CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 5 **CX/MAS 20/41/7**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

41st Session

Budapest, Hungary, 11 – 15 May 2020

DRAFT REVISION OF THE GUIDELINES ON MEASUREMENT UNCERTAINTY
Comments at Step 6 in reply to CL 2019/80-MAS

Comments of Chile, Costa Rica, Egypt, Honduras, Iraq, Japan, Mexico, Morocco, New Zealand, Peru, CCTA, ICUMSA, and IUFOST

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/80-MAS issued in July 2019. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

ANNEX I

GENERAL COMMENT	MEMBER/OBSERVER
Regarding the document worked at the last CCMAS meeting, it is considered that the document has the appropriate structure to be a guideline in matters of uncertainty, and that it would be important to improve and harmonize aspects of its content. In the introduction there is a repeated reference to the evaluation of the uncertainty and the importance of the measurement, which is suggested to be improved, so that the repetition does not lead to confusion. In the scope of application there should be a separate and clearly described point stating that this guideline does not include uncertainty from sampling or sampling plans. A mention is made in the document but later there is a clarification that leads rather to confusion. Therefore, it would be better to incorporate in a separate point for the same field the clear indication of: "The estimation of sampling uncertainty is excluded, i.e. the document does not address the uncertainty component associated with sampling made prior to entering the sample into the laboratory." In Prerequisites, this is correctly focused as it points out the importance for a laboratory to meet the requirements of ISO/IEC 17025, and that the uncertainty is a requirement of this relevant standard. Similarly, it makes a reference that standards of ISO 10576 and JCGM 106:2012 should be revised. In Terms and definitions it would be important to include a definition of uncertainty. It is suggested to eliminate normative references to sampling as this can lead to confusion. It is suggested to change the term composite sample to composite laboratory sample in order to specify that the composite sample will be made in the laboratory and not in the course of sampling. It is suggested to eliminate terms referring to sampling such as "sampling increment" and "inspection by variables" since as indicated above, the estimation of uncertainty associated with sampling is excluded. For the sake of better understanding of terms it is suggested to modify "element" to "unit of sample" in all the definitions that include the term. It is suggested to include the definitions of true value, conventional true value, reference value and coverage factor, to make it clear what they refer to when these terms are used in the guideline; it is suggested to include definitions of the VIM. References to all official references currently available for the assessment of measurement uncertainty should be preferably included in one single paragraph or at the end of the document indicating that the following references are recommended or suggested as a guidance for the evaluation of the uncertainty of the measurement, and should be named all together. The top-down uncertainty estimation approach is mentioned in the document but there is no further explanation, so it is not clear. It is very important to provide in-depth explanation for the 4 cases of uncertainty assessment so that they are well understood by those who use the guideline, and include a simple example for each case. We thank the eWG for the work done to improve the guideline, which will be useful for all countries in the application of measurement uncertainty.	**Chile**
Egypt agrees the proposed draft revision of the "Guideline on Measurement Uncertainty (CXG 54-2004)" with no comments.	**Egypt**
we are agree with proposed draft of guidelines , and we have no comments.	**Iraq**
(Paras. 23 and 27)	**Mexico**

It is suggested to change the term "extended uncertainty" to "uncertainty range". (Para. 8) It is recommended to include in para. 8 the definitions of "Uncertainty" and "Standard deviation"; the latter in terms of its classical formula. It is recommended to use a hyphen in the terms "bottom-up" and "top-down" when mentioning the uncertainty assessment approaches.	
Two key technical areas where improvement is needed to progress the revision are: - Guidance on measurement uncertainty (MU) as an input in conformity assessment and sampling inspection; - Providing consistent advice about the treatment of bias.	**New Zealand**
Paragraph 18 where it is stated: "If the estimate of a standard deviation is obtained from a low number of tests run by a single laboratory or from a collaborative study conducted by a low number of laboratories each with a single measurement, the true standard deviation can be up to 2-3 times the estimated standard deviation. This factor can be calculated with the following Excel formula: SQRT((N-1)/CHISQ.INV(0.05,N-1). This uncertainty of measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of measurement uncertainty." We question whether Codex should be recommending a formula developed with a proprietary software in a Guideline. Paragraphs 26 – 27 (Examples of Situations occurring when measurement uncertainty is considered) Some reference should be made to the Codex Procedural Manual where it is clearly stated in the section dealing with "the Use of Analytical Results: Sampling Plans, Relationship Between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards" and in section 2, Measurement Uncertainty, in particular where it is stated: An allowance is to be made for the measurement uncertainty when deciding whether or not an analytical result falls within the specification. This requirement may not apply in situations when a direct health hazard is concerned, such as for food pathogens. We would like to remind CCMAS that it was the intention when Codex Standards were being developed that Codex Committees were aware that there is a difference between the value of a characteristic in a Standard and the effective enforcement limit. It was anticipated that this influence the development of CXG 54 – 2004. This requirement was first included in the 16th Edition of the Procedural Manual and some cross referencing should now be given in the revision of CXG – 54, i.e. to be far more positive than it is at present. General Comment. In the Explanatory Note 7 of the current CAG - 54 it is stated: Stipulating information on the anticipated values of measurement uncertainty estimates is frequently not supported by analysts. The users of analytical data and the customers of the laboratories producing such data frequently ask for such information regarding the level of uncertainty that may be expected for test results. They have concerns that some laboratories underestimate the size of their uncertainties and so report unrealistically small uncertainties to their customers. We are concerned that the issue of unrealistically small uncertainties has not been sufficiently addressed in this revision of CXG 54 -2004, an issue which is often of concern to contractors of analytical results.	**ICUMSA**
This document does not seem to take into account the basic principles of food analysis that have been used by competent government agencies to test foods for various criteria and which have been used to provide evidence in court cases related to seizure of non-conforming foods or prosecution of companies or individuals violating food laws	**IUFOST**

Since such evidence is subject to challenge in court proceedings, analytical systems must be adequate to show convincingly that test results are robust and correct.analytical test methods should be based on collaborative examination by several laboratories of methods that are approved, and test results should be based wherever possible on original analysis results confirmed by a second approved method that confirms the original analysis. This document should explore the use of such systems that reduce uncertainty, and should emphasize test methods that have been collaboratively developed. With regard to sampling, similar sampling plans that have been tested with regard to legal requirements of food law should be emphasized where law enforcement is involved. For in-process testing by food processors, similar robust systems should be uesed to assure quality, safety and compliance with food standards	

SPECIFIC COMMENTS	**MEMBER / OBSERVER AND RATIONALE**
Para. 1	
Analytical measurement results in food control are used to assess whether food products meet relevant specifications. The accuracy of measurement results is affected by various error components, and it is important to ensure these errors are properly considered. Since the true value of the quantity being measured is unknown, errors cannot be known exactly. The focus thus shifts to an evaluation of the uncertainty associated with a measurement result. All measurement results have an associated uncertainty; the non-estimation of measurement uncertainty does not mean that there is no uncertainty. ~~The estimation of measurement uncertainty is required to establish the metrological traceability of the measurement results.~~ Accordingly, measurement uncertainty is of utmost importance in analytical testing and subsequent decision-making. It should be noted that, in this guideline, the evaluation of sampling uncertainty is not included.	**New Zealand** This paragraph states that estimation of MU is required to establish metrological traceability. It is true that traceability, e.g. to a reference standard, relates to bias but it does not relate to MU expressed purely in terms of variation. The mention of metrological traceability also introduces a distinctly different purpose to that given in para. 2, i.e. compliance with ISO 17025. This creates confusion about the purpose of the document.
Analytical measurement results in food control are used to assess whether food products meet relevant specifications. The ~~precision~~ accuracy (editorial change) of measurement results is affected by various error components, and it is important to ensure these errors are properly considered. Since the true value of the quantity being measured is unknown, errors cannot be known exactly. The focus thus shifts to an evaluation of the uncertainty associated with a measurement result. All measurement results have an associated uncertainty; the non-estimation of measurement uncertainty does not mean that there is no uncertainty. The estimation of measurement uncertainty is required to establish the metrological ~~traceability~~ traceability (editorial change) of the measurement results. Accordingly, measurement uncertainty is of utmost importance in analytical testing and subsequent decision-making. It should be noted that, in this guideline, the evaluation of sampling uncertainty is not included.	**Peru**
Para. 2	
The Codex Alimentarius Commission has developed Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods (CXG 27-1997). They recommend that laboratories involved in food control for import/export should adopt the general criteria set forth in ISO/IEC 17025. According to ISO/IEC 17025, [1]. This standard requires that **the laboratories should identify and estimate the contributions to the**	**Honduras** Quote 1 mentions the ISO 17025 standard, it is not related to the content of the footnote; I think this explanation is found elsewhere in the document.

uncertainty and where necessary for the interpretation of the test results and where applicable measurement uncertainty shall be included in the test report. The ISO/IEC 17025 standard also requires that the measurement uncertainty and its level of confidence must be made available to the user (customer) of the results, on request. The use of measurement uncertainty in establishing decision rules must be documented. In summary, the ISO/IEC 17025 standard requires that information regarding measurement uncertainty must should be provided in test reports insofar as it is relevant to the validity or application of the test results, in response to a customer's request, or when the uncertainty affects compliance to a specification limit.	
The Codex Alimentarius Commission has developed *Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods* (CXG 27-1997). They recommend that laboratories involved in food control for import/export should adopt the general criteria set forth in ISO/IEC 17025. According to ISO/IEC 17025, ~~[1]. This standard requires that where necessary for the interpretation of the test results and where applicable measurement uncertainty shall be included in the test report. The ISO/IEC 17025 standard also requires that the measurement uncertainty and its level of confidence must be made available to the user (customer) of the results, on request. The use of measurement uncertainty in establishing decision rules must be documented. In summary, the ISO/IEC 17025 standard requires that~~ information regarding measurement uncertainty ~~must~~ should be provided in test reports insofar as it is relevant to the validity or application of the test results, in response to a customer's request, or when the uncertainty affects compliance to a specification limit.	**Japan** To keep the document as short as possible and remove redundancy of the text, the third and fourth sentences should be removed. In addition, the last sentence may mislead the readers that providing measurement uncertainty is mandatory in the context of Codex, but the document is a guideline.
The Codex Alimentarius Commission has developed Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Foods (CXG 27-1997). They recommend that laboratories involved in food control for import/export should adopt the general criteria set forth in ISO/IEC 17025 [1]. This standard requires that where necessary for the interpretation of the test results and where applicable measurement uncertainty shall be included in the test report. The ISO/IEC 17025 standard also requires that the measurement uncertainty and its level of confidence must be made available to the user (customer) of the results, on request. The use of measurement uncertainty in establishing decision rules must be documented. In summary, the ISO/IEC 17025 standard requires that information regarding measurement uncertainty must be provided in test reports insofar as it is relevant to the validity or application of the test results, in response to a customer's request, or when the uncertainty affects compliance to a specification limit.	**Morocco** Morocco proposes to replace in the French text the term "procès-verbal d'analyse" by either "rapport d'analyse" , or "rapport d'essai" (in line with the standard ISO 17025) (*the English text is not affected*).
Scope	
Para. 3	
This guideline covers general aspects of measurement uncertainty for quantitative analysis, gives definitions of measurement uncertainty and related terminology and clarifies the role of measurement uncertainty in the interpretation of test ~~results~~ results, in conformity assessment, and ~~the relationship between measurement uncertainty and~~ in sampling ~~plans~~inspection. This guideline does not address the uncertainty component associated with sampling and focuses on uncertainty contributions which arise in connection with obtaining a test sample from the laboratory sample, taking a test portion from a test sample (i.e. the errors due to the heterogeneity[1] between test portions) and the analysis of a test portion in the laboratory.	**New Zealand** The concept of a 'relationship' between MU and sampling plans is not appropriate. MU does however have a role in conformity assessment to assess whether the true value of the tested sample complies with the limit, and as an input to the design of sampling plans when measurement error is significant, as noted in para. 23.
Para. 4	

While chemical analysis in food control often produces results of *quantitative* analytical measurements, *qualitative* results are also relevant. For the estimation of the measurement uncertainty associated with the qualitative results, a different approach should be applied than for quantitative results. **For qualitative tests an evaluation or estimation of the uncertainty as such is not required; however, it is expected for the laboratory to identify the critical factors that influence the outcome of that analysis and establish quality assurance mechanisms to control them.**	**Honduras**
While the role of chemical analysis in food control often involves quantitative analytical measurement results, qualitative results are also relevant. For the estimation of the measurement uncertainty associated with qualitative results, a different approach should be applied than for quantitative results.	**Morocco** in paragraphs 4 and 5 only chemical analysis is referred to, however the Codex product specification standards include physical parameters as well (refractive index, specific gravity, etc.) Therefore reference should be made to both chemical and physical analyses.
Para. 5	
Laboratories which perform measurements in chemical analysis should have effective quality ~~guarantee~~ **assurance** (editorial change) procedures in place (properly trained staff, equipment maintenance, calibration of equipment, reference materials and standards, documentation, participation in proficiency tests, quality control charts etc.), which can be used for the evaluation of measurement uncertainty. Furthermore, sufficient statistical knowledge either by qualified staff or external consultants is recommended, in order to ensure that statistical methods, mathematical formulas and decision rules are correctly applied, and that criteria for producer and consumer risks are met. Examples and explanations of the rules governing decisions can be found in the ISO 10576 and JCGM 106:2012 standards.	**Honduras**
Laboratories which perform measurements in chemical analysis should have effective quality assurance procedures in place (properly trained staff, equipment maintenance, calibration of equipment, reference materials and standards, documentation, participation in proficiency tests, quality control charts etc.), which can be used for the evaluation of measurement uncertainty. Furthermore, sufficient statistical knowledge either by qualified staff or external consultants is recommended, in order to ensure that statistical methods, mathematical formulas and decision rules are correctly applied, and that criteria for producer and consumer risks are met. Examples and explanations of decision rules can be found in ISO 10576 and JCGM 106:2012.	**Morocco** in paragraphs 4 and 5 only chemical analysis is referred to, however the Codex product specification standards include physical parameters as well (refractive index, specific gravity, etc.) Therefore reference should be made to both chemical and physical analyses
Laboratories which perform measurements in chemical analysis should have effective quality assurance procedures in place (properly trained staff, equipment maintenance, calibration of equipment, reference materials and standards, documentation, participation in proficiency tests, quality control charts etc.), which can be used for the evaluation of measurement uncertainty. Furthermore, sufficient statistical knowledge either by qualified staff or external consultants is recommended, in order to ensure that statistical methods, mathematical formulas and decision rules are correctly applied, and that criteria for producer and consumer risks are met. ~~Examples and explanations of decision rules can be found in ISO 10576 and JCGM 106:2012.~~	**New Zealand** The final sentence is not a prerequisite. It should be placed in para. 23.
Laboratories which perform measurements in chemical analysis should have effective quality ~~guarantee~~ assurance (editorial change) procedures in place (properly trained staff, equipment maintenance, calibration of equipment, reference materials and standards, documentation, participation in proficiency tests, quality control ~~tables~~ charts (editorial change) etc.), which can be used for the evaluation of measurement uncertainty. Furthermore, sufficient statistical	**Peru**

knowledge either by qualified (editorial change) staff or external consultants is recommended, in order to ensure that statistical methods, mathematical formulas and ~~rules governing decisions~~ decision rules (editorial change) are correctly applied, and that criteria for producer and consumer risks are met. Examples and explanations of ~~rules governing decisions~~ decision rules (editorial change) can be found in the ISO 10576 and JCGM 106:2012 standards.	
Para. 6	
~~For the purposes of this guideline, the terms and definitions of the following documents apply.~~	**Japan** Japan propose to combine Paragraph 6 and Paragraph 7 into one paragraph. There is no need to separate these two paragraphs.
Para. 7	
For the purposes of this guideline, the terms and definitions of the following documents apply.Guidelines on analytical terminology (CXG 72-2009) ISO 2859-1:~~2014~~ 1999 Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection ISO 3951-1:~~2016~~ 2013 Sampling procedures for inspection by variables – Part 1: Specification of single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL	**Japan** Japan propose to combine Paragraph 6 and Paragraph 7 into one para. There is no need to separate these two paragraphs. Publication year of ISO standards should be corrected. The terms “sample”, “test sample” and “lot” are differently defined in CXG 50 and the listed ISO standards.
	Morocco Morocco proposes to add the standard ISO 17025:2017 as a reference for the terms and definitions, as this standard has offered some definitions for certain terms included in the proposed draft revision.
ISO 2859-1:2014 *Sampling procedures for inspection by attributes. Part 1: Sampling schemes indexed (editorial change, classified in Spanish) by ~~acceptance~~ acceptable quality limit (AQL) for lot-by-lot inspection* ISO 3951-1:2016 *Sampling procedures for inspection by variables – Part 1: Specification of single sampling plans indexed (editorial change, classified in Spanish) by ~~acceptance~~ acceptable quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*.	**Peru**
Para. 8	
	Honduras Sort the definitions alphabetically
For convenient reference, the following definitions are ~~provided here~~applied in this guideline:	**Japan** To avoid misunderstanding caused by the use of different definitions

	for the same terms, text in the first sentence of para. 8 should be changed.
	New Zealand It would be helpful to clarify other terms used in the document, e.g. - Level of reliability (para 13) - Matrix mismatch uncertainty component (para 15) - Random variability of the standard deviation figures (para 16).
Para. 8 **Item**	
~~Compound~~ Component of a sample or lot that can be individually described and considered.	**Mexico** The word "compound" may suggest a different connotation in chemical nomenclature, so the term "component" is suggested.
Sample size	
Sample size (editorial change)	**Peru**
Number of elements ~~of the~~ in a sample.	**Mexico** The definition is better described.
Sampling plan	
~~combination of sample size(s)~~Sample size, methodology for selection the sample(s) to be used and associated lot acceptability criteria	**Mexico** The definition is better described.
Sample increment	
~~**sampling increment**~~ **Increment:** ~~amount~~ Quantity of ~~bulk~~ material ~~taken in~~ drawn at one ~~action by~~ time from a ~~sampling device~~larger quantity of material to form a sample	**Japan** The term does not exist in the body of the guideline, but “increment” is included in a footnote. We propose to replace “sampling increment” with “increment” in the headline. The definition of increment should be “Quantity of material drawn at one time from a larger quantity of material to form a sample” to be in line with the definition in CXG 50.
Composite sample	
~~**composite sample**~~ ~~aggregation of two or more sampling increments taken from a lot for inspection of the lot~~	**Japan** The term should be removed as it does not exist in the guideline.
General considerations	
Para. 9	
When a measurement is performed, it is generally assumed that a “true value” of the quantity being measured exists. However, this true value is unknown and is thus only available as a	**New Zealand**

reference value or a conventional true value. For this reason, measurement error cannot be reliably estimated and the focus shifts to the evaluation of measurement uncertainty. Measurement uncertainty is expressed as an interval within which values which can reasonably attributed to the measured quantity will lie with a stated coverage probability. It is assumed that any necessary bias correction has been correctly performed. Since all measurement results are subject to error, laboratories are expected to estimate and, if necessary, report the measurement uncertainty associated with every result.	This paragraph says it is assumed that bias correction is correctly performed, but paras 10, 15 and 25 imply that this is either not possible or that bias should be reported only if significant. These inconsistencies should be corrected.
Para. 10	
Measurements are affected by many influences – e.g. effects which arise in connection with changes in temperature, pressure, humidity, matrix variability or with the judgement of the analyst. These errors can be classified as either *systematic* or *random*. The term *bias* is often used to refer to a systematic error. Even if all *systematic* error components could be evaluated and corrected for, measurement results would remain subject to random errors which cannot be corrected for, leading to an uncertainty range. An example of the manner in which a random error manifests itself is the dispersion of measurement results observed when measurements are performed within one laboratory under near-identical, i.e. repeatability, conditions~~. The individual components of measurement uncertainty should be identified and estimated.~~ . Some of these components can be evaluated from the statistical distribution of a series of measurement results and characterized by standard deviations. The other components, which can also be characterized by standard deviations, are evaluated on the basis of distributional assumptions derived from experience or other information. All components of uncertainty, including those arising from systematic effects such as the uncertainty of bias corrections and reference standards, contribute to the dispersion.	**Japan** The sentence starting at the line 7 (The individual components of measurement uncertainty should be identified and estimated.) may be interpreted as “component-by-component approach” should be taken for the estimation of MU, which is contradiction to para 14. Japan therefore proposes to delete the sentence.
Measurements are affected by many influences – e.g. effects which arise in connection with changes in temperature, pressure, humidity, matrix variability or with the judgement of the analyst. These errors can be classified as either systematic or random. The term bias is often used to refer to a systematic error. Even if all systematic error components could be evaluated and corrected for, measurement results would remain subject to random errors which cannot be corrected for, leading to an uncertainty range. An example of the manner in which a random error manifests itself is the dispersion of measurement results observed when measurements are performed within one laboratory under near-identical, i.e. repeatability, conditions. The individual components of measurement uncertainty should be identified and estimated. Some of these components can be evaluated from the statistical distribution of a series of measurement results and characterized by ~~typical~~ standard (editorial change) deviations. The other components, which can also be characterized by ~~typical~~ standard (editorial change) deviations, are evaluated on the basis of distributional assumptions derived from experience or other information. All components of uncertainty, including those arising from systematic effects such as the uncertainty of bias corrections and reference standards, contribute to the dispersion.	**Peru**
Para. 11	
It is important to note that **state of art,** time and financial resources do not allow for the evaluation and correction of all measurement errors. For this reason, the focus lies on the identification and evaluation of the main components of measurement uncertainty..	**Honduras**
Uncertainty components	

Para. 12	
While performing a measurement, it is important to consider all possible uncertainty components **or contributions** which will influence the result of the measurement. Typical uncertainty components include effects associated with instrumental equipment, analyst, sample matrix, method, calibration, time and environment. These sources may not be independent, in which case the respective correlations should be taken into account in the uncertainty budget – i.e. in the computation of the total uncertainty. Moreover, under certain circumstances, the effect associated with a particular uncertainty component may change over time and a new estimation of measurement uncertainty may be necessary as a result. For more information on this subject, please refer to the EURACHEM / CITAC Guide CG 4.	**Honduras**
Procedures for Estimating Measurment Uncertainty	
Para. 13	
There are many procedures available for estimating the uncertainty of a measurement result, notably those described in ISO/IEC Guide 98-3:2008 and EURACHEM / CITAC Guide CG 4. The Codex guidelines do not recommend a particular approach for estimating measurement uncertainty, but it is important that whatever approach is used be scientifically acceptable2. Choosing the appropriate procedure depends on the type of analysis, the method used, the required level of reliability, and the urgency of the request for an estimate of measurement uncertainty. In general, procedures are based either on a “bottom-up” approach or on a “top-down” approach, with the latter using data from ~~tests in collaboration~~ **collaborative** (editorial change) trials, proficiency **studies** (editorial change), validation studies or intra-laboratory quality control samples, or a combination of such data.	**Honduras** *Category : TECHNICAL*
There are many procedures available for estimating the uncertainty of a measurement result, notably those described in ISO/IEC Guide 98-3:2008 and EURACHEM / CITAC Guide CG 4. The Codex guidelines do not recommend a particular approach for estimating measurement uncertainty, but it is important that whatever approach is used be scientifically acceptable[2]. No one approach may be said to be better than any other provided the procedure used is appropriate and credible - i.e. there is no “hierarchy” of the procedures. Choosing the appropriate procedure depends on the type of analysis, the method used, the required level of reliability, and the urgency of the request for an estimate of measurement uncertainty. In general, procedures are based either on a “bottom-up” approach or on a “top-down” approach, with the latter using data from collaborative trials, proficiency studies, validation studies or intra-laboratory quality control samples, or a combination of such data.	**Japan** To clearly explain that procedures corresponding to the purpose should be selected, Japan proposes to include the following sentence (in the current version of CXG 54) between the second and the third sentence: No one approach may be said to be better than any other provided the procedure used is appropriate and credible - i.e. there is no “hierarchy” of the procedures.
There are many procedures available for estimating the uncertainty of a measurement result, notably those described in ISO/IEC Guide 98-3:2008 and EURACHEM / CITAC Guide CG 4. The Codex guidelines do not recommend a particular approach for estimating measurement uncertainty, but it is important that whatever approach is used be scientifically acceptable[2]. Choosing the appropriate procedure depends on the type of analysis, the method used, the required level of reliability, and the urgency of the request for an estimate of measurement uncertainty. In general, procedures are based either on a “bottom-up” approach or on a “top-down” approach, with the latter using data from collaborative trials, proficiency studies, validation	**New Zealand** Several standards published by other organisations are cited in this paragraph and elsewhere. It should be made clear whether these standards are therefore considered as normative in the context of Codex.

studies or intra-laboratory quality control samples, or a combination of such data.	
There are many procedures available for estimating the uncertainty of a measurement result, notably those described in ISO/IEC Guide 98-3:2008 and EURACHEM / CITAC Guide CG 4. The Codex guidelines do not recommend a particular approach for estimating measurement uncertainty, but it is important that whatever approach is used be scientifically acceptable[2]. Choosing the appropriate procedure depends on the type of analysis, the method used, the required level of reliability, (editorial change) and the urgency of the request for an estimate of measurement uncertainty. In general, procedures are based either on a "bottom-up" (editorial change) approach or on a "top-down" (editorial change) approach, with the latter using data from ~~tests in collaboration~~ collaborative trials (editorial change), proficiency studies (editorial change), validation studies or intra-laboratory (editorial change) quality control samples, or a combination of such data.	**Peru**
Para. 14 **Bullet point 1**	
Bottom-up (editorial change) evaluation component by component according to (editorial change) the ISO GUM standard.	**Peru**
Bullet point 2	
Top-down (editorial change) approach e.g. according to Nordtest TR 537, NMKL procedure No. 5, EURACHEM / CITAC Guide CG 4 (uncertainty of results obtained using the same procedure in a single laboratory varying (editorial change) conditions as described above).	**Peru**
Bullet point 3	
Interlaboratory (editorial change) validation	**Peru**
Top-down (editorial change) approach using the reproducibility standard (editorial change) deviation (ISO 21748) (uncertainty of results obtained using the same procedure in different laboratories).	
Top-down approach using the reproducibility standard deviation (ISO 5725 and ISO 21748) (uncertainty of results obtained using the same procedure in different laboratories)	**New Zealand** ISO 5725, as the primary reference, should be added to the reference under inter-laboratory validation, in addition to ISO 21748.
Bullet point 4	
Top-down approach using the target reproducibility standard deviation (uncertainty of results obtained by analysing the same sample(s) in different laboratories) • Monte Carlo simulation (IISO guide 98-3:2008 suppl 1.)	**Honduras**
Top-down (editorial change) approach using the target reproducibility standard (editorial change) deviation (uncertainty of results obtained by analysing the same sample(s) in different laboratories).	**Peru**
Para. 15	

These procedures are not equivalent and may produce different estimates of the measurement uncertainty. In the top-down approach, the reproducibility standard deviation obtained from collaborative studies is often used as a measure of measurement uncertainty. The matrix mismatch uncertainty component should be adequately taken into account during the estimation of measurement uncertainty. To overcome this deficiency different matrices and concentration levels – depending on the scope of the method – could be used. In the case of a single-lab validation study, intermediate precision (within-lab reproducibility) is used for the estimation of the uncertainty and the laboratory bias is therefore missing with the result that the uncertainty may have been underestimated. Depending on the case, this can be addressed e.g. by estimating and correcting for the bias via a recovery experiment (with the uncertainty of the recovery correction duly taken into account in the uncertainty) or by simulating the laboratory bias by varying influencing effects like analytical instruments, analysts, time span, equipment for sample preparation etc. However, laboratories that have traceable reference materials can obtain the bias (veracity) through the use of such materials, in order to contribute to their calculation of uncertainty.	**Honduras**
These procedures are not equivalent and may produce different estimates of the measurement uncertainty. In the top-down approach, the reproducibility standard deviation obtained from collaborative studies is often used ~~as a measure~~ for estimation of measurement uncertainty. The matrix mismatch uncertainty component should be adequately taken into account during the estimation of measurement uncertainty. To overcome this deficiency different matrices and concentration levels – depending on the scope of the method – could be used. In the case of a single-lab validation study, intermediate precision (within-lab reproducibility) is used for the estimation of the uncertainty and the laboratory bias is therefore missing with the result that the uncertainty may have been underestimated. Depending on the case, this can be addressed e.g. by estimating and correcting for the bias via a recovery experiment (with the uncertainty of the recovery correction duly taken into account in the uncertainty) or by simulating the laboratory bias by varying influencing effects like analytical instruments, analysts, time span, equipment for sample preparation etc.	**Japan**
These procedures are not equivalent and may produce different estimates of the measurement uncertainty. In the top-down approach, the reproducibility standard deviation obtained from collaborative studies is often used as a measure of measurement uncertainty. The matrix mismatch uncertainty component should be adequately taken into account during the estimation of measurement uncertainty. To overcome this deficiency different matrices and concentration levels – depending on the scope of the method – could be used. In the case of a single-lab validation study, intermediate precision (within-lab reproducibility) is used for the estimation of the uncertainty and the laboratory bias is therefore missing with the result that the uncertainty may have been underestimated. Depending on the case, this can be addressed e.g. by estimating and correcting for the bias via a recovery experiment (with the uncertainty of the recovery correction duly taken into account in the uncertainty) or by simulating the laboratory bias by varying influencing effects like analytical instruments, analysts, time span, equipment for sample preparation etc.	**New Zealand** This paragraph mentions different ways of estimating measurement uncertainty. More clarity should be provided about the differences between these studies and how to overcome them, in particular when allowances for bias need to be made. For some of these, single lab validation and intra-laboratory reproducibility, it is necessary to make allowance for laboratory bias, which is otherwise accounted for in estimates of inter-laboratory reproducibility obtained through inter-laboratory validation or proficiency testing. We recognise this could be somewhat complex, depending on the conditions under which the estimate of bias is established.
These procedures are not equivalent and may produce different estimates of the measurement	**Peru**

uncertainty. In the top-down approach (editorial change), the reproducibility ~~typical~~ standard (editorial change) deviation obtained from ~~studies in collaboration~~ collaborative studies (editorial change) is often used as a measure of measurement uncertainty. The matrix mismatch uncertainty component should be adequately taken into account during the estimation of measurement uncertainty. To overcome this deficiency different matrices and concentration levels – depending on the scope of the method – could be used. In the case of a single-lab validation study, intermediate precision (within-lab reproducibility) is used for the estimation of the uncertainty and the laboratory bias is therefore missing with the result that the uncertainty may have been underestimated. Depending on the case, this can be addressed e.g. by estimating and correcting for the bias via a recovery experiment (with the uncertainty of the recovery correction duly taken into account in the uncertainty) or by simulating the laboratory bias by varying influencing effects like ~~analytical instruments~~ equipment, analysts, time span, equipment for sample preparation etc.	
Para. 16	
These procedures may vary with regard to the influencing effects included there is also often considerable variation due to random variability of the standard (editorial change) deviation figures (intermediate precision, ~~within-lab~~ [intralaboratory] reproducibility, reproducibility, repeatability). Therefore, both the chosen approach for estimating measurement uncertainty (in-house validation, collaborative (editorial change) study, ~~bottom-up~~ top-down approach etc.) and the estimated level of confidence of the measurement uncertainty should be provided.	**Peru**
Para. 17	
Almost all uncertainty data are expressed as ~~typical~~ standard (editorial change) deviations or functions of ~~typical~~ standard (editorial change) deviations. If a ~~typical~~ standard (editorial change) deviation is calculated using a small amount of data, there is considerable uncertainty in the estimate of measurement uncertainty obtained.	**Peru**
Para. 18	
If the estimate of a standard deviation is obtained from a low number of tests run by a single laboratory or from a collaborative study conducted by a low number of laboratories each with a single measurement, the true standard deviation can be up to 2-3 times the estimated standard deviation. This factor can be calculated with the following Excel formula: SQRT((N-1)/CHISQ.INV(0.05,N-1)). This uncertainty of measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of measurement uncertainty.	**Honduras** SQRT((N-1)/CHISQ.INV(0.05,N-1). Enter the entire formula
If the estimate of a standard deviation is obtained from a low number of tests run by a single laboratory or from a collaborative study conducted by a low number of laboratories each with a single measurement, the true standard deviation can be up to 2-3 times the estimated standard deviation. ~~This~~ The multiplier factor can be calculated with the following Excel formula: SQRT((N-1)/CHISQ.INV(0.05,N-1). ~~This uncertainty~~ The reliability of measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of measurement uncertainty. .	**Japan** Japan proposes some editorial changes for clarity. (The meaning of “the uncertainty of measurement uncertainty components” is uncertain, isn’t it?).

If the estimate of a standard deviation is obtained from a low number of tests run by a single laboratory or from a collaborative study conducted by a low number of laboratories each with a single measurement, the true standard deviation can be up to 2-3 times the estimated standard deviation. This factor can be calculated with the following Excel formula: SQRT((N-1)/CHISQ.INV(0.05,~~N-1~~)N-1)). This uncertainty of measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of measurement uncertainty. .	**New Zealand** A bracket is missing in the formula. It should be mentioned that "N" is the number of laboratories.
If the estimate of a ~~typical~~ standard (editorial change) deviation is obtained from a low number of tests run by a single laboratory or from a ~~joint~~ collaborative (editorial change) study conducted by a low number of laboratories each with a single measurement, the true ~~typical~~ standard (editorial change) deviation can be up to 2-3 times the estimated standard (editorial change)deviation. This factor can be calculated with the following Excel formula: SQRT((N-1)/CHISQ.INV(0.05,N-1). This uncertainty of measurement uncertainty components should be taken into account in the design of experimental studies and the evaluation of measurement uncertainty.	**Peru**
Para. 19	
It is recommended that laboratories which perform food testing with quantitative methods should always evaluate measurement uncertainty. In cases where a rigorous evaluation cannot be made, measurement uncertainty should at least be estimated on the basis of principles, experience and "state of the art" knowledge based e.g. on results from comparable laboratories, concentration levels, matrices, analytical methods or analytes, approached from a quality assurance approach.	**Honduras** Consider creating guidelines on uncertainty in qualitative methods
It is recommended that laboratories which perform food testing with quantitative methods should always evaluate measurement uncertainty. ~~In cases where a rigorous evaluation~~ Even if some components of measurement uncertainty cannot be ~~made~~evaluated, estimation of measurement uncertainty ~~should at least~~ can be ~~estimated~~ done on the basis of principles, experience and "state of the art" knowledge based e.g. on results from comparable laboratories, concentration levels, matrices, analytical methods or analytes.	**Japan** Japan is of the view that "rigorous evaluation" in the second sentence needs further explanation and propose simpler description.
Para. 20 b	
b. the laboratory uses an official and/or standardized method with established characteristics related to the performance (editorial change) of the method and verifies that it can meet or exceed the parameters of performance (editorial change) of the laboratory according to the official standardized method and that all the determining factors are under control.	**Honduras**
Para. 21	
Most of the methods used in food testing and recommended in Codex documents are well-recognized methods which have been reliably validated. As long as the laboratory's competence in the application of a validated method has been demonstrated following either one of the two approaches described, the measurement uncertainty evaluation/estimation is considered to have been successfully performed and any requirements regarding the measurement uncertainty are considered to have been met.	**Honduras** From the fact that the method has been validated correctly it cannot be assumed that the uncertainty has been correctly estimated. This may vary between laboratories.

Most of the methods used in food analysis and recommended in Codex documents are well known methods that have been validated in a reliable (editorial change) manner. As long as the laboratory's competence in the application of a validated method has been demonstrated following either one of the two approaches described, the measurement uncertainty evaluation/estimation is considered to have been successfully performed and any requirements regarding the measurement uncertainty are considered to have been met.	**Peru**
Para. 22	
~~The~~ ISO/IEC 17025 requires laboratories to use validated methods; thus, data from the interlaboratory or single-lab validation study can be used for the estimation of MU with a top-down approach. In Section 7.6.2 of the ~~*Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food* (CXG 27-1997) requires laboratories involved in the import/export of foods to comply with the general criteria set forth in ISO/IEC 17025. This standard requires laboratories to use validated methods; it is thus usually recommendable to use data from the interlaboratory or single-lab validation study rather than another approach such as the bottom-up approach. In Section 7.6.2 of the~~ EURACHEM / CITAC Guide ~~CG 4~~CG~~EURACHEM / CITAC Guide CG 4~~, a procedure for evaluating measurement uncertainty using collaborative study data is provided. The EURACHEM / CITAC Guide ~~CG 4~~CG~~EURACHEM / CITAC Guide CG 4~~ also references ISO 21748 as the primary source for the estimation of uncertainty on the basis of "collaborative study data acquired in compliance with ISO 5725".	**Japan** As information in the first sentence about CXG 27 has already mentioned in para. 2, the sentence should be removed to avoid duplication. With regard to the fourth line beginning with "it is thus usually recommendable", the guideline should not recommend any of approaches to estimate MU (bottom-up or top-down), but be neutral for selection of the approach.
The Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food (CXG 27-1997) requires laboratories involved in the import/export of foods to comply with the general criteria set forth in ISO/IEC 17025. This standard requires laboratories to use validated methods; it is thus usually recommendable to use data from the interlaboratory (editorial change) or single-lab validation study rather than another approach such as the bottom-up top-down approach. In Section 7.6.2 of the EURACHEM / CITAC Guide CG 4EURACHEM / CITAC Guide CG 4, a procedure for evaluating measurement uncertainty using collaborative (editorial change) study data is provided. The EURACHEM / CITAC Guide CG 4EURACHEM / CITAC Guide CG 4 also references ISO 21748 as the primary source for the estimation of uncertainty on the basis of "collaborative study data acquired in compliance with ISO 5725".	**Peru**
Para. 23	
Bullet point 1	
In general, the measurement uncertainty is reported as expanded (editorial change) uncertainty of the measurement, that is, as the typical uncertainty multiplied by a coverage factor which, in the case of normal (Gaussian) distribution corresponds to a coverage probability of approximately 95%. Note: The higher the uncertainty of the standard deviation used for the calculation of the measurement uncertainty, the lower the coverage probability of the latter. In such cases it may be sensible to increase the coverage factor by taking the corresponding factor *k* of the Student *t* distribution.	**Honduras**

In general, the measurement uncertainty is reported as extended (editorial change) ~~expanded~~ uncertainty of the measurement, that is, as the ~~typical~~ standard (editorial change) uncertainty multiplied by a coverage factor which, in the case of normal (Gaussian) distribution corresponds to a coverage probability of approximately 95%. Note: The larger the uncertainty of the ~~typical~~ standard (editorial change) deviation used to calculate the uncertainty of the measurement, the lower the coverage probability of the latter. In such cases it may be sensible to increase the coverage factor by taking the corresponding factor *k* of the Student *t* distribution.	**Peru**
Bullet point 2	
Assessing the **performance** (editorial change) of laboratories (see ISO 13528)	**Honduras**
- For conformity assessment, to assess whether the true value of the tested sample complies with the limit (see paras 26 and 27). This is different from sampling inspection where acceptance or rejection of a lot is assessed. Examples and explanations of decision rules can be found in JCGM 106:2012.• Assessing the performance of laboratories (see ISO 13528)	**New Zealand** This should be included following the first bullet point, as this is the typical usage of MU. It includes a clear statement of the difference between conformity assessment and sampling inspection, which appears to be a source of on-going confusion in Codex. In the last sentence (moved from para. 5) we have removed the reference to ISO 10576 because this standard does not use MU.
Assessing the performance (editorial change) of laboratories (see ISO 13528)	**Peru**
Bullet point 3	
For the design of ~~acceptance~~ **representative** sampling (see ISO 3951 and GL50):	**Honduras**
For the design of acceptance sampling plans based on inspection by variables (see ISO 3951 and GL50):	**New Zealand** The word “plans” should be inserted; ISO 3951 covers only inspection by variables. The current GL50 does not contain any information on sampling plans in the presence of significant measurement error, which is specifically excluded, but this will be covered in the proposed revised document.
Bullet point 4	
The determination of sample size and acceptance number for inspection by attributes, and of sample size and acceptability constant for inspection by variables is based on the procedures and the sampling plans provided in ISO standards and/or Codex guidelines~~. This calculation has to take into account the components of measurement uncertainty~~.	**Japan** As CCMAS had agreed that the Guideline does not include the aspect of sampling uncertainty component, the last sentence in the fourth bullet points should be deleted.
The determination of the sample size and ~~acceptance number for inspection by attributes, and of sample size and~~ acceptability constant for inspection by variables is based on the procedures and the sampling plans provided in ISO standards and/or Codex guidelines. This calculation has to take into account the components of measurement uncertainty.	**New Zealand** This comment applies only to inspection by variables plans (ISO3951 and GL50). This point therefore follows from the previous bullet point, and should

	not be a separate point.
How to report measurement uncertainty in test results	
Para. 24	
In accordance with the ISO/IEC 17025 standard, measurement uncertainty must be reported in order to decide whether a ~~*laboratory sample*~~ **test item** meets a specific specification based on analytical result.	**Honduras**
Para. 25	
However, ISO/IEC 17025 does not state how measurement uncertainty should be taken into account. It is clear, however, that it is not sufficient to consider measurement uncertainty only, but it is necessary to include information on the method bias (if significant) and on whether or not a correction was applied. .	**Japan** Japan is of the view that the information on recovery, available in Section 8.2 of Explanatory Note of the current CXG 54, is useful. Thus, Japan proposes to insert Section 8.2 of Explanatory Note of the current CXG 54 just after para. 25.
Examples of situations occurring when measurement uncertainty is considered	
Para. 26	
The figure below illustrates how measurement uncertainty can affect decisions whether the true values of the samples tested conform to specification limits. However, this figure is for illustrative purposes of the principle. Measurement uncertainty intervals such as those in Figure 1 cannot be used as a valid ~~product~~ lot assessment procedure.	**New Zealand** This wording change provides greater clarity about the difference between conformity assessment, which is appropriate for assessment of compliance of the true value a sample, and sampling inspection, which is appropriate for assessment of a lot.
The Figure 1 below illustrates how measurement uncertainty can affect decisions whether the true values conform to specification limits. However, Figure 1 is for illustrative purposes of the principle. Measurement uncertainty intervals such as those in Figure 1 cannot be used as a valid product lot assessment procedure.	**CCTA**
Figure 1	
Figure 1: Taking into account the expanded (editorial change) measurement uncertainty in the comparison of test results with a Maximum Level. For each situation, the red point represents an individual test result and the vertical bar represents the associated measurement uncertainty interval.	**Honduras**
~~*Figure 1: Taking into account the expanded measurement uncertainty in the comparison of test results with a Maximum Level. For each situation, the red point represents an individual test result and the vertical bar represents the associated measurement uncertainty interval.*~~ "Figure 1: Consideration of the measurement uncertainty intervals in different scenarios of test results with specification of a maximum level. For each situation, the red point represents the result of an individual test and the vertical bars represent the interval of the corresponding measurement uncertainty.	**Mexico** Recommendation for technical (editorial) change for better clarity and understanding.
Figure 1: Taking into account the expanded (editorial change) measurement uncertainty in the comparison of test results with a Maximum Level. For each situation, the red point represents an	**Peru**

individual test result and the vertical bar represents the associated measurement uncertainty interval.	
Situation i	
The analytical result minus the expanded (editorial change) measurement uncertainty exceeds the maximum level. The conclusion is that it is above the specification.	**Peru**
Situation ii and iii	
The analytical result differs from the maximum level to a lesser extent than the expanded (editorial change) measurement uncertainty. The usual ~~standard~~ interpretation here is the outcome is inconclusive. Action on this result depends on existing agreements between the trading partners.	**Peru**
Situation iv – note 2	
Note: The implications of situations *i* to *iii* in the case of testing MRL compliance are extensively discussed in the Guidelines on estimation of uncertainty of results (CXG 59-2006). If, as in situations *ii* and *iii*, it cannot be concluded beyond reasonable doubt (in relation to the consumer and producer risks involved) that the MRL (editorial change) or Maximum level (ML) is exceeded or that a compliant test result has been obtained, the decision will depend on national practices and on existing agreements between the trading partners, which may thus have a considerable impact on the acceptance of trade consignments. This question is addressed in the guideline CXG 83-2013 “Principles for the Use of Sampling and Testing in International Food Trade”. It is stated that “the exporting country and the importing country should agree on how the analytical measurement uncertainty is taken into account when assessing the conformity of a measurement against a legal limit”.	**Costa Rica** Costa Rica wishes to thank for the opportunity to comment. In that regard, an addition to paragraph 27 has been made so that the note applies to both MRL and ML, with "maximum levels" being the form of expression of contaminant limits.