Principles for the Use of Sampling and Testing in International Food Trade

Explanatory Notes

# Introduction

This document provides practical notes which refer to the *Proposed Draft Principles for the Use of Sampling and Testing in International Food Trade (REP12/MAS, Appendix IV)* 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.

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.

# Scope

These explanatory notes are intended to assist governments in the establishment and use of sampling and testing procedures for determining, on a scientific basis, whether foods in international trade are in compliance with particular specifications.

**Explanatory Notes to Principles**

**Principle 1: Agreements before initiating trade**

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

*Agreement is desirable:*

* *to allow the producers’ and consumers’ risks associated with the procedures to be assessed and maintained at reasonable levels fair to both parties*
* *to avoid future disputes concerning the appropriateness of the methods of sampling and analysis or the criteria used to judge the results.*

[Canada: the following points may fit equally well in the Transparency section where they would build on the stated Principle which suggests what might be included in an agreement]

[New Zealand: The way we see it the current section is about agreeing what is to be done (in the future), and section 2, Transparency, is about letting the exporting country know what you’ve done, are doing or are going to do, and why. An item appearing in section 2 but not in section 1 is effectively at the discretion of the importing country, and thus transparency is relevant. We would prefer to keep the present structure.]

[Germany: We would like to advocate the arguments of New Zealand. The *Agreements* are to be achieved before initiating trades and therefore before any inspection activities whereas *Transparency* is a requirement for making decisions comprehensible. Therefore, we also would prefer to keep the present structure.]

Hungary agrees with Can, NZ and DE

Jamaica agrees with Germany’s explanation and as such would prefer to keep the present structure

*The agreements should contain:*

* *Language of communication* [Canada: may be deleted if moved to Principle 2, Transparency where language is stated in the Principle.]
* *Specification of the quantities that will be used to quantify the quality level of a lot (for example the mean analyte level or the percentage of product above a certain level)*

Hungary: The accept reject limit (A/RL) should be specified based on prior experience and taking into account the know uncertainties of sampling and analysis.

The A/RL should be lower than the maximum or higher than the minimum permitted concentration. The A/RL shall be applied for the analyte content or the tested parameter of the duplicate samples taken by the producer/exporter. The first sample shall be analysed before the shipping of the product, the second sample shall be retained for analysis in case of dispute. Utmost precaution shall be taken to ensure that the content of the two samples is as similar as possible and the second sample is stored under conditions which assure the integrity of the sample material.

The A/RL may be linked to AQL and LQ discussed in principle 5.

* *Specification of maximum acceptable producers' and consumers´ risks, and the quality levels (see above) at which they are to apply* [Canada: The producer and consumer risks are often unknown or difficult to estimate without significant work. Sound sampling strategies should balance risks. We suggest this point might be deleted or revised to “specification of maximum acceptable producers’ and consumers’ risks where known….”.]

[New Zealand: The point here is to specify risks that a suitable sampling strategy should achieve, not to document the risks that a strategy that has already been decided on does in fact achieve.  The risks are set as matters of policy, possibly revised in the light of what is achievable in the presence of measurement error; it will not be possible to “balance” risks if they are not known. In deciding whether a strategy is suitable the relevant risks appertaining to this strategy will of course have to be worked out. We agree that to estimate the risks, or even upper limits to them, for a given sampling strategy may involve significant work, but this is work that needs to be carried out.]

[Germany: We agree with New Zealand. The specification and communication of risks or upper limits to them is essential in order to avoid disputes.]

Jamaica: Whilst we agree that conducting risks assessment is important, as stated by Hungary it is expensive and time consuming. Therefore, Jamaica agrees with Canada’s revision as stated above.

Hungary: In case of inhomogeneous lots such as raw agricultural commodities the extent of heterogeneity may vary from lot to lot. Consequently an appropriate sampling strategy assuring specified consumer/producer risk cannot be defined without extensive (expensive and time consuming) case-by case testing. One possible solution is the agreement on an A/RL which is decided based on all available prior experience and scientific results. The A/RL should be re-evaluated time to time.

* *Specification of the manner in which production lots or consignments may be linked to ~~inspection lots and~~ inspection samples ~~(see graphic chart below)~~.* ***).***[Canada: We agree that there must be a clear link between the shipment exported and imported. It is more straightforward where the consignment and lot are the same. If a consignment contains multiple lots, acceptance may be for individual lots within the consignment or for the entire consignment. This situation must be clarified in the agreements as outlined in CAC/GL 47-2003 Guidelines for Import Control Systems paragraph 28. We support this point and agree with the removal of the diagrams.]

[New Zealand: Thanks to Germany for the changes in this section – we think it is a great improvement.

This particular point would be clearer if the order was reversed, i.e. *“Specification of the manner in which inspection samples may be linked to production lots.”*

We agree with Canada’s comment, but to clarify the third sentence, if the entire consignment is to be accepted or rejected, it should be treated as a single lot.

On the other hand the point still needs to be made, as Canada has done, that there are valid reasons for dividing a consignment into several lots, and that when this is done any rejected material needs to be identifiable to the exporter.  We suggest paragraphs to cover this, as follows:

*It is not necessary that the entire consignment be treated as a single lot. Particularly where there is reason to suppose that a consignment may not be homogeneous, it may be divided into several lots, each to be sampled, and accepted or rejected, independently. For example a consignment could consist of product from several different producers, or there may be reason to suppose that the various containers in which a consignment of perishable product was shipped were exposed to different storage conditions in transit. When this is done, care must be taken to ensure that the product contained in any rejected lot can be identified by the exporter.*

*It should be emphasised that if the entire consignment is to be accepted or rejected as a whole, then that entire consignment must be treated a single lot, and must thus be assessed by random sampling throughout the entire consignment.*]

[Germany: We agree with New Zealand´s amendments but the considerations dealing with non homogeneity are already given in Principle 8 and the amendments might be merged with paragraph 4 of the notes. This would also keep this bullet point with application of the reversed order as proposed by NZ clear and short.]

JAMAICA: As Germany has already stated, Principle 8 covers product variation and non homogeneity. We support Germany in keeping this bullet point but considering reversed order proposed by NZ.

* *Sampling procedure (that is, methods used to select and physically take the samples, and the specific portions of material to be analysed).*
* *Analytical methods (that is, methods used to estimate the relevant characteristics of the samples).*
* *Specification of the allowances to be made for sampling and analytical measurement uncertainty* [Canada: It is important to know if there are any “tolerances” to be considered in decision making. Often there is no allowance for uncertainty. It seems that this point may be merged with the next point.]

*Specification of the conditions under which, following sampling and analysis, an ~~inspection~~ lot will be deemed to be acceptable(for example the maximum number of the inspection samples taken from the lot that may fail to comply with the provision in the standard, or limits within which the average of the set of samples must fall and, in either case what tolerance to allow for sampling and measurement error is to be given)*

[Canada: We suggest that this point may be merged with the previous point. Using some text suggested by Uruguay, we propose: “Specification of the acceptance criteria following sampling and analysis, including specification of any allowances to be made for sampling and analytical measurement uncertainty.”]

[New Zealand: We agree with this suggestion.]

[Germany: We also agree with the proposed amendment.]

H: agrees

JAMAICA: We also agree.

* *Agreement on a process for resolving disputes over analytical (test) results (for example CAC/GL 70-2009)*
* *Specifications regarding the retention of reserve samples by the importing country for the purposes of resolving disputes*

H: reserve sample(s) should be taken before the shipment and stored by the exporter(supplier). Alternately an A/RL could also be specified and applied at the importer side.

Good example for this is the EC regulation specifying 50% uncertainty on the results of pesticide residue analysis (lots are rejected if the residue measured in the sample is larger than times the MRL. Ideally, if the A/RL is properly selected at the producer/exporter side no sample taken from a compliant lot should contain residue above the importers A/RL.

* *Communication procedures in case of any variations of the above-mentioned terms*

*~~The link between the particular ´production lot´ and ´production consignment´ of the exporter and the ´inspection lot´, ´inspection consignment´ and ´inspection samples´ of the importer might be illustrated by the following graphic chart. Between the presented archetypes different intermediate types are possible:~~*

**Principle 2: Transparency**

The selection of sampling and testing procedures and the process for comparing test results to specifications should be documented, communicated and agreed upon by all parties. All relevant information should be shared between governments using mutual agreed upon format and language(s).

*[CUBA: In order to minimize the inconveniences that can be caused by the application of different ways to identify production lots or consignments in the original country (exporter) with respect to inspected lots or consignments in the destination country (importer), which becomes frequently, a serious problem, the exporter and the importer should apply the same sampling procedures, to the same portions of the commodity (lot, consignment, container, hold of ship, production date, etc.) and identical or equivalent testing methods must be used. These situations should be very well stated and clarified in the previous agreements before initiating trade to make possible the quality results' comparison of commodities produced in origin and inspected in destination.]*

[Canada: As suggested for Principle 1, the notes describing what should be contained in an agreement may fit here under Transparency. By merging those points with those listed below, we may eliminate some duplication.]

[New Zealand: Where points appear in both sections, we see more reason to merge them in Section 1 than in Section 2. See our earlier comments. This probably applies to the point above.]

JAMAICA: In agreement with Canada and New Zealand re: descriptive notes explaining the contents of an agreement should be merged in Principle 1: Agreements before initiating trade, as it would be more appropriate, rather than being in Principle 2: Transparency - where it may seem repetitive.

*In order to build and maintain the necessary confidence in the inspection and certification systems of the exporting and importing countries, the GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 26-1997) should be consulted.*

[Canada: Canada agrees that these Guidelines are an effective means of gaining confidence that the food being traded is of good quality and safe. Use of these Guidelines can significantly reduce the amount of duplicative sampling and testing conducted. Therefore, we suggest that this point may be moved to Principle 6, Practical considerations, to supplement CAC/GL 47 already cited there.]

[New Zealand: Yes, we agree there is a case for moving it to section 6.]

[Germany: We agree.]

JAMAICA: Supports the suggestion made by Canada, New Zealand and Germanyre: specific guidelines relating to confidence in the inspection and certification systems for both exporter and importer – reference should be made to CAC/GL 26 – 1997 as a supplementary document to CAC/GL 47 and this information included in Principle 6: Practical considerations.

We also endorse the point put forward by New Zealand re: specific guidelines relating to rejection of products for both exporter and importer – reference should be made to CAC/GL 25 – 1997 and this material also be included in Principle 6: Practical considerations

*In the case of a rejection the exchange of information should be done according to the Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997). The information should document the link between the particular ’production lot‘ or ’production consignment' of the exporter and ~~the ’inspection lot‘ or ’inspection consignment‘~~  inspection samples of the importer. The information should contain:*

* *The details of the applied sampling procedure*
* *A description of the inspection ~~lot~~ samples (e.g. size, location in the consignment)*
* *The analytical method used to measure the inspection samples, and the laboratory performing the measurements, including fit for purpose evaluation according to Principle 9*
* *The measured result for each* *inspection sample, together with any information (e.g. container identification, manufacturer’s codes) which may identify to the exporter the part of the production consignment from which it was drawn*
* *Values for any components of measurement and sampling uncertainty used in the assessment, and their source*
* *A description of the raw data and the calculations performed and the results obtained, sufficient for the exporting country to comprehend these results*
* *A description of the criteria applied in deciding to reject the production lot or consignment*
* *Justification for these criteria, (e.g. in terms of prior agreement, use of published sampling plans, mathematical argument and so on).*

H: it would be more appropriate to exchange all necessary information listed above and agree on the procedures which would be applied and specify them in the trade agreement before the shipments of goods. In case of rejection, only potential deviations should be listed and justified. Otherwise we open the door for a lengthy dispute situation.

JAMAICA: In agreement with Hungary (H) as it definitely be deemed appropriate for both the importer and exporter to exchange all relevant information in order to concur on specific procedures that are applicable in trade agreements, prior to shipments of products. Jamaica also agrees that potential deviations should be listed and justified in order to reduce the possibility of disputes between both parties.

**Principle 3: Components of a product assessment procedure**

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

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

*For a given lot, this decision may not be predictable because of variation between samples and variation due to measurement error: of two identical lots, one may be accepted and the other rejected, because of this variation. On the other hand, the probability of such a discrepancy can be controlled, if the sampling and measurement uncertainties are considered correctly. This is a fact that must be well understood and considered by both the producer and consumer when making and acting on decisions.*

H: If the concept of A/RL is accepted, then the above problem is eliminated

JAMAICA: Endorses the rationale that due to variations between samples from two similar lots on account of measurement error, a rejection of one sample is possible. Hence as stated, once sampling and measurement uncertainties are correctly accounted for, both parties would be able to understand the implications of decisions which are made after product assessment.

**Principle 4: Consumers' Risk and Producers' Risk**

Whenever food is sampled and tested, the probability of wrongly accepting or wrongly rejecting a lot or consignment affects both exporters and importers and can never be entirely eliminated. The Consumers' Risk and Producers' Risk should be evaluated and controlled, preferably using methodology described in internationally recognized standards.

*The Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007) provide guidance to national governments for risk analysis (risk assessment, risk management and risk communication) with regard to food related risks to human health.* [Canada suggests that this reference might be deleted. It is our recollection that the discussion of Risk within the scope of this Working Group is to address the risks of wrongly accepting or rejecting food in trade and that references to human health risks are not within the scope of this work.]

[New Zealand: We would prefer to retain this reference is to ensure that the CCMAS work is read in the appropriate context within Codex. Border testing and its reliability are an important component to be considered in a risk analysis, and hence there are several references in the Working Principles that deal with sampling and testing. There is a feed back: a risk analysis may suggest suitable test parameters, and the parameters once chosen can be used in re-assessing risk. The paragraph in question does little more than draw attention to the existence of a relationship.]

[Germany: We would also recommend the retention of the reference as an information about the procedure of risk analysis including human health considerations, which influence the definition of AQL in the following text.]

H: the CAC/GL 62-2007 is very general and does not provide any useful information for deciding on the acceptable consumer risk in connection with a particular commodity analyte combination. It might be useful to include a section to link this GL to relevant general Codex Principles.

JAMAICA: agrees with Germany/New Zealand  proposal to keep the clause on the basis that it is useful to draw attention to the need for risk analysis/health considerations.

*The General Guidelines on Sampling (CAC/GL 50-2004), sections 3, 4 and 5, provide guidance on sampling plans for various situations. Principle 1 recommends consultation between exporting and importing countries in selecting a plan.  Whether agreement is reached or not, the choice of plan to be used is ultimately the responsibility of the importing country.  Particularly where consultation has not taken place or agreement has not been reached, the responsible authority should have regard to principles of fairness towards the producer.  This means making sure that compliant product is not exposed to an unduly high probability of rejection.  In other words, the producers’ risk should not be too high.  What is “too high” may depend on the product and analyte concerned, and also the AQL considered appropriate.  The “usual” value for the producer’s risk (as stated in the GL 50, section 2.2.14, second paragraph) is 5%, the sampling plan being chosen to apply this producers’ risk at a lot quality (the AQL) appropriate to the hazard presented by non-compliant material.* *As stated in the GL 50, section 2.2.14, the characteristics which may be linked to critical defects (for example to sanitary risks) shall be associated with a low AQL (i.e. 0,1 % to 0,65 %) whereas the compositional characteristics such as the fat or water content, etc may be associated with a higher AQL (e.g., 2,5 % or 6,5 % are values often used for milk products).*

*The determination of the AQL, LQ and their associated risks may involve risk analysis. 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.*

*Prior information may be useful in managing these risks efficiently. For example, the importing country can take into account the rate of non-compliances of certain exporter/importer combinations in controlling risk, using procedures with relatively low sampling rates (and therefore relatively high consumers’ risks) in cases where past records show that there is in any case a low risk of non-compliance, and higher sampling rates for other situations.*

*It may also be possible to take into account testing that has already been carried out in the exporting country. Export control procedures generally include a combination of end-product testing with a range of other controls, and effective management of these is vital. These management measures should involve HACCP and traceability aspects, where appropriate. Auditing of the exporting country’s control system can lead to choosing a less strict sampling plan compared to the situation without prior knowledge, in accordance with the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999).*

*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*

**Principle 5: Selecting appropriate sampling and testing procedures**

The sampling and testing procedures selected should be scientifically based and appropriate to the commodity and lot or consignment to be sampled and tested, fit for intended purposes and applied consistently.

*Information that is needed in order to define an appropriate sampling plan and method of analysis includes:*

* *Definition of a quantity defining the “quality level” of ~~an inspection~~ a lot* as defined by the inspector *(e.g. a mean analyte level or a percentage of the ~~inspection lot samples~~* ***lot*** *with analyte concentrations outside a certain range) which the sampling and testing procedure is to control, and in terms of which the AQL and LQ (see below) are to be stated.*

[New Zealand: This amendment has inadvertently created an error. The bullet point refers to defining the quality level of a lot. This is a “true” value, not an estimate, whereas inspection samples would give an estimate of lot quality.]

[Germany: The term "Analyte concentration" is associated *a priori* to inspection samples. This was the reason to refer deliberately to "inspection samples" which are to be representative of the lot.]

JAMAICA: We agree with Netherlands suggestion to use ‘lot as defined by the Inspector instead of ‘inspection lot’ which is subjective

Percentage can refer to an estimate as stated by New Zealand as well as a value e.g. (10% of a known value/lot size), analyte concentration would also allude to true values

* *Determination of the levels at which the probabilities of acceptance are to be controlled and the specification of the Acceptable Quality Level (AQL), which is a quality level at which a ~~production~~ lot or ~~production~~ consignment will be rejected with a specified low probability (the producer’s risk) and of the Limiting Quality (LQ) which is a quality level at which a ~~production~~ lot or ~~production~~ consignment will be accepted with a specified low probability (the consumers’ risk).*
* *Specification of the two specified probabilities of acceptance above, the producer’s and consumer’s risks.*

* *Whether the measurement methods available to assess the quality of inspection samples ~~from an inspection lot~~ are qualitative or quantitative.*

*JAMAICA: We prefer if ‘ from an inspection lot’is changed to ‘* ***from a lot’.*** *This change we believe, better defines the scope for measurement.*

* *The measurement errors associated with these measurement methods: e.g. the probabilities of false positives and false negatives, the probability distribution of measurement errors.*
* *In the case of quantitative measurements, whether the values obtained after random~~ly~~ sampling ~~an inspection lot~~ can be treated as normally distributed (possibly after a suitable transformation).* [New Zealand: A small grammatical change – “random” (the adjective).]

[Germany: Thank you.]

* *In the case of quantitative measurements, whether there is information on the likely variability within the ~~inspection~~ lot, for example based on historical information or manufacturer’s information.*
* *In cases where an assessment procedure is based on an estimate of the mean analyte(s) content in ~~an inspection~~ a lot and a predetermined estimate of within-~~inspection~~ lot variation, the extent to which individual inspection ~~lots~~ samples may be expected to vary about this latter estimate should be considered, along with variation in producers’ and consumers’ risks that may result.*

* *Whether the procedure is to apply to single ~~inspection~~ lots considered in isolation, or to ~~inspection~~ lots forming part of a continuing series.*

*JAMAICA: We would like to know,* Is the continuing series a consignment? Or just goods of a similar nature being shipped together ? This would make the assumption of analyte concentration in a lot heterogeneous / homogeneous which would be treated differently in a sampling plan.

*Sampling procedures should be performed in accordance with appropriate Standards related to the commodity of concern (for example ISO 707 for sampling of milk and milk products or RECOMMENDED METHODS OF SAMPLING FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR COMPLIANCE WITH MRLS (CAC/GL 33-1999)).*

*The General Guidelines on Sampling (CAC/GL 50-2004) should be consulted when developing appropriate sampling plans. The Guidelines cover the following sampling situations for the control exclusively of homogeneous goods:*

* *control of percentage of defective items by attributes or by variables, for goods in bulk or in individual items,*
* *control of a mean content.*

*Each ~~production~~ lot or ~~production~~ consignment that is to be examined must be clearly defined. In order to avoid any dispute over the representativeness of the sample, a random sampling procedure as described in GL 50, section 2.3.3 should be chosen, whenever possible, alone, or in combination with other sampling techniques:*

*If it is required to control the percentage of non-conforming items in a ~~production~~ lot, then (provided measurement uncertainty is negligible, in relation to sampling uncertainty)*

*JAMAICA:We would like to know,* What is the contribution that a sampling procedure makes to uncertainty measurements used to determine analyte concentrations?

* *If the inspected parameter is qualitative (including quantitative data classified as attributes, for example "conforming" or "not conforming", with respect to a limit) or distributed in an unknown manner (consult ISO 5479:1997, "Statistical interpretation of data - Tests for departure from the normal distribution"), Attributes Plans (CAC/GL 50-2004, 4.2) should be performed for sampling.*
* *In case of measurable parameters with normally distributed variability, Variables Plans (CAC/GL 50-2004, 4.3) should be chosen.*

*If it is required to control the average of a characteristic in a ~~production~~ lot, then (again providing measurement uncertainty is not an issue)*

* *Single Sampling Plans for Average Control (CAC/GL 50-2004, 4.4) are recommended as tests which aim~~s~~ at ensuring that, on average, the content of the controlled characteristic is at least/at most equal to either the quantity given on the label of the product, or the quantity fixed by the regulation or a code of practice (e.g. net weight, net volume etc.).*

*The Guidelines are applicable for control at reception, but may not be applicable for quality control of end-products by manufacturers.*

*The selection of a sampling plan will often depend on the variability of the product being assessed. The exporting country is likely to have greater knowledge of a food's variability. In many cases producers, who have access to the food before it is packed and put in containers, may well carry out more extensive product testing before export than it is feasible for the importing country to apply. It may also be easier for the producer to conduct valid sampling procedures, for example random sampling. Information from such testing, if made available to the importing country, may be useful in estimating the variability of product, and may reduce the testing burden of the importing country. For instance if the producer’s data showed that production was in control, it would allow the sigma method to be used instead of the s method.*

[The Netherlands: I’m not so sure it is an improvement to strike out the earlier additions of “production lot/consignment and “inspection lot/consignment”. In many cases inspectors see only part of a production lot/consignment and define the lot base on the visible characteristics. The striked out additions helped being alerted to this issue. If “inspection lot” is not a good description, I suggest “lot as defined by the inspector”, see above]

H: we agree with NL comment

Principle 6: Practical considerations

The selection of sampling and testing procedures should take into account practical matters such as cost and timeliness of the assessment and access to lots or consignments, provided that Consumers' Risk is not compromised.

*In some cases, reliance on sampling and testing by importing countries may not be a feasible means of providing assurance that the 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 the product should be considered, such as reliance on the manufacturer’s or exporting country’s assessment. For further details, the General Guidelines for Food Import Control Systems (CAC/GL 47-2003) should be consulted. However, 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 ~~production~~ lot or ~~production~~ consignment may become heterogeneous. In such cases, sampling and testing by importing countries may provide assurance that the product still meets specifications.*

*Deviations from accepted analytical methods and sampling plans may change producers’ and consumers’ risks; the new risks should be considered and accepted by both parties.*

[Canada: Perhaps GUIDELINES FOR THE DESIGN, OPERATION, ASSESSMENT AND ACCREDITATION OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CAC/GL 26-1997) may be cited here as well. See the suggestion made in Principle 2.]

[New Zealand: We agree: it seems very relevant at this point,]

[Germany: We also agree with that additional citation.]

JAMAICA: agrees with Canada/Germany/New Zealand to add citation suggested by Canada.

**Principle 7: Taking account of analytical measurement uncertainty and its implications**

The selection of the product assessment procedure should take into account analytical measurement uncertainty.

*The GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006) and the GUIDELINES ON MEASUREMENT UNCERTAINTY (CAC/GL 54-2004) describe acceptable procedures for estimating the measurement uncertainty based on different combinations of in-house validation data, in-house precision data and inter-laboratory data and illustrate how the concept of analytical measurement uncertainty might be taken into account, in the most simple case when decisions are made based on a single test sample. Note that such decisions, if based only on an estimate of the measurement uncertainty, do not satisfactorily control the producers’ and consumers’ risks. In order to control these risks it is necessary to specify a quantity that the standard deviation of measurement error is not expected to exceed, such as a 95% confidence limit. The analytical measurement uncertainty is composed of contributions by sample preparation, sample processing, extraction, cleanup, evaporation, derivatisation and instrumental determination.*

*In many situations the impact of measurement uncertainty on the test statistic may be negligible compared to its sampling uncertainty. In that case it will therefore have a negligible impact on the operating characteristics of the sampling plan and need not be taken into account in the assessment.*

*Other things being equal, a high measurement uncertainty will increase either the producers risk (high rate of rejection of compliant products in quality control may make trade uneconomic) or the consumers risk (high probability of acceptance of non compliant products may affect consumer protection) and possibly both.*

*{Jamaica:* Agree with New Zealand and Hungary. The statement regarding use of measurement uncertainty as a basis of rejecting a value is misleading. Additionally, the acceptable confidence level should be agreed on between the trading countries prior to commencement of trade so as to avoid subsequent disputes. We also share Hungary's concern that a large expanded uncertainty could result in a sample being rejected, particularly if sampling uncertainty is taken into account.

[Canada: Guidelines on uncertainty from CCPR, CAC/GL 59-2006, Sections 5.1 and 5.2 deal with the use of uncertainty, particularly in decision making. The last paragraph of 5.2 illustrates that MU has implications for both importer and exporter that each should consider. It may be important to state this point and cite this document.]

[New Zealand: We are concerned about referring to section 5 of GL 59, as this section seems likely to be interpreted is a misleading way.

First of all, readers may mistakenly think that these sections apply generally, when in fact they are intended to apply only to decisions regarding compliance with MRLs for plant products (and may possibly also apply to egg and dairy products) for which measurement uncertainty is applied to results from a composite bulk sample derived from 1-10 primary samples according to GL 33.

Secondly we have noted shortcomings of this section in other comments. Some examples may be useful to illustrate our concerns:

Paragrah 3 of 5.2

*The decision-making in Situation (i) is clear. In order to avoid lengthy explanation of the uncertainty involving the performance of the analysis for testing compliance with the MRL at the national level in locally produced or imported commodities, the laboratory may report the results as the sample contains “not less than ‘x – U’ residues”. This satisfies the requirement that the MRL was exceeded beyond any reasonable doubt accounting for measurement uncertainty.*

The final sentence is quite simply false, as statisticians will confirm. Statistical significance at the 2-sigma level does not prove anything “beyond any reasonable doubt”. The statement is likely to mislead readers as to the strength of the evidence of non-compliance that they may reasonably claim.

H: perhaps we may add … beyond any reasonable doubt at the specified probability level.

H: our concern related to the CCPR guide is that it does not clearly state that for deciding on compliance at the exporter/producer side the expanded uncertainty shall be calculated with SRes which includes sampling uncertainty.

The difference between the calculation of uncertainty for deciding on the compliance at exporting side and importing side shall be made clear for all cases where the legal limits refer to the average analyte content of the sample taken according to specified standards (all food contaminats are in this category)

Paragraph 2 of 5.2

*Since the residues in every sample that concurs with the minimum sample size and sample mass specified in the Codex Sampling Procedure should comply with the MRL, the expanded uncertainty should be calculated using SL from equation 1 as U = kSL.where SL = CVL\* residue.*

This is likely to be misinterpreted as meaning that several samples may be taken from a lot, and individually tested against the same expanded uncertainty that applies to a single sample. In actual fact, the more samples one takes from a lot, the more likely it is that U will be exceeded for at least one of them.

H: this sentence draws the attention that in principle residues in any sample satisfying the minimum sample size requirements should be ≤ MRL. Consequently for compliance assessment the sampling uncertainty should not be taken into account.

Second last sentence before the glossary

*For countries importing commodities with residue levels as described in situation (ii) it may be difficult to verify compliance with the MRL with an acceptable level of confidence.*

This seems to hint that, having failed to convince itself, using whatever resources it chooses to devote to the job, that the lot is in fact compliant, an importing country is entitled to reject product on the grounds that compliance has not been verified with an acceptable level of confidence. There also may be a risk that countries may interpret situation (iv) as meaning that they HAVE verified compliance at an acceptable level of confidence.

 For the concept of verification at a level of confidence to even make sense, the sample must be a composite from a large number of places within the lot. This is not made clear. Although this may perhaps be the usual situation for residues, readers may be likely to apply it more generally.]

H: we consider case ÍV to be a clear indication of compliance if the SRes is selected properly. Introduction of and pre-agreed A/RL would solve this problem

[Germany: We agree with Canada, that the implication of MU should be emphasised. We also follow the arguments of New Zealand, that the consideration of the expanded MU does not ensure compliance or non compliance beyond any reasonable doubt. Therefore, as a compromise, it might be appropriate to advise of that risk of misinterpretations as expressed by New Zealand:

*The GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006), Sections 5.1 and 5.2 deal with the use of uncertainty, particularly in decision making. It must be emphasised, that the statistical significance of 95% does not prove compliance or non compliance beyond any reasonable doubt. The more inspection samples are taken from a lot in the importing country, the more likely it is that at least one of them does not meet the quality requirements. On the other hand, for the same reason the exporting country, under consideration of the expanded MU, may inadvertently interpret their analytical results as verification of compliance. Therefore, as stated in principle 1, the agreements should include the specification of the statistical significance (for example the maximum number of the inspection samples taken from the lot that may fail to comply with the provision).*]

[The Netherlands: As far as I know “beyond reasonable doubt has not been defined properly. Actually, the text above rather defines it as this 95% confidence]

H: Agrees with NL**Principle 8: Product variation**

The selection of sampling and testing procedures should take into account the potential variations within a lot or consignment.

*Variation of foods may exist* per se *and may be caused or influenced by differences due to storage and transport conditions. However it may be difficult or impossible to determine estimates of within ~~inspection~~ lot ~~or consignment~~ variation that are universally applicable, even for a well-defined single food type. In these cases there may be a need for lot- ~~or consignment-~~specific estimation of within ~~inspection~~ lot ~~or consignment~~ variation, normally requiring a ~~multi inspection lot and~~ multi inspection sample ~~(as illustrated on graphic chart)~~ assessment.* [New Zealand: We have deleted “or consignment” because within-consignment variation is only relevant where the consignment is a lot.]

[Germany: Thank you, we agree.]

Jamaica: We do not object to the original principle and suggests that it remains as is. The *General Guidelines on Sampling (CAC/GL 50-2004), Section 2.2* have clearly defined these terms and we do not agree that within-consignment variation is only relevant where the consignment is a lot.

*As stated in the General Guidelines on Sampling (CAC/GL 50-2004), Section 2.4, and in the GUIDELINES ON ESTIMATION OF UNCERTAINTY OF RESULTS (CAC/GL 59-2006), Section 2, it is desirable that the sampling uncertainty (expressed by the sampling standard deviation associated with any sampling plan, as well as the measurement uncertainty associated with the analysis should be quantified and combined.*

*The sampling uncertainty can be based on an estimate of standard deviation obtained from experimental data on an extended period of production, made available to the inspectors by the professionals (σ-method) or can be estimated by testing a number of primary samples (s-method) in case of nonsufficient product experience.*

*It must be considered that the Guidelines on Sampling (CAC/GL 50-2004) do not cover the control of* *non-homogeneous goods. In case of non-homogeneous lots or consignments, an appropriate sampling procedure should be selected. The sampling procedure should consider the risk and the intended use of the product. Large ~~production~~ lots or consignments should be subdivided ~~into inspection lots or -consignments~~ into parts to be sampled separately and accepted and rejected independently. As far as possible primary samples (CAC/GL 50-2004, p. 17, 2.3.5.1) should be taken at various places distributed throughout the ~~inspection~~ lots or consignments, preferably using random sampling.*

*The influence of the intended use on the selection of sampling and testing procedures is illustrated by the following examples for products with health-related properties:*

*For products subjected to further sorting or mixing treatment, the analytical result of the composite sample of the mixed primary samples or the average of the analytical results of the primary samples might be used for assessment. Acceptance might be achieved if the result of the composite sample (CAC/GL 50-2004, p. 17, 2.3.5.2) or the average of the results of the primary samples do not exceed the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. For products intended for direct human consumption acceptance might be achieved if in addition none of the analytical results of the primary samples exceeds a higher limit at which health or safety is significantly compromised. This latter test would preclude compositing of the samples.*

**Principle 9: Fitness for purpose**

A testing procedure is fit for purpose in a given product assessment procedure, if , when used in conjunction with the sampling plan and the decision criteria, it has accepted probabilities of wrongly accepting or wrongly rejecting a lot or consignment.

*A method of analysis 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 method of analysis and sampling plan are acceptable( to both parties). To ensure that their own test results are fit for purpose and of the highest quality, the testing laboratories employed should adhere to the Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food (CAC/GL 27-1997) and to Food Control Laboratory Management: Recommendations (CAC/GL 28-1995. rev.1997).*

*The following quality criteria should be adopted by laboratories involved in the import and export control of foods:*

* *Compliance with the general criteria for testing laboratories laid down in the standard ISO/IEC 17025:2005 (CAC/GL 27-1997) “General requirements for the competence of calibration and testing laboratories”.*
* *Participation in appropriate proficiency testing schemes for food analysis which conform to the requirements laid down in FOOD CONTROL LABORATORY MANAGEMENT: RECOMMENDATIONS (CAC/GL 28-1995, Rev.1-199).*
* *Whenever available, use of methods of analysis which have been validated according to the principles laid down by the Codex Alimentarius Commission (CAC/GL 27-1997)*

 *[CUBA: when they are not available, then, a sampling plan and a method of analysis for a parameter in a specification could be interpreted as an implied statement of fitness for purpose for the product, provided that they could be: registered procedures and used historically, internationally recognized or based in international methods and appropriate to the commodity and lot or consignment to be sampled and tested; always previous agreement among exporter and importer.]*

* *Use of internal quality control procedures, such as those described in the Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories (CAC/GL 65-1997).*

*Fitness for purpose of an alternative method of analysis can be assessed in terms of its effect on consumers' and producers' risks arising from the use of that method, in*

*conjunction with a sampling plan, compared to the specified method and sampling plan.*

*JAMAICA: Altenative methods of analyses are fit for intended purpose when fully validated using international performance criteria*

**Principle 10: Review procedures**

Sampling and testing procedures should be reviewed periodically to ensure they take into account new science and information.

*According to the “General requirements for the competence of calibration and testing laboratories” (ISO/IEC 17025:2005) ,(CAC/GL 27-1997) the analytical laboratories should maintain a quality management system, which implements a fixed time period of scientific literature research and a revision service promptly based on the current technical documentation in force.*

*JAMAICA:* No objections. Periodic review of procedures is simply good practice.