot would be considered acceptable with respect to protein if $\bar{X} - kS \geq L$, where $\bar{X}$ is the average of the protein results and 's' is their standard deviation, and L = 4%, the minimum limit for protein.

The Operating Characteristic for this plan is shown below, showing 95% acceptance at 5% nonconforming and 10% acceptance at 20% nonconforming in a lot.



In the same way a lot would be considered acceptable with respect to moisture if $\bar{X} + kS \leq U$, where $\bar{X}$ is the average of the moisture results and 's' is their standard deviation, and U = 55%, the minimum limit for moisture.

Design Scenario 1 - Measurement error is negligible

Plans for Capsaicin

Obviously for capsaicin it is not feasible to perform more than relatively few tests on each lot.

As above, if measurement error is negligible plans based on the beta distribution (CXG50 Section 4.3.1) would be applicable. Use of these plans would mean that:

(1) a composite sample is formed from a requisite number of subsamples, that number being determined in the design of the plan based on specifications of allowable risks

(2) Acceptance of the lot would be determined by an acceptance criterion of the form $P - k \times s \geq L$ where *P* is the test result or average test result and $s = \sqrt{P(1-P)/\theta}$, ***L*** is the minimum limit (10ppm) and k is the acceptability constant for the plan.

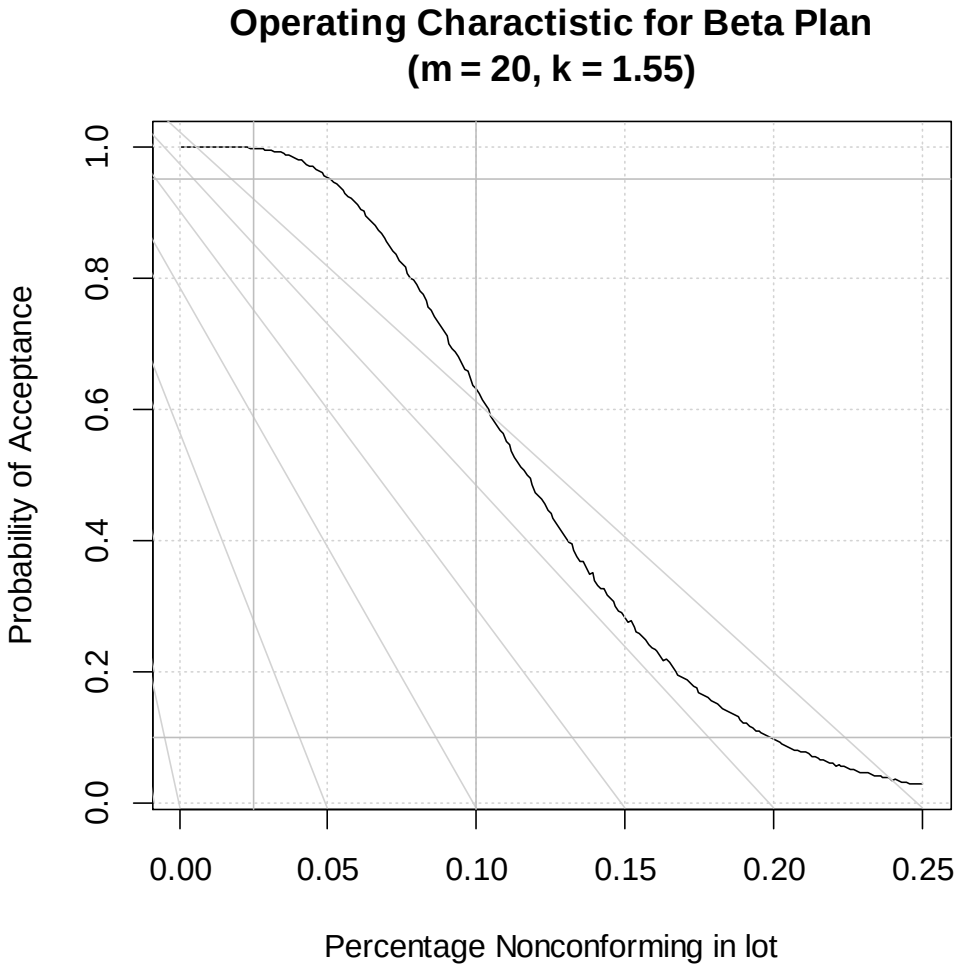
As an example, some hypothetical data were analysed to produce an estimate of the precision parameter of theta $\theta = 44 \times 10^6$. (Note that the app for performing these calculations is not yet available in the e-book).

Following that, a sampling plan can be derived using App10.

For example, using the same consumer's and producer's risk as those for protein and moisture above (a 5% chance of rejecting lots containing 5% nonconforming product and a 10% chance of accepting

lots containing 20% nonconforming product) the resulting plan is (m=13, k=1.20) i.e. a composite sample would be formed from 13 subsamples randomly taken from the lot and the composite would be tested once to produce the estimate of "*P*".

The Operating Characteristic for this plan is shown below.



If however, we decided that capsaicin was a more critical parameter for the product then we may wish to reduce the consumer's risk – instead of decreasing the chance of acceptance at the CRQ we can reduce the CRQ itself, to 10%, and also reducing the PRQ to 2.5%.

Consumer's Risk Quality level (CRQ)

What percentage nonconforming would you allow in lots that you would want to reject most of the time?	10%
How often would you want to accept such lots (default = 10%)?	10%

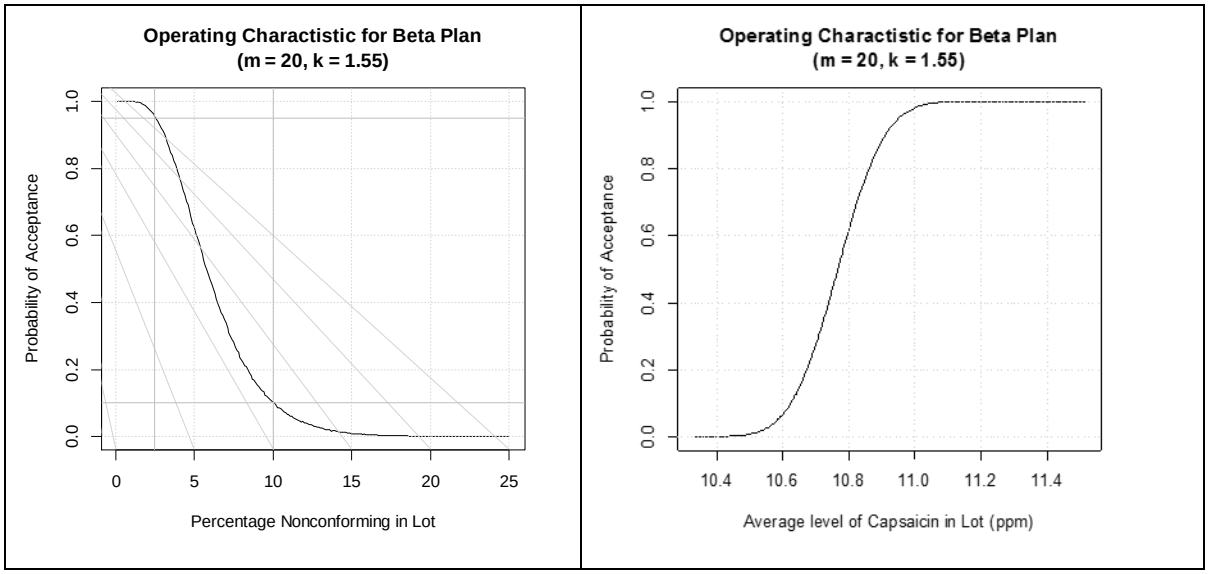
Producer's Risk Quality level (PRQ)

What percentage nonconforming would need to be present in lots that you would want to accept most of the time?	2.5%

How often would you want to reject such lots (default = 5%)?	5%

The corresponding sampling plan is (m=20, k=1.55) i.e. a composite sample would be formed from 20 subsamples randomly taken from the lot and the acceptance criterion would use a multiplier of the standard deviation of k=1.55.

The Operating Characteristics for this plan are shown below, in terms of both the percentage nonconforming in a lot and by the average level of capsaicin.



Note:
In order to design plans for capsaicin historical data would first need to be analysed to estimate the precision parameter θ.

Design Scenario 2 - Significant repeatability-type measurement error, without bias

Significant repeatability-type measurement error, without bias, i.e. the non-repeatability error component of measurement error contributing to reproducibility is negligible.

Crude protein and Moisture

In addition to the producer's and consumer's risks above, we suppose that repeatability measurement error is significant, and that the error-variance ratio is equal to:

$$\gamma = \frac{\sigma_r^2}{\sigma^2} = 0.25$$

Where σ_r represents the repeatability standard deviation and σ the standard deviation representing the variation in the process, referred to as the "uncertainty from sampling" in other contexts.

Using a trial and error approach, App15 can be used to design a sampling plan that allows for the measurement error that controls risks in the same way as the error-free plan above. It is not possible to get an exact match, but the error-free plan can be approximated by the plan (n=20, k=1.11). Note that measurement error has already been taken into account in the design of this plan and it is not necessary to make any further allowance for it.

The OC curves for both plans are shown below.

Plan	n	k	PRQ	PR	CRQ	CR
Error-free Plan	24	1.22	4.9	5	19.5	10
Error-prone Plan	20	1.11	4.0	5	20.7	10

Design Scenario 3 - Significant general measurement error, with bias, i.e. reproducibility error

Crude Protein and Moisture

Significant general measurement error, with bias, i.e. reproducibility error.

This example shows options for a sampling plan designed to allow a 5% chance of rejecting lots containing 5% nonconforming product and a 10% chance of accepting lots containing 20% nonconforming product.

In the case of general measurement error, it is simpler to use the Fractional Nonconformance (FNC) approach than to rely on the methods of ISO3951-6 for measurement error adjustment.

Provisional calculations indicate that the FNC sampling plan requires n=26 samples with a maximum acceptance number of Ac = 0.114 to control the producer's and consumer's risks to the levels specified above.

An app is being developed for the design of FNC plans.