CODEX ALIMENTARIUS COMMISSION E

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Agenda Item 3 **CX/MAS 12/33/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Thirty-third Session

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PROPOSED DRAFT PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE

at Step 3 of the procedure

(Prepared by the eWG chaired by New Zealand with the assistance of the Netherlands and the United States of America)

Governments and interested international organizations are invited to submit comments on the above document at Step 3 in writing preferably by email to the Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, Fax +39-06-5705-4593, e-mail codex@fao.org with copy to the Hungarian Codex Contact Point, Hungarian Food Safety Office, H-1097 Gyáli út 2-6. Budapest Hungary, Fax: +36 13879400, e-mail: HU_CodexCP@mebih.gov.hu, by **5 February 2012**.

Background

1. At its 32nd Session the CCMAS agreed that an electronic working group chaired by New Zealand, with the assistance of the Netherlands and the United States, working in English only, would develop Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade for circulation at Step 3 and consideration by the next session.

2. The Committee agreed that the proposed principles would not provide detailed guidance to governments but would provide a framework for the development of guidance on the choice of an appropriate sampling and testing procedure taking into account sampling variability; considerations on measurement uncertainty; consideration of preventive measures in exporting countries to ensure exported foods meet requirements, and the possible implications of those measures for the design of sampling and testing procedures at the point of import; and reducing the probability of a subsequent dispute occurring through pre-market procedures.

3. It was understood that the concepts of producer's and consumer's risks would be addressed while considering sampling issues.

4. The Committee agreed that the new work should not result in a reconsideration of current approaches and procedures for establishing food safety provisions and in particular maximum limits or levels, and that no changes should be made to existing documents.

5. The project document that was proposed to the Commission, and approved, is presented in Appendix IV of the Report of the 32nd Session (REP 11/MAS).

Preliminary activities: preparation of the working environment

6. New Zealand prepared the environment for facilitating the development of the Proposed Draft Principles:

- an invitation letter to Codex members and international organizations to nominate participants and guests was circulated on 19 July 2011;
- a web-based shared workspace (https://see.govt.nz/nzfsa/ccmas/default.aspx) to be the forum for discussion;
- elaboration of the proposed timeframe;
- provision of reference documents and reference links to assist the working group.

7. New Zealand hosted, developed and managed the workspace. After the workspace was ready, a welcome message with information on how to access it was sent to all participants and guests as they indicated their interest.

8. The names, contact details and statuses of the nominated persons were uploaded in the website. A total of 26 member countries, 1 member organization and 9 international organizations nominated their participants and guests (Annex I).

9. The eWG had a preliminary discussion on its working procedure, and agreed that the Proposed Draft Principles would be discussed as a whole, during the time period 12 September to 18 November 2011.

10. Some working group members reported problems with using the web-based shared workspace. Problems included registering for access to the site, logging in to the site, finding material or finding discussions on the site or being able to respond on the site. New Zealand dealt with these issues as far as possible, and where necessary conducted discussion by email.

The development of the Proposed Draft Principles

11. The initial draft of the Proposed Draft Principles was prepared by New Zealand and assisting countries. The text of the initial draft was taken from:

- The project document (ALINORM REP 11/MAS, Appendix IV);
- The discussion paper on Conformity assessment, based on test results of foods in trade, and implications for resolution of disputes (CX/MAS 11/32/5); and
- The *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).

12. These source texts were amended by:

- Identifying principles from the source material and drafting as such. Other text was drafted as commentary, and simplified by removing text that was not relevant to the topic;
- Rearranging into a logical order;
- Removing or amending text that was outside the scope of the project, particularly any aspects of conformity assessment and resolution of disputes that did not relate to sampling and testing; and
- Other necessary rewording to suit the new context and suggested text added by the New Zealand team.

13. New Zealand posted the initial draft on the workspace on 29 August, prior to the start of discussion, and as a backup circulated the document to all participants and guests by email.

14. Comments were received from 11 countries and 2 international organizations (Canada, Chile, Cuba, Germany, Japan, Netherlands, New Zealand, Norway, Philippines, United States and Uruguay, CropLife and ICGMA), and some countries posted complete versions of the document. The discussion proceeded interactively, the document was amended as the discussion proceeded, and a current version was maintained on the workspace.

15. A concluding version was posted on the workspace for comment from 21 November to 5 December. The concluding version appears in Annex II.

Points for further consideration

16. The working group disagreed on some points, and was not able to deal with some issues raised. Points needing further consideration are noted below, and are marked by square brackets in Annex II.

Relationship between sampling, testing and conformity assessment

17. Japan considered that before the principles could be fully discussed it was necessary to clarify the relationship between sampling, testing, and conformity assessment, and particularly the relationship between sampling and testing. Japan's comments are included in this report as Annex III. The eWG did not have sufficient time to consider this question.

Including trading partners

18. The US, CropLife and ICGMA believed the Principles would be used not only by countries, but also by other trading partners (e.g. private companies), and proposed to refer to "trading partners" in the text.

19. The eWG noted that Codex documents were intended primarily for use by governments, but others could use them at their discretion. Some documents, such as codes of practice, were intended to be applied by industries, but nevertheless they were intended for use by governments as instruments of regulation. References to trading partners have not been included.

Including feeds

20. Four participants (Canada, US, CropLife and ICGMA) considered that the principles should apply to feeds. The eWG noted that the project document is clear that the principles should apply to foods, and references to feeds have not been included.

The term "measurement uncertainty"

21. Canada and Cuba commented that the note below the term "measurement uncertainty" differed from that in GL 72, and could be confused with bias. Cuba suggested a different term could be used; Canada suggested different wording.

22. It was observed that the note intentionally introduces a different concept to that used in other Codex documents such as GL 72, so possibly a different term is needed. The term may also need a qualifier such as "analytical". The term and the note have been placed in square brackets for further consideration.

Simplifying the document

23. Uruguay suggested simplifying the document by placing the text of Principles 3, 7 and 11 and some commentary from Principles 3, 4, 7 and 11 under Principle 2, deleting some commentary and adding some new commentary.

24. This comment was not followed because of lack of time for other eWG members to comment on a complex rearrangement, and because other eWG members had contributed to commentary points that were proposed for deletion.

Deleting some principles

25. The US suggested deletion of Principle 1 (*Agreements before initiating trade)*, because the topic was already addressed in Paragraph 5 of the introduction and Principle 11 (*Issues to address in dispute resolution)* because it was outside the scope of the document as described in the Project Document. ICGMA suggested deleting Principle 12 as it made little sense.

26. In regard to Principle 1, paragraph 5 of the Introduction has since been amended on a recommendation of Japan, thus removing the reference to agreement by importing and exporting countries.

27. In regard to Principle 11, Canada noted that where the rejection of a lot by the importing country is based on sampling and testing to any extent, a principle might be needed to address these issues. An open and transparent exchange of the relevant information regarding the sampling, testing, decision criteria and results could be a factor for avoiding disputes. Canada suggested alternative wording.

28. In regard to Principle 12, the US suggested alternative wording.

29. It was noted that other members of the eWG had commented on these principles and evidently considered they were useful. These principles, with the proposed alternative wordings for Principles 11 and 12, have been placed in square brackets for further consideration.

Additional principles

30. ICGMA considered some important principles were not apparent in the initial document including: (1) transparency (Principle 9); (2) “fit for purpose methods” (Principle 7); (3) scientific basis (Principle 9); recognition of international standards (Principle 3); and variations in commodities and products (Principle 5). The eWG did not have sufficient time to discuss these points.

Removal of commentary

31. Some participants proposed removing all or most of the commentary. Cuba considered that the commentary points were not an integral part of the final document and should be withdrawn so that readers could more readily locate the central idea. The document would be less extensive, more comprehensible and more rigorous as to its content. The US considered a document with only limited commentary would be consistent with previous Codex Principles documents and the terms of the new work proposal. A document with large amounts of commentary would be more consistent with a Guideline, and the focus would begin to creep outside of the terms of reference for CCMAS. CropLife supported a document that was easy to interpret and streamlined in its text. ICGMA considered the commentary was unnecessary and confusing.

32. It was noted that other members of the eWG had commented on the commentary and added further points, and evidently considered it was useful. The commentary has been placed in square brackets for further consideration, apart from sections the US wished to retain.

33. Japan considered a commentary point under Principle 4, concerning reliance on sampling and testing, was outside the terms of reference of CCMAS. This point has been placed in square brackets.

34. Japan also proposed to delete a sentence under Principle 12, referring to changes to consumers' and producers' risks that can result from further sampling and testing, or reappraisal of the data, since such changes were dependent on how additional sampling, inspection, or re-analysis of data was conducted. However it was observed that the following sentence notes that further sampling and testing, or reappraisal of the data, provides a second opportunity by which product, whether satisfactory or unsatisfactory, may be passed as acceptable, so changes to risks are inevitable. The sentence has been placed in square brackets.

Process for further development of the Principles

35. The US, CropLife and ICGMA suggested that the document should be developed in a stepwise fashion, that is, first, reaching consensus on the scope and introduction of the document; second, determining the text and order of the Principles, and finally assessing the need and inserting explanatory text.

Conclusion

36. The Working Group agreed to submit this report with the Proposed Draft Principles to the CCMAS Chairperson and the Codex Secretariat, in order to facilitate to follow the next steps anticipated in the 32nd CCMAS report: the circulation of the document for comments at Step 3, in preparation for its consideration at the 33rd CCMAS session.

Attachments:

Annex I: List of participants and guests

Annex II: Proposed Draft Principles for the Application of Sampling and Testing Activities in International Food Trade

Annex III: General comments (Japan)

Annex I

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Annex II

PROPOSED DRAFT PRINCIPLES FOR THE APPLICATION OF SAMPLING AND TESTING ACTIVITIES IN INTERNATIONAL FOOD TRADE

SECTION 1 - INTRODUCTION

1. Sampling and testing procedure are utilized to determine if foods and feeds in trade are compliant with particular requirements or specifications. These procedures establish the level of protection afforded to exporters, importers and consumers. The procedures used should ensure that risks to all stakeholders are considered equally. Without defined, scientifically valid procedures, *ad hoc* practices may be used, leading to incorrect decisions and an increased occurrence of disputes.

2. To ensure the sampling and testing procedures are valid, they should be based upon suitable, sound, scientific, internationally accepted principles, and it is necessary to ensure that they can be applied fairly. In regard to sampling, the *General Guidelines on Sampling* states that "Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard." As for methods of analysis, those endorsed by Codex could be considered as a good source of information and could be used as sound methods.

3. Sampling and testing in international food trade are often used for the purpose of risk management related to safety. For this purpose, sampling and testing should be established as an integral part of a national food safety system to the extent possible.

4. Risk management decisions should be commensurate to the assessed risk, and should take into account the economic consequences and feasibility of risk management options. Risks due to conditions during storage and transport should be considered by all business operators in the food distribution chain. In order to achieve this there should be an understanding of the impacts of sampling and testing options on all affected parties. Risk management itself should be a continuing process that takes into account all newly generated information, including scientific information, in the evaluation and review of risk management decisions based on sampling and testing.

5. Methods of sampling and testing are important considerations in achieving agreed risk management outcomes. Sampling and testing used in international food trade should comply with available Codex standards, guidelines and recommendations.

6. This document does not affect existing Codex limits or the current way of setting those limits. These responsibilities are set out in committees' terms of reference.

SECTION 2 - SCOPE

7. These principles are intended to assist governments in the establishment and use of sampling and testing for determining, on a scientific basis, whether foods in international trade are in compliance with particular requirements and/or specifications. Compliance with these principles will also assist in avoiding potential disputes. The document does not discuss other uses of sampling and testing, nor other means of establishing that foods in trade meet specifications.

8. This document provides principles for assessing impacts of sampling and testing procedures on affected parties in terms of producers' and consumers' risks but does not give guidance on choosing an appropriate level of risk for affected parties.

SECTION 3 - DEFINITIONS

Dispute
A situation in which there is disagreement between countries concerning rejection by an importing country of a consignment or lot of product in international trade. The situation is initiated when the aggrieved country presents a formal appeal to the competent authorities of the importing country, explaining its grounds for disagreement and requesting the establishment of a dispute resolution process, and ends when a consensus is reached about the outcomes of the dispute resolution process.

[Lot (producer)

A lot is a definite quantity of some commodity manufactured or produced under conditions, which are presumed uniform (for the purposes of these Guidelines).
Reference: CAC/GL 50, *General Guidelines on Sampling*, 2.2.1

Lot (consumer)
A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc.
Reference: Codex CAC/GL 33, *Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs*]

Testing
Process to examine the specified characteristics of a [sample / lot] for conformity assessment of the lot.

Testing procedure
[Operational requirements and/or instructions relating to the testing; i.e. sampling plan and procedure, method of analysis to yield knowledge of the characteristic(s) of the lot. /
Operational requirements and/or instructions relating to the testing; i.e. method of analysis to yield knowledge of the characteristic(s) of the sample.]

Sampling procedure
Operational requirements and/or instructions relating to the use of a particular sampling plan; i.e. the planned method of selection, withdrawal and preparation of sample(s) from a lot to yield knowledge of the characteristic(s) of the lot.
Reference: ISO 3534-1:4.5(1993), ISO 11704-2

Other definitions relevant to these principles include:

Sample[1]

Sampling[1]

Sampling plan[1]

Result[2]

[Measurement uncertainty]

Note
[In this document we use "measurement uncertainty" in a general sense as some quantification of the likely size of the difference between measured and true values.]

Risk

Producers' risk and Consumers' risk[1]

[Note 1
The definitions of producers' and consumers' risks refer to the probability of wrongly rejecting or accepting a lot. The risk of an incorrect decision (the one used in acceptance sampling) does not incorporate any assessment of the cost, in monetary terms or otherwise, of the incorrect decision.]

Note 2
The word "probability" is open to various interpretations. Here it should be interpreted as the proportion or percentage of time that lots identical to the given lot would be incorrectly decided by the specified sampling and testing procedure. [This is the probability on which the manufacturer's and importing country's profits, costs and losses depend. Other concepts of probability, such as those quantifying a person's reasonable degree of belief that a lot is or is not compliant, are less directly (if at all) related to such profits and losses.]

SECTION 4 - PRINCIPLES

To meet the objectives for the use of sampling and testing in the context of international trade, the following principles should apply:

4.1 INITIAL AGREEMENT

[Principle 1: Agreements before initiating trade
It is very desirable that before starting trading activities, the parties concerned should reach agreement related to the sampling and testing procedures that will be applied to determine whether the food in

1 *General Guidelines on Sampling* (CAC/GL 50)
2 *Guidelines on Analytical Terminology* (CAC/GL 72)

trade meets the specifications of the importing country and also on the sampling and testing procedure to be followed in the case of a dispute.]

[Commentary:

- Absence of rules might prolong a dispute while rules are developed, and the process of development of rules might be affected by pressure caused by the dispute already in hand.
- Exchange of information during dispute resolution is a key step to facilitate the advancement of the process. The information should be given [in languages agreed upon by the exporting and importing countries/ in the official languages of the exporting and importing countries, in addition to other language agreed upon by the parties/ in any international language of common use agreed between the exporting and importing countries, whenever their own languages are not applicable.] It is recommended that the exchange of information be done according to the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* (CAC/GL 25-1997), especially the points mentioned in paragraphs 14 to 17 related to 'reasons for rejection'.
- To verify if a dispute is based on samples of the same lot the traceability chain must be fully documented. If this is not the case no further investigations make sense.
- If product is rejected by an importing country's testing and sampling procedure, this rejection should be communicated to the exporting country by means of an exchange of information. This communication has to specify the sampling and testing procedures used, and the outcome obtained in a clear way, indicating in particular any variation from agreed procedures and stating the grounds for failure.
- Types of dispute not covered by the definition (for example, a dispute over the sanctions resulting from a finding of failure to meet the specifications, or over the party to whom they should be applied) are excluded from these principles.
- The conditions under which a dispute can reasonably be raised should be considered in a general way, particularly in respect of the type of data that can be submitted by the exporting country to justify an appeal. Sometimes suggestions for dealing with this question assume that each party is in possession of a result from a single sample from a lot, and these are effectively treated as results from analytical duplicates. A more general treatment is advisable, particularly in respect of the type of data that can be submitted by the exporting country to justify an appeal. For example they may have extensive data on lots manufactured under the same conditions, but none on the particular lot in question, which may have been formed more or less arbitrarily from a larger consignment. In other words the exporting country may have data from "production lots" or "delivery lots" but not necessarily relating to the "inspection lot" that has failed in the importing country.
- Dispute resolution must be a cooperative process between the parties to avoid a lengthy and costly process and to guarantee a fair decision on the fate of a food in international trade.
- When from documentation it is clear that the dispute is of analytical nature the recommendations of CAC/GL 70 should be followed.]

4.2 RISKS

Principle 2: Components of sampling and testing

Sampling and testing of food in trade to determine whether the food meets requirements or specifications involves three components, and all three of these should be considered when an assessment procedure is selected:

- *Selection of samples from a lot as per the sampling plan;*
- *Examination or analysis of these samples to produce test results (sample preparation and test method); and*
- *Criteria upon which to base a decision using the results.*

[Commentary

- For a given lot, this decision may not be predictable because of variation in the samples selected and variation in the value of the measurand observed with the analytical method used: of two identical lots, one may be accepted and the other rejected, because of this variation. This is a risk that must be well understood and considered by both the producer and consumer when making decisions.

- The *General Guidelines on Sampling* (CAC/GL 50), sections 3, 4 and 5, provide guidance on sampling plans for various situations.]

Principle 3*: *Risks to consumers and producers

Whenever food is sampled and tested, the probability of wrongly accepting or rejecting a lot affects both exporters and importers and can never be entirely eliminated. The probability of an incorrect decision should be evaluated and controlled preferably using internationally recognized standards.

[Commentary:

- The risks of making incorrect decisions (i.e. producers' risk and consumers' risk) can never be entirely eliminated.
- The chosen sampling and testing procedures should control the producers' and consumers' risks in a way that does not penalize a compliant product by the application of acceptance criteria with a high risk of rejection in order to provide adequate consumer protection. In selection of sampling and testing procedures taking consumers' risk into consideration, it is desirable to specify a maximum acceptable producers' risk. Sample numbers and testing methods are then chosen to give adequate protection to the consumer within this constraint.
- Competent authorities should define adequate measures to control both the producers' and consumers' risks within this constraint, in a way that is understood and agreed by both parties. Suitable procedures can be sought for this purpose.]

4.3 PROCEDURES OF SAMPLING AND TESTING

Principle 4*: *Selecting an appropriate sampling and testing regime

The sampling and testing procedure applied should be appropriate to the commodity or lot to be sampled and tested, fit for intended purposes and applied consistently.

Commentary:

- Information that is needed in order to define an appropriate sampling and testing procedure includes:
  - A determination of the levels to which risks are to be controlled
  - An estimate of variation of the analyte(s) content in a lot and an estimate of the uncertainty of this variation. [This may be derived from data obtained as part of the assessment or may be a predetermined estimate (Principle 5)
  - In cases where a predetermined estimate of within-lot variation is used, the extent to which individual lots may be expected to vary about this estimate
  - A complete validation study according to ISO/IEC 17025 including fit for purpose evaluation]
  - Estimates of any components of measurement uncertainty relevant to the assessment
  - An estimate of the testing method bias, and uncertainty of the estimate, where relevant.
  - [Estimates of the uncertainty of these parameters
  - An estimate of the testing method bias, and uncertainty of the estimate, where relevant. This might replace the need for some of the estimates of components of measurement uncertainty noted above
  - Records and procedures needed to demonstrate the methodology performed
  - A "model" for the heterogeneity of the lot (which might be that there is none). This might have a bearing on how risks are specified in the heterogeneous case.
- The *General Guidelines on Sampling* (CAC/GL 50-2004) is an important document to be consulted when developing appropriate sampling plans for foods in trade.
- It should be considered whether the indexing of sampling plans to lot sizes, as used in the *General Guidelines on Sampling* (and other international standards) is appropriate. Such indexing avoids the need for explicit (and possibly unrealistic) consideration of the consumers' risk in choosing a sampling plan, but its arbitrary nature creates difficulties in applying attribute sampling plans to bulk product, leaving control of the mean (or average)

as currently the only option for scientific assessments such lots. The *General Guidelines on Sampling* includes sampling plans for average control.

- When foods are assessed against a maximum limit, the assessment is often made on the percentage of product above the limit. However in some situations the percentage of product above the limit is not the critical factor: it may be more important how far outside specified limits the product is.

  In many cases, limits are set with reference to good manufacturing practice or good agricultural practice, and they are considerably below levels that are significant to the end user, e.g. levels that pose a risk to the consumer. However if such a limit is wrongly regarded as a safety limit, this may lead to a requirement for unrealistically precise testing methods, or unrealistically large numbers of samples, in order to yield a high probability of rejection of product that is outside the limits, even though it is not a significant health risk to the end user. High probabilities of rejection (of the order of 90% or 95%) may not be necessary for the safety of the end user unless products are well above the limit.

  Product limits can be designed with a sufficient margin between the analyte level requiring rejection with high probability and the analyte level requiring acceptance with high probability (the GMP/GAP limit). Exporting countries are still deterred from presenting lots outside the limits of GMP or GAP, because of the probability of rejection, which increases the further outside the limits the product is, and an exporting country has no cause for complaint for the rejection.

[- In some cases, reliance on sampling and testing by importing countries may not be a feasible means of providing assurance that product meets specifications (e.g. costs may make trade uneconomic, or turnaround times may be too slow for perishable product, or it might not be possible to determine a sampling plan that will control the risks satisfactorily). In such cases, alternative or supplementary means of assessing conformity should be considered, such as reliance on the manufacturer's or exporting country's assessment. For further details, see Section 5 – References.]

- Testing laboratories should operate in accordance with CAC/GL 27, *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Export and Import Control of Food*, in order to provide a framework for the implementation of quality assurance measures to ensure the competence of testing laboratories involved in the import and export control of foods.]

Principle 5: Product variation

Sampling and testing procedures should take into account the potential variations within a lot due to factors such as the origins of raw materials, species/variety, season of the year, varied farming and manufacturing processes, differences between manufacturers and differences due to storage and transport conditions. Variation will also differ in different parts of a heterogeneous lot. The type of sampling should also be taken into account.

[Commentary:

- Estimation of a lot standard deviation is usually not an end in itself, but a means by which appropriate allowances may be made for sampling variation in the measured criteria by which the lot is to be judged: for example based on its mean or the percentage above certain prescribed analyte levels. It is this variation, together with measurement uncertainty, that gives rise to the possibility of incorrect decisions being made. Various options, as follows, can be envisaged to deal with situations where variability in analyte levels (as measured, for example, by the within-lot standard deviation) may be expected to differ significantly from lot to lot.
- In some situations allowance is made for within-lot variation by using an estimate of typical variation for specified commodity-attribute combinations. This method might be chosen when, for instance, it is not practical to analyse several samples and estimate a lot-specific standard deviation.
- However it may be difficult or impossible to determine estimates of within-lot variation that are universally applicable, even for a well-defined single food type. In these cases there may be a need for lot-specific estimation of within-lot variation, normally requiring a multi-sample assessment.

- A further possible option is to take reasonable minimum and maximum values for the within-lot standard deviation, and ensure that the assessment method will yield satisfactory operating characteristics for all possibilities within that range.
- The sampling procedure must be appropriate to the sampling plan used. The consumers' and producers' risks calculated for the plan assuming one sampling procedure (e.g. strict random sampling) may not be correct for another (e.g. sampling in clusters).
- If the producers' and consumers' risks cannot be controlled to the desired level for some reason (e.g. it is not practicable to test enough samples, or measurement uncertainty is too big) the sampling plan should not be designed in a way that creates an excessive probability of rejection at analyte levels that fall within the range of good manufacturing practice/good agricultural practice.
- For heterogeneous products stratification must be considered in cases where the heterogeneity can be visually observed.
    - If the heterogeneous lot is considered as a single lot[3], this implies the acceptance or rejection of the entire lot using an estimate of the mean analyte level based on the sample(s) taken or of the percentage non-conforming derived from a stratified random sample. At a minimum samples should be spread throughout the lot, preferably in proportion to the amounts of product in the various parts.
    - Alternatively the heterogeneous lot should be divided into more homogeneous sub-lots, each to be sampled, and accepted or rejected, independently. Note that the *General Guidelines on Sampling* apply to assessments of individual lots or to series of lots originating from the same supplier, being quantities of product that are homogeneous[4].
- Random sampling followed by compositing, may be preferred for practical considerations (as in Principle 6). However where sample estimates of within-lot variation are required, plans involving the compositing of several samples are likely to result in a substantial reduction in the number of results available for analysis. This may have a severe effect on the precision of such estimates and on the ability of the sampling plan to differentiate between acceptable and unacceptable product.
- Variation of foods may also be influenced by differences due to storage and transport conditions.]

Principle 6: Practical considerations

The choice of a sampling and testing procedure should take account of practical matters such as cost and timeliness of the assessment and access to lots, provided that consumers' risk is not significantly compromised.

[Commentary:

- In choosing an appropriate sampling plan, due consideration must be given to the following characteristics: whether the lot is considered in isolation or is part of a continuous series; whether the measurement is qualitative or quantitative; and whether it is required to control the percentage non-conforming with the specifications, the average analyte content, or some other specified criterion of lot acceptability.
- Consideration of costs and timeliness might require the use of test methods and sampling plans different from those originally accepted. Deviations from accepted test methods and sampling plans may change producers' and consumers' risks; the balance between these risks should be considered.
- The case of non-stable or perishable foods may need special consideration. For example a perishable food may change its state during transport; or a lot may become heterogeneous.]

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[3] Note: if heterogeneity is obvious by visual observation then the product may not be considered as a single lot.

[4] A lot is **homogeneous** *relative to a given characteristic* if distribution of the characteristic throughout the lot can reasonably be considered to have arisen from the operation of a single probability law.
NOTE: A lot being homogeneous for a given characteristic does not mean that the value of the characteristic is the same throughout the lot.
A lot is **heterogeneous** relative to a given characteristic if the characteristic is **not** uniformly distributed throughout the lot. Items in a lot may be homogenous on one characteristic whilst heterogeneous on another characteristic.

Principle 7: Fitness for purpose

A testing method is fit for purpose in a given assessment procedure if the method, when used in conjunction with the sampling plan and the decision criteria, has an acceptable probability of wrongly accepting or rejecting a lot.

[Commentary:

- A test method and a sampling plan for a parameter in a specification could be interpreted as an implied statement of fitness for purpose for the product. This in turn would imply that the consumers' and producers' risks resulting from use of both the test method and sampling plan are acceptable.
- Fitness for purpose of an alternative testing method can be assessed in terms of its effect on consumers' and producers' risks arising from and the use of that testing method, in conjunction with a sampling plan, compared to the specified method and sampling plan.
- To ensure that the test results are fit for purpose and of the highest quality, the testing laboratories employed should adhere to the guidelines for laboratory quality assurance and competence outlined in CAC/GL 27, *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food* and in CAC/GL 28, *Food Control Laboratory Management: Recommendations.*]

Principle 8: Review procedures

Sampling plans and test methods should be reviewed periodically to ensure they take account of new science and information.

[Commentary:

- Sampling plans and test methods should be reviewed in the light of such new science to ensure they manage risks as desired.]

4.4 PREVENTIVE MEASURES IN EXPORTING COUNTRIES

This is the consideration of preventive measures in exporting countries that ensure exported foods meet requirements, and the possible implications of those measures for the design of sampling and testing procedures at the point of import.

Principle 9: Selecting appropriate sampling and testing procedures

Sampling and testing procedures should be scientifically based, appropriate to commodity, applied consistently, and communicated between importers and exporters in a transparent manner. It should be recognised that an end-product sampling and testing procedure is only one of the methods by which an exporter can validly claim confidence that product meets a requirement and/or specifications.

[Commentary:

- The exporting country is likely to have greater knowledge of a food's variability. The exporting country's export control procedures generally include a combination of end-product testing as well as a range of other controls, and effective management of these is vital. These management measures should involve HACCP and traceability aspects.
- An importing country's overall risk management strategy, of which sampling and testing at the border is one of a number of measures used to manage risk, should take account of the exporting country's risk management strategy. An importing country that bases its risk management strategy on sampling and testing at the border may find it is difficult or impossible to obtain satisfactory consumers' risk at moderate cost (that is, using small numbers of samples), while at the same time ensuring that producers' risk is adequately controlled.
- The risk management of the importing country can take into account the rate of non-compliances of certain exporter/importer combinations to prevent too high consumer risks.
- Auditing of the exporter control system can lead to choosing a less strict sampling plan compared to the situation without prior knowledge, in accordance with CAC/GL34.]

4.5 MEASUREMENT UNCERTAINTY

Principle 10: Taking account of measurement uncertainty

Appropriate acceptance sampling plans will take into account the presence or absence of significant measurement uncertainty.

[Commentary:

- In many situations the measurement uncertainty may be negligible compared to within-lot variation, caused by variation in analyte levels, or product quality, within a lot. The fate of a lot will then be determined largely by which particular sample or samples happen to have been selected for assessment against specifications, and measurement uncertainty will have a negligible impact on the operating characteristics of the sampling plan. In such a situation the theory of acceptance sampling, on which the *General Guidelines on Sampling* are based, is well developed and appropriate.
- An acceptance sampling plan is a set of rules by which a lot is to be inspected and classified. The plan will stipulate the number of items to be randomly selected from the lot under inspection, which will comprise the sample. (*General Guidelines on Sampling.*)
- Additional work would be required to determine how to account for significant measurement uncertainty in acceptance sampling procedures. Sampling plans and test methods should be reviewed in the light of such additional work.
- CAC/GL 54-2004, *Guidelines on Measurement Uncertainty*, Section 8.1 of the Explanatory Notes, illustrates how the concept of measurement uncertainty might be taken into account when interpreting analytical results on a tested sample, in the simplest case when decisions are made based on a single test sample.]

4.6 SETTLING OF DISPUTES

[Principle 11: Issues to address in dispute resolution

Issues that should be addressed in a dispute include (a) whether the sampling and testing procedure was such as to expose acceptable product to an unacceptably high probability of failure (producers' risk), (b) whether the sampling and testing procedure was applied correctly and (c) changes in quality due to transport and storage conditions./

Where consignments (or lots) of imported food (or feed) are rejected on the basis of analysis performed in the importing country, the importing country authority (or trading partner) should make available upon request details of the sampling and analytical methods employed and the results obtained.]

[Commentary:

- Sampling and testing procedures are likely to expose adverse changes in quality due to transport and storage conditions. CAC/GL 25, *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* are considered applicable in circumstances “where there is evidence of systematic failures in handling, storage or transport subsequent to inspection/certification by the authorities in the exporting country.” Evidence of such failures should be included in an information exchange for rejected food products.]

[Principle 12: Impact of procedures on producers' and consumers' risks

The sampling and testing procedure to be followed in the case of a dispute should alter, by as little as possible, the agreed consumers' and producers' risks. /

In the case of a dispute, the sampling and testing procedures should remain the same.]

[Commentary:

- During the dispute resolution procedure it may be necessary to establish whether the sampling and testing procedure was appropriate to the nature of the product and to the risks associated with its consumption. An appropriate sampling and testing procedure could be evidenced by, for example, prior agreement on the sampling and testing procedure by the parties themselves or recommendation by Codex or its commodity committees; otherwise a specific assessment of the sampling and testing procedure may be needed as part of dispute resolution. Note that such an assessment may prolong the dispute.
- [The only changes to consumers' and producers' risks that can result from further sampling and testing, or reappraisal of the data, are a reduction in producers' risk and an increase in consumers' risk.] The importing country’s original sampling and testing, results in a certain level of consumers' and producers' risks; further sampling and testing, or reappraisal of the data, provides a second opportunity by which product, whether satisfactory or unsatisfactory, may be passed as acceptable.
- It should be the aim of the dispute resolution procedure to rectify or allow for deficiencies in carrying out the sampling and testing on the lot in question in a way that increases as little as

possible the probability of passing unacceptable product (i.e. increases the consumers' risk as little as possible).

- A checklist is a useful way to identify possible causes of a dispute and their effects. For example, a checklist to determine whether the sampling and testing procedure has been applied correctly should cover laboratory outliers, systems failures, improper sample selection, mistakes in data transcription, and other relevant points.
- At the satisfactory conclusion of a dispute, the parties in dispute agree on the outcome of the dispute resolution, to the extent possible identify the cause of the dispute, take all the necessary measures to prevent the recurrence of similar disputes and ensure the appropriate disposition of any rejected food product. Data for the entire chain from production to import is potentially relevant.]

SECTION 5 - REFERENCES

- *Guidelines for Food Import Control Systems* (CAC/GL 47-2003)
- Publications and resources of the ISO Committee on Conformity Assessment (ISO CASCO) at http://www.iso.org/iso/resources/conformity_assessment.htm.

Annex III

General Comments (Japan)

It is required first to clarify the relation of *sampling*, *testing*, and *conformity assessment* dealt with in this text as a premise for fully discussing about these principles. Especially to clarify the relation between *sampling* and *testing* is essential for efficient consideration.

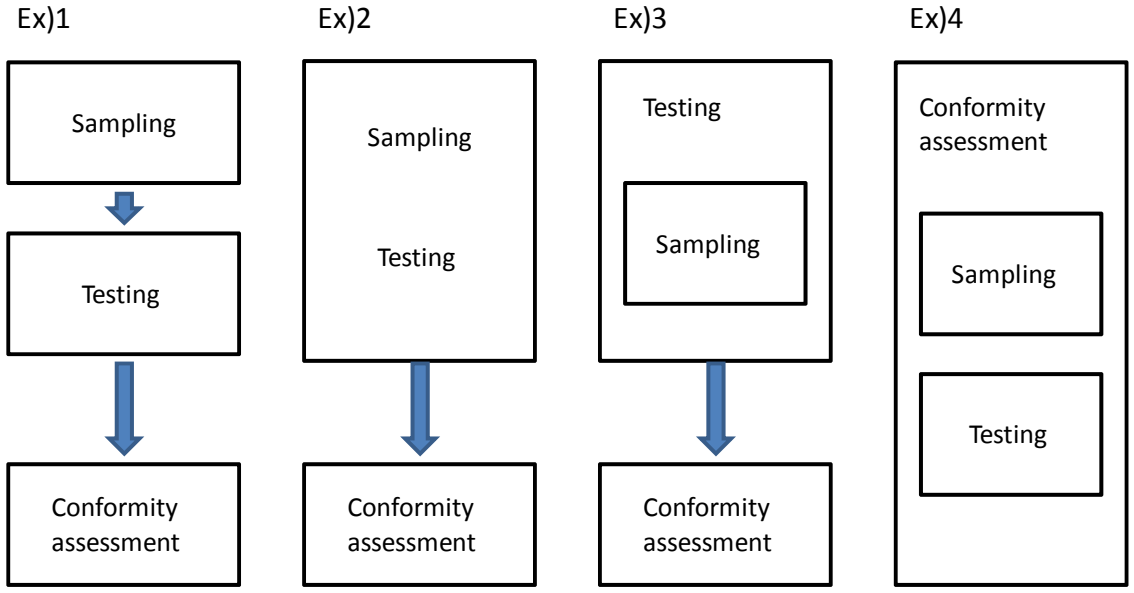
Examples of all possible assumption are given to below.

Ex) 1. *Sampling* and *testing* are considered to be the independent processes. That is, *sampling* is the process of extracting and preparing sample which is tested, and it distinguishes *testing* as a process to know the characteristic in the sample by a measure to examine, such as a method of analysis. Furthermore, *conformity assessment* is also the process which is independent of *sampling* and *testing*.

Ex) 2. *Sampling* and *testing* are obtaining a result used for conformity assessment, and are not independent. Only *conformity assessment* becomes independent.

Ex) 3. *Sampling* is a part of *Testing*. *Conformity assessment* is also independent.

Ex) 4 *Conformity assessment* is the process of checking the lot etc. meet a standard based on the result obtained through them including *sampling* and *testing*.



After clarifying the relationship among *sampling*, *testing*, and *conformity assessment* in this document, it is necessary to define the following term.

- *testing*

Moreover, the following term definitions are recommended.

- *testing procedure*
- *sampling procedure.*